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, 2020**

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.)
7 Pinhas Sapir St., Floor 2, Ness Ziona, Israel	**7414002**
(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, included as part of the units	PHGE	NYSE American
Warrants included as part of the units	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, 2020, 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 $99,734,646 based on the closing sale price of the Registrant's shares of Common Stock on June 30, 2020 (the last trading day of the fiscal quarter) of $5.52 per share.

The number of shares outstanding of the Registrant's shares of Common Stock as of March 25, 2021 was 24,246,010.

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 2021 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, 2020.

BIOMX INC.
Annual Report on Form 10-K for the Year Ended December 31, 2020

PART I

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 plan, 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 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;
- the U.S. Food and Drug Administration's, or FDA's, classification of our BX001 product candidate for acne-prone skin as a drug or cosmetic and the impact of changing regulatory requirements on our ability to develop and commercialize BX001;
- obtaining 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;
- the ability of our product candidates to demonstrate requisite safety and tolerability for cosmetics, 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;

- our limited operating history;
- 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;
- 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 35.

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 development clinical-stage company with limited operating history, we have never generated any revenue from product sales and may never be profitable. We anticipate that our expenses will increase significantly and we will continue to incur increasing and 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.
- 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 tolerability for cosmetics, 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 may 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.

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 that affect the appearance of skin, as well as bacteria associated with chronic diseases, such as inflammatory bowel disease IBD, primary sclerosing cholangitis, or PSC, cystic fibrosis, or CF, atopic dermatitis 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.

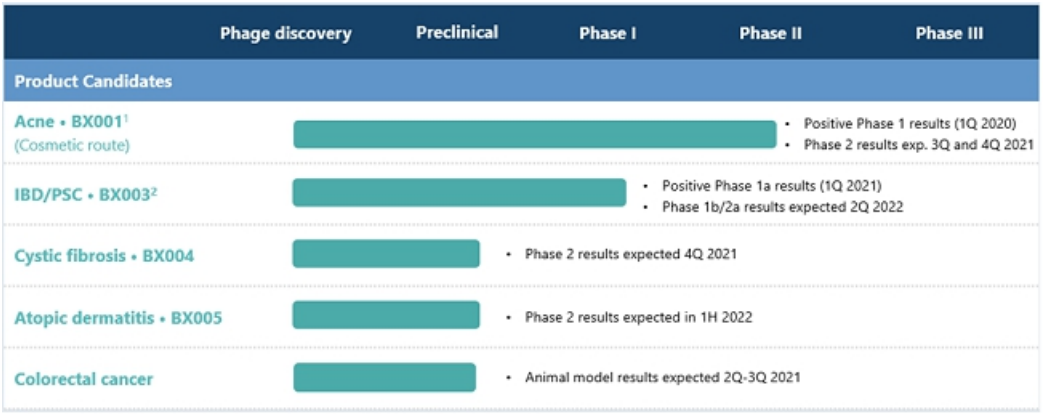
The microbiome refers to the collection of microorganisms, including phage, that reside on the skin, line the gastrointestinal tract and reside elsewhere in the body. The vast majority of these microorganisms are not pathogenic and instead exist in a symbiotic state with the human host, enabling the 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) BX001 is intended to be developed and commercialized as a cosmetic

(2) In November 2020, BiomX announced the consolidation of its 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)

We are developing BX001, our lead product candidate, to modify the appearance of skin in a range of skin types, including in 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. C. acnes* is thought to be associated with acne vulgaris (acne), and the local inflammation of cells surrounding hair follicles in this condition. In preclinical *in vitro* studies, BX001 has been shown to be active on antibiotic resistant *C. acnes* strains and not to target other bacteria found on the skin. Furthermore, it has been observed that the *C. acnes* phage are able to target bacteria found within biofilm, a matrix secreted by the bacteria which surrounds them and makes them less accessible to substances such as antibiotics.

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 March 2, 2021, we announced the initiation of our Phase 2 cosmetic clinical study of BX001. The study is a 12-week randomized, single center, double-blind, placebo-controlled trial with 140 individuals with mild-to-moderate acne vulgaris. Subjects enrolled are randomized into two cohorts: BX001 or placebo (vehicle) in a 1:1 ratio and will self-administer BX001 or placebo twice daily. The key endpoints will evaluate the safety, tolerability and efficacy of BX001. Results from the 8-week time point are expected to be available in the third quarter of 2021 and the full analysis including the 12-week time point is expected to be available in the fourth quarter of 2021.

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, or IND, application 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. Results from the Phase 1b/2a study are expected by mid-2022.

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 is now under development to treat both IBD and PSC, targeting bacterial strains of *Klebsiella pneumoniae*, ("*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.

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. On March 31, 2021, we announced the selection of the phage cocktail for BX004. Phase 2 results of a proof of concept clinical study evaluating safety and efficacy of BX004 administered through a nebulizer in CF patients are expected in the fourth quarter of 2021.

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). On March 31, 2021, we announced the selection of the phage cocktail for BX005. We expect to initiate a Phase 2 proof-of-concept clinical study evaluating the safety and efficacy of BX005 in atopic dermatitis patients in the second half of 2021, with results expected in the first half of 2022.

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. Preclinical results from animal studies evaluating use of our phage therapy in this program in combination with checkpoint inhibitors are expected in the second and third quarters of 2021.

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 the clinical efficacy and safety of BX001 in a Phase 2 cosmetic clinical study and advance BX001 using the available regulatory pathways in the relevant jurisdictions in order to commercialize BX001 with a cosmetic partner;
- Investigate clinical safety and efficacy of our phage-based product candidates in IBD/PSC, CF and atopic dermatitis;
- Evaluate the preclinical efficacy of our synthetic engineering approach for delivering therapeutic payloads to bacteria that are resident within CRC tumors followed by evaluation through clinical testing;
- Identify new pathogenic bacteria to be targeted by phage therapy for our existing indications and possible new indications; and
- Develop and partner microbiome-based biomarker tests, based on our proprietary XMarker platform, that can be used for disease diagnosis or as companion diagnostics.

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 IBD, 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 parallel phage cocktail development under two optional paths:

- A personalized approach aimed at conducting a rapid initial clinical proof of concept study in patients (Phase 2 results) within approximately 12-18 months of project initiation. In certain indications the time to clinical proof of concept may be longer depending on the indication, identity of target bacteria, recruitment rate, cohort size and other factors. Under this path we develop an initial phage cocktail or cocktails of naturally-occurring phage designed to target the bacterial strains isolated from each study subject participating in the clinical proof of concept study. This phage cocktail or cocktails may differ from the final optimized phage cocktail to be commercialized, if approved. The ability to move quickly into clinical development is also driven by the strong safety profile of naturally-occurring phage, which we believe will allow us to bypass GLP toxicity studies and safety studies in healthy volunteers based on feedback from the FDA in connection with our IBD development program, and to proceed directly to Phase 2 proof of concept.

- Development of the final optimized fixed phage cocktail to be commercialized – the optimized 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 and will be conducted in parallel to developing the personalized product candidates and executing the clinical proof of concept studies described above.

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 manufacture of our product candidates. This process is designed to comply with current Good Manufacturing, or cGMP, to be scalable 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 BX001, we have engaged a vendor to provide purified active ingredients (phage) and established in house capabilities for formulation and fill-finish of our product candidates for clinical testing. For BX002, we have also engaged an additional third-party provider to supplement our in-house process development activities. We have selected these organizations based on their 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 capable of being extended or renewed. The production amounts identified in our current service agreements are sufficient to support our current clinical study needs.

We currently operate our own 550 square foot manufacturing facility at our headquarters in Ness Ziona, Israel. During the second quarter of 2021, we are planning to move into a new 6,500 square foot manufacturing facility at our new headquarters, which will also be based in Ness Ziona, Israel. This facility has been designed with the capacity to produce clinical quantities of our product candidates required for future early-stage clinical development. The new facility will consist 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 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 its 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 its 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 identified 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 three United States provisional patent application. We co-own one international patent family (Patent Cooperation Treaty, or PCT) 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 key product candidates, specifically: acne, 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.

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.

IBD

We solely own one United States provisional patent application, co-own with Keio one international patent family (PCT stage) 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, two United States provisional patent applications 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.

CF

We solely own one United States provisional patent application 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.

CRC

We solely own one United States provisional patent application 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.

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 its 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 its 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 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:

- *C. acne*: Adapalene, Epiduo, Zineryt, erythromycin and Acnecide
- *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)
- *CF:* Trikafta, Symdeco, Pulmozyme, Tobramycin, Aztreonam
- *Atopic dermatitis:* Elidel, Eucrisa, Ruxolitinib, Dupixent

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.

In addition, for any cosmetics products that we introduce, we will face intense competition from a broader range of cosmetics companies with more resources than ours.

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.

We seek to distribute BX001 without developing and relying on our own sales and marketing resources and instead relying on collaborations and other relationships with cosmetic companies to use their sales and marketing capabilities. However, we also may select an alternate method for distribution.

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. In addition, in certain countries, cosmetics are subject to a specific regulatory framework.

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 application, 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 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 filing 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.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates subject to this process will be granted on a timely basis, or at all.

The strategies, nature, and technologies associated with bacteriophage products are different from those of conventional biological products. From the regulatory requirements established in order to ensure the safety, efficacy and quality of bacteriophage preparations, there are several matters to consider during the development, manufacturing, characterization, preclinical study and clinical trials of bacteriophage, including:

- Preparation and design of bacteriophage cocktails (phage mixes) with individual phage characterization to ensure that they are strictly lytic and devoid of any antibiotic resistance or virulent sequences; wild-type phage versus genetically engineered phage;
- Proof of concept in development of bacteriophage products in the treatment of chronic diseases;
- Ability to deliver an adequate dose of bacteriophage formulation to target bacteria;
- Relevant animal models in preclinical studies; and
- Clinical safety and effectiveness on individuals that carry the bacterial strain.

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 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. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

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 both the product and the specific indication for which it is being studied. The sponsor of a biologic can request the FDA to designate the product for fast-track status any time before receiving BLA approval, but ideally no later than the pre-BLA meeting. 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 generally provides a meaningful advantage over available therapies. In addition, it must demonstrate 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 may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. If the FDA determines that the conditions of approval are not being met, the FDA can withdraw its accelerated approval for such drug or biologic.

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. While we opened our own manufacturing facility in the third quarter of 2019, we have historically relied, and expects to continue to rely, on third parties for the production of certain clinical and commercial quantities of its products in accordance with cGMP regulations. We and these manufacturers must comply with cGMP regulations that 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.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our product candidates and any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments. The Hatch Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved biologic is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent.

The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

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.

U.S. Cosmetics Regulations

In the United States, cosmetics are regulated by the FDA under the FDCA. The FDCA defines cosmetics as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) "articles intended for use as a component of any such articles; except that such term shall not include soap." The FDA clarifies that cosmetics "are intended to beautify, promote attractiveness, alter appearance or cleanse" and explicitly states that cosmetics are "not … intended to effect structure or function of the body." Manufacturers must ensure that cosmetics are safe for use as intended prior to marketing. To determine the safety of cosmetics, the FDA considers the ingredient safety, trace chemicals contamination and microbiological safety. Even "good" microbes may only be present at certain levels to meet the FDA's microbiologic safety standards for cosmetics. Product labeling must be truthful and not misleading and present all required labeling elements (including statement of identity, net weight, ingredients, and any relevant warnings).

In some cases, products that are intended for cosmetic use, but also have a drug application, are classified as both a cosmetic and a drug. Under the FDCA, a "drug" is defined an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," an article "(other than food) intended to affect the structure or any function of the body," and article intended as a component of any of the previously listed articles. Although product claims inform FDA's and the consumer's understanding of a product's intended use, FDA will also consider ingredients and the mode of action to make a final determination as to the actual intended use of a product. Biological products, more commonly referred to as biologics, are defined by the PHSA. Biologics also meet the definition of drug under the FDCA and FDA and include therapeutic products containing microorganisms. All drug products, regardless if they are also cosmetics, must meet all FDA requirements, including premarket approval. As part of the approval process, manufacturers must demonstrate that drugs are safe and effective for their intended uses and develop labeling, which also must be approved. If a substance has an open drug application with the FDA or it is an already approved drug, it cannot be a cosmetic.

A product claiming to impart activity to the skin may fall under either one or both definitions described above, according to the intended use that the manufacturer establishes for the product. That is, a product that claims only to alter the appearance of the skin would be regulated solely as a cosmetic, while a product that claims to induce a change in the structure or function of the body (skin included) would be regulated as a drug. Under the FDCA, a product that makes both types of claims would be considered both a cosmetic and a drug. This system of classification, however, in the context of the FDCA, does not make the product's composition irrelevant. Even though the classification of the product primarily depends on the claims associated with the product, the mention of drug substances on the product label (i.e. in the ingredient declaration) can be construed as implied drug claims.

From a practical point of view, and presuming that safety has been substantiated, the manufacturers of skin care products that could potentially affect the structure or function of the skin are confronted with a dilemma: if the product is marketed as a cosmetic, no claims may be made about any "active" ingredients that may alter the skin; if a physiological effect is claimed, on the other hand, the manufacturer would be faced with a lengthy and costly NDA process or a possible enforcement action by the FDA.

Violations of the FDCA are generally fall under at least one of two provisions: Products that contain substances that may be injurious to health or are otherwise impermissible (including the presence of a drug substances without proper labeling) are adulterated, and products that are not properly labeled (including claims) are misbranded. The presence of drug substances in a product that is solely being marketed as a cosmetic (and not also as an approved drug) would likely render the product adulterated in the eyes of FDA.

The FDCA requires that every cosmetic product and its individual ingredients be substantiated for safety and that product labeling be truthful and not misleading. Cosmetic manufacturers are responsible for ensuring that products comply with the law before they are marketed. If FDA determines that a cosmetic product does not meet the requirements established by law or is otherwise adulterated or misbranded under the FDCA, FDA has the authority to:

- Ban or restrict cosmetic ingredients for safety reasons
- Refuse importation of cosmetics that may be adulterated or misbranded
- Mandate warning labels
- Inspect manufacturing facilities
- Issue warning letters
- Seize unsafe or misbranded products
- Enjoin unlawful activities
- Prosecute and jail violators
- Work with cosmetic manufacturers in implementing nationwide product recalls
- Collect samples for examination and analysis as part of cosmetic plant inspections, import inspections, and follow-up to complaints of adverse reactions
- Conduct research on cosmetic and personal care products and ingredients to address safety concerns

Cosmetic products must be labeled in accordance with the Fair Packaging and Labeling Act and FDCA, including ingredient labeling. Cosmetic product advertising is also subject to regulation. Any claims made with regards to product efficacy to the extent such claims may affect a consumer's choice whether to purchase a product or not, are regulated by the Federal Trade Commission under the authority of the Federal Trade Commission Act, or FTCA.

European Union Cosmetics Regulation

Regulation (EC) No. 1223/2009, or the Cosmetic Regulation, is the key European legislation governing finished cosmetics products in the European Union. The European Union's framework of cosmetics regulations are binding on all member states and is enforced at the national level. Over the years, the European Union cosmetics legal regime has been adopted by many countries around the world.

Under the Cosmetic Regulation, a "cosmetic product" means any substance or mixture intended to be placed in contact with external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors. A substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product, nor shall a product (i) the composition of which is such that it has a significant action on the body through a pharmacological, immunological or metabolic action; or (ii) for which medical claims are made. Legally, such a product is a medicinal product, not a cosmetic.

The company that is 'responsible' for placing a cosmetic product on the European Union market is subject to a series of obligations. In particular:

- Manufacture cosmetic products in compliance with good manufacturing practice.
- Create for each cosmetic product a product information file, or PIF, that contains, among other information, "proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product" and the test results that demonstrate the claimed effects for the cosmetics product.
- Submit information on every product through the Cosmetic Products Notification Portal, or CPNP.
- Comply with Regulation (EU) No. 655/2013 that lists common criteria for claims.
- Report adverse experiences or keep them available for inspection by the competent authorities. Poison control centers have information available on standard formulations for medical emergency treatment.

The European Union legal regime is a risk-based legislation, with consumer safety as the main goal. As such, proof of the safety of the finished cosmetic product and each of its ingredients is the responsibility of the manufacturer or the importer in the European Union. The safety assessment report is a key part of the PIF.

With the exception of color additives, sunscreen active ingredients and preservatives, no pre-market approval is needed for cosmetics. However, the Cosmetic Regulation includes a list of ingredients that are prohibited and a list of ingredients that are restricted in cosmetic products. Nano-materials are authorized, provided that their presence is disclosed on the label. Moreover, animal testing is prohibited for finished cosmetic products and their ingredients.

Each member state appoints a competent authority to enforce the Cosmetic Regulation in its territory and to cooperate with each other and the European Commission. The European Commission is responsible for driving consistency in the way the Cosmetic Regulation is enforced.

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. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. 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 anti-inducement 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

- 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) 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; imposed a new federal excise tax on the sale of certain medical devices; 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 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 October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices.

The Tax Cuts and Jobs Act of 2017, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plan, the annual fee imposed on certain health insurance providers based on market share, and the medical device exercise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress may consider other legislation to replace or modify elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal, replacement or further modification could have on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

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 up to 2% per fiscal year that will remain in effect through 2027 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

In 2015, BiomX Ltd. entered into the Research and License Agreement, dated as of June 22, 2015, 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, 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 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, par value $0.0001 per share, or 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, 2020, we had 95 full-time employees and consultants and 11 part time employees. Thirty-three of our employees have Ph.D. or M.D. degrees and 87 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 Mountain Wood, LLC, 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.

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 7 Pinhas Sapir St., Floor 2, Ness Ziona, Israel 7414002 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	44	Chief Executive Officer and Director
Assaf Oron	46	Chief Business Officer
Dr. Sailaja Puttagunta	52	Chief Medical Officer
Dr. Merav Bassan	55	Chief Development Officer
Marina Wolfson	37	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. Sailaja Puttagunta M.D. has served as the Chief Medical Officer of the Company since October 2019. Dr. Puttagunta served as the Chief Medical Officer of BiomX Ltd. from December 2018 to October 2019. Prior to joining BiomX Ltd., Dr. Puttagunta served as Vice President, Development at Iterum Therapeutics plc, a clinical stage pharmaceutical company developing antibiotics against multi-drug resistant pathogens, from January 2016 to December 2018. Prior to Iterum, Dr. Puttagunta served as VP, Medical Affairs for Anti-infectives at pharmaceutical company Allergan plc from January 2015 to January 2016 and was the Vice President of Development and Medical Affairs from August 2014 to December 2014 and the Executive Director of Clinical and Medical Affairs from June 2012 through July 2014 at Durata Therapeutics, Inc., an innovative pharmaceutical company focused on the development and commercialization of novel therapeutics for patients with infectious diseases and acute illnesses, prior to its acquisition by Actavis plc. Prior to joining Durata, Dr. Puttagunta led teams within clinical development and medical affairs on various antibiotic compounds at pharmaceutical company Pfizer Inc. Dr. Puttagunta graduated from Gandhi Medical College in Hyderabad, India and completed her residency in Internal Medicine and a fellowship in Infectious Diseases at Yale University School of Medicine. She also holds an M.S. in Biochemistry from the New York University School of Medicine.

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

We are a development 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, 2020, our accumulated deficit was $72.3 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, 2020 and 2019, we had losses from operations of $30.3 million and $22.2 million, respectively. We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials with respect to our lead product candidate, BX001, and other product candidates in our pipeline;
- 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 subsidiary of a public company.

We will need to raise additional capital in the future to support our operations.

As of December 31, 2020, we had cash, cash equivalents and short-term deposits of $57.1 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 financings. 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 and through March 25, 2021, we sold an aggregate of 610,820 shares of Common Stock pursuant to the Sale Agreement for aggregate gross proceeds of $4,519,474. 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. 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 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 mid-2022, 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, and the impact recently seen associated with the coronavirus outbreak, 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.

We are seeking to develop product candidates using phage technology, an approach for which 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.

We are considering marketing our lead candidate product — BX001 — as a cosmetic, although this positioning also presents some challenges, as explained in this "Risk Factors" section.

Our product candidates must undergo clinical testing which may fail to demonstrate the requisite safety and tolerability for cosmetics, 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, we must undertake extensive preclinical and clinical testing in humans to demonstrate safety and efficacy 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. 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, 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 has 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, 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. For example, the FDA postponed most inspections of foreign manufacturing facilities and products and postponed routine surveillance inspections of domestic manufacturing facilities. 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 has had and may continue to 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, new drug application, or NDA, 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;
- we may be unable to demonstrate that a drug 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, non-IND human clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA 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 Paediatric 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.

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.

We intend to develop our lead product candidate, BX001 initially as a cosmetic gel designed to improve the appearance of acne-prone skin. BX001 contains known cosmetic ingredients combined with phage that are designed to help control the growth of *C. acnes*, and thereby help improve the appearance of acne-prone skin.

In the European Union, a product candidate is considered to be a cosmetic if it is intended to and presented as protecting the skin, maintaining the skin in good condition or improving the appearance of the skin, provided that it is not a medicinal product due to its composition. With regard to the ingredients, in the European Union, the composition of a cosmetic may not be such that it has a significant effect on the body through a pharmacological, immunological or metabolic mode of action. No test has been determined yet for the significance of the effect. By contrast, a product candidate is a drug if it is intended to or presented as treating or preventing a disease or restoring, correcting or modifying significantly physiological functions by a pharmacological, immunological or metabolic action. However, in the European Union, medical or biocidal (i.e. antibacterial) claims may be made for cosmetics, provided that they are ancillary to the cosmetic claims. As a result, we believe that we may develop BX001 as a cosmetic, including conducting non-IND human clinical studies in order to evaluate safety, tolerability and biomarkers for non-drug applications.

Some countries also regulate other categories of products that could be relevant such as biocides in the European Union.

Unlike medicinal products, cosmetic products are generally not subject to premarket approval by regulatory agencies. However, they must not contain certain ingredients or concentrations of ingredients and must be safe and properly labeled in relation to their cosmetic purpose. We remain unclear whether phage are authorized for use in cosmetic products, in the United States, the European Union and other countries.

Moreover, the FDA or equivalent foreign regulatory agencies may determine that BX001 is not governed by cosmetics regulations but by pharmaceutical regulations and, therefore may classify BX001 as being ineligible for use in clinical studies without a regulatory approval. A determination that BX001 does not meet the regulatory cosmetic requirements of the FDA or equivalent foreign regulatory agencies could cause a delay in the commercialization of BX001, which may lead to reduced acceptance by the public or others. Any such determination could prevent our reliance on existing regulatory frameworks to conduct non-IND human clinical studies for BX001 and could significantly increase the cost of and delay the commercialization of BX001.

Should we choose to continue to develop and commercialize BX001 as a cosmetic and if the FDA or equivalent foreign regulatory agencies determine BX001 falls outside the cosmetics regulations, the agency could ask us to withdraw BX001 from the market. In addition, if new safety issues are raised by cosmetic clinical studies for BX001, then our ability to seek an IND to conduct clinical trials intended to lead toward approval of the product as a drug, if pursued, could be adversely affected, for example the FDA or equivalent foreign regulatory agencies could ask us to modify approved labeling for or withdraw BX001 from the market.

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.

Depending in part on how BX001 is marketed, it may be classified as a cosmetic or a drug or as something else by the FDA and equivalent foreign regulatory agencies. There are fewer requirements to market cosmetics in the United States; however, if we attempt to market as a cosmetic and the FDA disagrees with its classification, we may be required to stop marketing the product to pursue approval as a drug and not market the product again until we receive such approval, which we may not receive.

The FDA and equivalent foreign regulatory agencies regulate products largely by their intended uses but may also consider the ingredients of the product. At the current time, such agencies have not approved an NDA, or a BLA for a phage product. Products intended to beautify, moisturize, cleanse, or change one's appearance may be regulated as cosmetics. Products intended to diagnose, prevent, cure or mitigate a disease or condition are regulated as drugs (or in some cases, as medical devices).

A premarket approval process is not required for cosmetic products. Manufacturers of cosmetics must test for and assure that finished products and all ingredients are safe prior to marketing them in the United States or the European Union, and claims may not be made that the product prevents, mitigates or cures a condition or disease. Products that claim to treat acne are generally regulated as drugs in the United States and the European Union. In the United States, drug products must either be approved through one of several FDA drug approval pathways or, in the case of some over-the-counter, or OTC, drugs, meet the monograph criteria established by U.S. regulation. Similarly, in the European Union, drugs must be approved by the national regulatory authority or the European Commission before being placed on the national or European market.

If we market BX001 as a cosmetic, as we currently plan to, we will not be able to promote the product for the treatment of acne, and our main claims would be limited to those that are consistent with permitted cosmetic claims, to beautify, moisturize, cleanse or change the appearance of the skin such as "for beautiful, bright skin" and similar claims. If we market the product as a cosmetic, it is possible that the FDA or equivalent foreign regulatory agencies will disagree with us and find that the product should be marketed as a drug. Although the FDA or equivalent foreign regulatory agencies have not affirmatively decided the regulatory status of phage, given that their function is antibacterial, it is possible that such agencies will decide that products containing phage are drugs regardless of the claims presented on the product or any other considerations. If the FDA evaluates BX001 and determines that the product is a drug and marketing it as a cosmetic is a prohibited act under the FDCA, it may issue a Warning Letter and demand that we stop marketing the product unless and until the product is approved as a drug. If the FDA issues a Warning Letter, it will be made available on the FDA's website, and we may suffer reputational damage. The same applies to the national competent authorities in the European Union. There is the risk that if we go to market with BX001 as a cosmetic, potential competitors will bring the FDA's or equivalent foreign regulatory authorities' attention to the marketing of BX001 as a cosmetic to encourage the FDA or equivalent foreign regulatory authorities to take this very type of enforcement action against us.

It is possible that the regulatory requirements or framework will change by the time we are ready to market our product and these changes may eliminate the possibility of marketing BX001 as a cosmetic. For example, the FDA could affirmatively determine that phage are to be regulated as drugs and are not permitted in cosmetic products. If this were to occur, then BX001 would need to be approved as a drug in order to be marketed in the United States and would need to be approved as an OTC drug rather than a prescription drug in order to be sold in products that are also cosmetics. The same applies in the European Union.

Depending on the regulatory environment and requirements at the time BX001 is ready for market, we may decide that pursuing a drug approval (either prescription or OTC) is the better pathway to market, in which case, it will take longer to bring BX001 to market in the United States and in other countries. And in this case, all other risks generally related to approval pathways would also be applicable to BX001.

Finally, even if we are permitted to market BX001 as a cosmetic in one country, this does not guarantee that we will be permitted to market BX001 as a cosmetic in other countries. Each country has its own distinct requirements for marketing products as cosmetics and BX001 would need to independently meet each jurisdiction's requirements.

We are seeking to develop product candidates to improve the appearance of acne-prone skin and 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, or BX001 is permitted to be marketed as a cosmetic, 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 dermatologists, 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 BX001 and 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 safety for any cosmetic product, and 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.

For products that require regulatory approvals, we 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.

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 may 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 bacteriophages 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;
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining IRB 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. Similarly, such adverse effects would prevent marketing BX001 as a cosmetic. 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. Adverse events in studies with BX001 as a cosmetic may lead us to stop our marketing.

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 initial formulations of BX001 and BX003, there can be no assurance that these initial formulations will be the final formulations of these product candidates 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 current cGMP manufacturing facility at our headquarters in Ness Ziona, Israel and we have executed cGMP manufacturing for our first in human clinical study (IBD project). Our facility undergoes ongoing inspections for compliance with cGMP regulations before the respective product candidates are approved for use in clinical trials or commercialization. In the event this facility does not receive a satisfactory cGMP inspection 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.

The manufacturing facility will be subjected to ongoing periodic inspection for compliance with European, FDA and cGMP regulations as progress will be made in clinical phases. 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.

BX001 faces significant competition in the market.

The facial aesthetic market is highly competitive and dynamic, and is characterized by rapid and substantial technological development and product innovations. If BX001 can be marketed as a cosmetic, we may face significant competition from other facial aesthetic products. Due to less stringent regulatory requirements, there are many more possibilities for marketing cosmetics in international markets than there are in the United States. There are also fewer limitations on the claims that our competitors in international markets can make about the effectiveness of their products and the manner in which they can market them. As a result, if we partner with other companies in these markets and launch our products, we may face more competition in these markets than in the United States.

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 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.

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. We are initially implementing the ability 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.

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.

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.

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 revenues.

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, 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. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. 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 seek a priority review designation for one or more of our other product candidates for therapeutic indications, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

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.

Our strategy may include filing for the orphan drug designation where applicable for our product candidates for therapeutic indications. We currently believe that our product candidate under development for cystic fibrosis patients may qualify for such a designation in the United States, the European Union, and the other countries supporting the development and marketing of drugs for rare diseases.

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. For example, certain policies of the current administration may impact our business and industry. Namely, the current administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities, such as implementing statutes through rulemaking, the issuance of guidance, and the review and approval of marketing applications. It is difficult to predict how these executive actions, including any executive orders, will be implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, 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, 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.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the United States population, and the data must be applicable to the United States population and United States medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws, and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable United States laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional trials, which would be costly and time-consuming and may delay aspects of our business plan.

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, subjects biological products to potential competition by lower-cost biosimilars; addresses 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; increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program; and extends the rebate program to individuals enrolled in Medicaid managed care organizations. It also establishes 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 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.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA.

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, including for 35 days beginning on December 22, 2018, 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 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 or cosmetic 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 bacteriophages. 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, 2020 and 2019, we recorded grants totaling $0.5 million, $0.3 million, from the IIA, respectively. The grants represented 2.4% and 2.3% of our gross research and development expenditures for the years ended December 31, 2020 and 2019, 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.

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 and 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. 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.

In addition, since the end of 2010, numerous acts of protest and civil unrest have taken place in several countries in the Middle East and North Africa, many of which involved significant violence, including in Syria and Egypt that border with Israel. The ultimate effect of these developments on the political and security situation in the Middle East and on Israel's position within the region is not clear at this time. Such instability may lead to deterioration in the political and trade relationships that exist between the State of Israel and certain other countries.

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.

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, 2020, we had received an aggregate of $2.7 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. As of December 31, 2020, the balance of the principal and interest in respect of our commitments for future payments to the IIA totaled approximately $2.3 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.

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, 2020, we had an aggregate of 10,265,418 warrants outstanding to purchase an aggregate of up to 6,765,418 shares of Common Stock with a weighted average exercise price of $11.09, 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, 2020, we had outstanding vested and unvested options to purchase 3,569,769 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.

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 recently 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 and civil monetary penalty 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;

- HIPAA, as amended by HITECH and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- 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) 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; 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 state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; 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.

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.

We are subject to a code of business conduct and ethics, but 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 the 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. 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, 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 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. 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 are planning to move 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, 2021, there were 24,246,010 issued and outstanding shares of our Common Stock held by 75 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, if we incur any indebtedness, our ability to declare dividends may be limited by restrictive covenants we may agree to in connection therewith.

ITEM 6. SELECTED FINANCIAL DATA

Because we are considered to be a "smaller reporting company" under SEC rules and regulations, we are not required to provide the information required by this item in this report.

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.

The Business Combination was treated as a "reverse merger" in accordance with Generally Accepted Accounting Principles in the United States, or US GAAP. For accounting purposes, BiomX Ltd. was considered to have acquired Chardan Healthcare Acquisition Corp., or CHAC. Therefore, for accounting purposes, the Business Combination was treated as the equivalent of a capital transaction in which BiomX Ltd. issued stock for the net assets of CHAC. The net assets of CHAC were stated at historical cost, with no goodwill or other intangible assets recorded. The post-acquisition financial statements of the Company show the consolidated balances and transactions of the Company and BiomX Ltd. as well as comparative financial information of BiomX Ltd. (the acquirer for accounting purposes).

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 that affect the appearance of skin, as well as harmful bacteria in associated with chronic diseases, such as IBD, PSC, liver disease, CF, atopic dermatitis and CRC. Bacteriophages or phage are bacterial, species-specific, strain-limited viruses that infect, amplify and lyse the target bacteria and are considered inert to mammalian cells. viruses that 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 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 activities for our product candidates. We do not have any products approved for sale, most of our products are still in the preclinical development stage, and we have not generated any revenue from product sales. As we move our product candidates from preclinical to clinical stage, we expect our expenses to increase. To date, we have funded our operations with proceeds from sales of Common Stock and preferred shares. Through December 31, 2020, we had received gross proceeds of approximately $120 million from sales of our securities. To date, we received approximately $384 thousand from our collaboration agreements and recorded a reduction from research and development expenses of $327 thousand since 2015 through the year ended December 31, 2020.

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 $30.1 million and $20.6 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $72.3 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, 2020, we had cash and cash equivalents and short-term deposits of $57.1 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 mid-2022, as discussed further below under " — Liquidity and Capital Resources"

Change in Fiscal Year End

In November 2019, after the Business Combination, we elected to change our fiscal year end from June 30 to December 31. Our 2019 fiscal year consists of the year ended December 31, 2019, and our 2020 fiscal year consists of the year ended December 31, 2020. In view of this change, this Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations or MD&A, includes a discussion and analysis of our financial statements for fiscal years ended December 31, 2020 and 2019.

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, amortization 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,	
	2020	2019
	USD In thousands	
BX001	2,845	1,160
BX002/BX003	3,206	4,058
BX004	152	-
BX005	28	-
CRC	592	374
Salaries and related benefits	11,026	6,854
Depreciation and amortization	2,171	317
Infrastructure & other unallocated research and development or R&D expenses	1,593	1,192
Less grants from the IIA & income from collaboration agreement	(678)	(466)
Total research and development expenses, net	20,935	13,489

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.

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, 2020 and 2019

The following table summarizes our consolidated results of operations for the years ended December 31, 2020 and 2019:

	Year ended December 31,	
	2020	2019
	USD In thousands	
R&D expenses, net	20,935	13,489
General and administrative expenses	9,323	8,718
Operating loss	30,258	22,207
Financial income, net	(172)	(1,644)
Income tax	-	-
Net Loss	30,086	20,563

R&D expenses, net (net of grants received from the IIA and consideration from research collaborations) were $21.0 million for the year ended December 31, 2020, compared to $13.5 million for the year ended December 31, 2019. The increase of $7.5 million, or 55%, in the year ended December 31, 2020 compared to the prior year, is primarily due to the following:

- an increase of $4.1 million in stock-based compensation and salaries and related expenses, mainly due to the growth in the number of employees;
- an increase of $1.9 million due to manufacturing of materials for clinical trials of BX001, BX002 and BX003, the Company's product candidates for acne-prone skin, IBD and IBD/PSC, respectively; and
- an increase of $1.5 million in amortization expenses.

The Company received grants from the IIA totaling $0.5 million and $0.3 million for the years ended December 31, 2020 and December 31, 2019, respectively.

General and administrative expenses were $9.3 million for the year ended December 31, 2020, compared to $8.7 million for the year ended December 31, 2019. The increase of $0.6 million, or 7%, is primarily due to the following:

- an increase of $1.7 million in expenses associated with operating as a public company, such as directors' and officers' insurance, filing and legal and accounting expenses;
- an increase of $1.6 million in stock-based compensation and salaries and related expenses, mainly due to the growth in the number of employees; and
- partially offset by a decrease of $2.7 million in expenses associated with the Business Combination.

Financial income, net was $0.2 million for the year ended December 31, 2020, compared to $1.6 million for the year ended December 31, 2019. The decrease of $1.4 million, or 90%, is primarily due to the USD/NIS exchange rate differences and the decrease in interest rates on bank deposits and money market funds.

Liquidity and Capital Resources

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, and through the Business Combination. Through December 31, 2020, we had received gross cash proceeds of approximately $120 million from sales of our common stock and preferred shares. In addition, in 2020 and 2019 we received approximately $678 thousand and $466 thousand 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. From December 23, 2020 through December 31, 2020, we sold an aggregate of 10,176 shares of Common Stock pursuant to the Sale Agreement for aggregate gross proceeds of $61,776. From January 1, 2021 through March 25, 2021, we sold an aggregate of 600,644 shares of Common Stock pursuant to the Sale Agreement for aggregate gross proceeds of $4,457,698. 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.

We believe that our existing cash resources will be sufficient to meet our capital requirements and fund our operations for at least until mid-2022. 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. However, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption 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 commitments to obtain such additional financing 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,	
	2020	2019
	USD In thousands	
Net cash used in operating activities	(24,447)	(17,577)
Net cash provided by (used in) investing activities	(10,857)	19,740
Net cash provided by financing activities	134	61,554
Net increase (decrease) in cash and cash equivalents	(35,170)	63,717

Operating Activities

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 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.

During the year ended December 31, 2019, operating activities used $17.6 million of net cash, primarily due to a net loss of $20.6 million, net cash used by changes in our operating assets and liabilities of $2 million and non-cash charges of $0.9 million. Non-cash charges for the year ended December 31, 2019 mainly consisted of stock-based compensation expenses of $0.9 million and depreciation of $0.3 million, partially offset by non-cash revaluation of contingent liabilities expenses of $0.3 million. Net changes in our operating assets and liabilities for the year ended December 31, 2019 consisted primarily of an increase in trade account payables of $3 million, an increase in other account payables of $0.8 million and an increase in operating lease liability of $0.1 million, offset by an increase of $1.8 million in other receivables.

Investing Activities

During the year ended December 31, 2020, investing activities used net cash of $10.9 million, mainly consisting of 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.

During the year ended December 31, 2019, investing activities provided net cash provided of $19.7 million, mainly consisting of maturities of investments in short-term deposits of $21.0 million partially offset by purchase of property and equipment of $1.3 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, 2020, we had outstanding foreign exchange contracts in the amount of approximately $1.5 million. As of December 31, 2019, we had no outstanding foreign exchange contracts.

Financing Activities

During the year ended December 31, 2020, financing activities provided net cash provided of $0.1 million, consisting of $0.075 million due to the Business Combination, $0.1 million from issuance of Common Stock and $0.3 million from exercise of stock options.

During the year ended December 31, 2019, financing activities provided net cash of $61.6 million, consisting of $59.7 million due to the Recapitalization Transaction, $1.8 million from issuance of shares and $0.1 million from exercise of stock options.

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, 2020, we had received an aggregate of $2.7 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 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 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, 2020, 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 $2.3 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 increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. Our expenses will also increase as we:

- continue the development of our product candidates, including our lead product candidate, BX001;
- complete IND-enabling activities and prepare to initiate clinical trials for other 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 mid-2022. 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 the sales of our securities, 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, 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.*"

Off-Balance Sheet Arrangements

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, 2020, the Company had outstanding foreign exchange contracts in the amount of approximately $1.6 million. As of December 31, 2019, the Company had no outstanding foreign exchange contracts.

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 statements of comprehensive loss. We recognize stock-based award forfeitures as they occur, rather than estimate by applying a forfeiture rate.

In June 2018, the Financial Accounting Standards Board or FASB, issued Accounting Standards Update, or ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Stock-Based Payment Accounting," which simplifies the accounting for nonemployee stock-based payment transactions by aligning the measurement and classification guidance, with certain exceptions, to that for stock-based payment awards to employees. The amendments expand the scope of the accounting standard for stock-based payment awards to include stock-based payment awards granted to non-employees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance related to equity-based payments to non-employees. We adopted these amendments on January 1, 2019.

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 its most recent sales of stock as well as additional factors that we deem relevant. 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.

In-process research and development

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. Significant changes in assumptions and estimates subsequent to completing the allocation of the purchase price to the assets and liabilities acquired, as well as differences in actual and estimated results, could impact our financial results. 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, 2020. 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, 2020.

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, 2020. 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, 2020, 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 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

We intend to file a definitive proxy statement for our 2021 Annual General Meeting of Stockholders, or the 2021 Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after December 31, 2020. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2021 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 2021 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 2021 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, 2020, options to purchase 2,714,066 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, 2020, there were 60,041 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, 2021, 930,813 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, 2020, 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, 2020		
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	855,700	$ 6.16	60,041
Equity compensation plans not approved by security holders	2,714,066	2.16	—
Total	3,569,766	$ 3.12	60,041

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 2021 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 2021 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 2021 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
2.1	Merger Agreement (Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed by the Company on July 17, 2019)
2.2	Amendment Agreement to the Merger Agreement (Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed by the Company on October 11, 2019)
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
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)
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	Voting Agreement dated October 28, 2019 (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed by the Company on November 1, 2019)
10.3**	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)
10.4*	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)
10.5*	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)

10.6*	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)
10.7*	Share Purchase Agreement, dated November 19, 2017, among BiomX Ltd., RondinX Ltd. and Guy Harmelin, as the Shareholders' Representative (Incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed by the Company on November 1, 2019)
10.8**	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)
10.9**	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)
10.10	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)
10.11**	Form of Non-Qualified Stock Option Agreement (U.S. Awards to Non-Executives) (Incorporated by reference to Exhibit 10.19 to the Company's Periodic Report on Form 10-K filed by the Company on March 26, 2020)
10.12**	Form of Non-Qualified Stock Option Agreement (U.S. Awards to Executive Officers) (Incorporated by reference to Exhibit 10.20 to the Company's Periodic Report on Form 10-K filed by the Company on March 26, 2020)
10.13**	Form of Option Agreement (Israeli Awards) (Incorporated by reference to Exhibit 10.21 to the Company's Periodic Report on Form 10-K filed by the Company on March 26, 2020)
10.14*	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)
10.15*	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)
10.16	Open Market Sale Agreement℠, 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).
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
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* 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, 2021

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 Dr. Russell Greig	Chairman of the Board of Directors	March 30, 2021
/s/ Jonathan Solomon Jonathan Solomon	Chief Executive Officer (Principal Executive Officer) and Director	March 30, 2021
/s/ Marina Wolfson Marina Wolfson	Senior Vice President of Finance and Operations (Principal Financial Officer and Principal Accounting Officer)	March 30, 2021
/s/ Dr. Gbola Amusa Dr. Gbola Amusa	Director	March 30, 2021
/s/ Jonas Grossman Jonas Grossman	Director	March 30, 2021
/s/ Dr. Alan Moses Dr. Alan Moses	Director	March 30, 2021
/s/ Paul Sekhri Paul Sekhri	Director	March 30, 2021
/s/ Lynne Sullivan Lynne Sullivan	Director	March 30, 2021

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP.)

CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2020

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP.)

CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2020

CONTENTS

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 sheets of BiomX Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period 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 2019 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, effective January 1, 2019, the Company adopted the Financial Accounting Standards Board's new standard related to leases using the modified retrospective approach.

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 audits 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 audits, 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 audits 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 audits 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 audits provide 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.

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP.)
CONSOLIDATED BALANCE SHEETS
(USD in thousands, except share and per share data)

	Note	As of December 31, 2020	2019
ASSETS			
Current assets			
Cash and cash equivalents		36,477	72,256
Restricted cash		763	154
Short-term deposits	3	19,851	10,003
Related parties	10	-	50
Other current assets	4	3,576	2,068
Total current assets		60,667	84,531
Non-current assets			
Lease deposit		-	5
Operating lease right-of-use asset	8	4,430	1,148
Property and equipment, net	5	2,228	1,881
In-process research and development ("R&D")	7	3,038	4,556
Total non-current assets		9,696	7,590
		70,363	92,121

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

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP.)
CONSOLIDATED BALANCE SHEETS
(USD in thousands, except share and per share data)

	Note	As of December 31, 2020	2019
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Trade account payables		2,320	3,253
Current portion of lease liabilities	8	863	375
Other account payables	9	3,978	2,596
Total current liabilities		7,161	6,224
Non-current liabilities			
Lease liabilities, net of current portion	8	5,032	856
Contingent liabilities	6,11	701	585
Total non-current liabilities		5,733	1,441
Commitments and Contingent Liabilities	11		
Stockholders' equity			
Common stock, $0.0001 par value ("Common Stock"); Authorized - 60,000,000 shares as of December 31, 2020 and 2019. Issued - 23,270,337 and 22,862,835 as of December 31,2020 and 2019, respectively. Outstanding - 23,264,637 and 22,862,835 as of December 31, 2020 and 2019, respectively.	12	2	2
Additional paid in capital		129,725	126,626
Accumulated deficit		(72,258)	(42,172)
Total Stockholders' equity		57,469	84,456
		70,363	92,121

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

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP.)
CONSOLIDATED STATEMENTS OF OPERATIONS
(USD in thousands, except share and per share data)

	Note	Year ended December 31, 2020	2019
Research and development expenses, net	13	20,935	13,489
General and administrative expenses	14	9,323	8,718
Operating loss		30,258	22,207
Finance income, net	15	(172)	(1,644)
Loss before income tax		30,086	20,563
Income tax	16	-	-
Net Loss		30,086	20,563
Basic and diluted loss per share of Common Stock	17	1.30	3.66
Weighted average number of shares of Common Stock outstanding, basic and diluted		23,062,216	5,615,856

** Number of shares has been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the Recapitalization Transaction (refer to Note 1).

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

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP.)
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(USD in thousands, except share and per share data)

	Common stock		Preferred A Shares (pre-merger - BiomX Ltd.)		Preferred B Shares (pre-merger - BiomX Ltd.)		Additional paid in capital	Accumulated deficit	Total Stockholder' equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of January 1, 2019	2,307,871	(*)	7,543,831	1	5,170,357	1	64,410	(21,609)	42,803
Acquisition of treasury stock	(5,700)	(*)	-	-	-	-	(19)	-	(19)
Issuance of shares (**)	-	-	-	-	308,628	(*)	1,800	-	1,800
Effect of Recapitalization Transaction	20,486,082	2	(7,543,831)	(1)	(5,478,985)	(1)	59,397	-	59,397
Stock-based payment	-	-	-	-	-	-	938	-	938
Exercise of stock options	74,582	(*)	-	-	-	-	100	-	100
Net loss	-	-	-	-	-	-	-	(20,563)	(20,563)
Balance as of December 31, 2019	22,862,835	2	-	-	-	-	126,626	(42,172)	84,456
Issuance of Common Stock under Open Market Sales Agreement (***)	10,176	-	-	-	-	-	(98)	-	(98)
Stock-based payment	-	-	-	-	-	-	2,890	-	2,890
Exercise of stock options	391,626	-	-	-	-	-	307	-	307
Net loss	-	-	-	-	-	-	-	(30,086)	(30,086)
Balance as of December 31, 2020	23,264,637	2	-	-	-	-	129,725	(72,258)	57,469

(*) Less than $1.

(**) Net of issuance expenses of $114.

(***) Net of issuance expenses of $158.

**** Number of shares has been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the Recapitalization Transaction (refer to Note 1).

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

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP.)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(USD in thousands, except share and per share data)

	Year ended December 31,	
	2020	**2019**
CASH FLOWS – OPERATING ACTIVITIES		
Net loss	(30,086)	(20,563)
Adjustments required to reconcile net loss to cash flows used in operating activities		
Depreciation and amortization	2,180	318
Stock-based compensation	2,890	938
Revaluation of contingent liabilities	116	(304)
Changes in operating assets and liabilities:		
Other current assets	(1,503)	(1,845)
Trade account payables	(858)	3,060
Other account payables	1,382	836
Operating lease liabilities	1,382	83
Related parties	50	(100)
Net cash used in operating activities	(24,447)	(17,577)
CASH FLOWS – INVESTING ACTIVITIES		
Decrease (Increase) in short-term deposits	(9,848)	21,052
Purchase of property and equipment	(1,009)	(1,312)
Net cash provided by (used in) investing activities	(10,857)	19,740
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of Common Stock, net of issuance costs	(98)	1,800
Outflows in connection with current assets and liabilities acquired in Recapitalization Transaction	(75)	59,673
Acquisition of treasury stock	-	(19)
Exercise of stock options	307	100
Net cash provided by financing activities	134	61,554
Increase (decrease) in cash and cash equivalents and restricted cash	(35,170)	63,717
Cash and cash equivalents and restricted cash at the beginning of the year	72,410	8,693
Cash and cash equivalents and restricted cash at the end of the year	37,240	72,410

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

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP.)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(USD in thousands, except share and per share data)

	Year ended December 31,	
	2020	**2019**
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES:		
Recognition of right-of-use asset and lease liability upon adoption of ASU 2016-02	-	662
Assets acquired under operating leases	4,547	690
Assets acquired (liabilities assumed) in Recapitalization Transaction:		
Current assets (excluding cash and cash equivalents)	-	(88)
Current liabilities	-	364
Recapitalization Transaction effect on equity	-	59,397
Cash acquired in connection with Recapitalization Transaction	-	59,673

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

NOTE 1 - GENERAL

A. General information:

BiomX Inc. (formerly known as Chardan Healthcare Acquisition Corp., individually prior to the Recapitalization Transaction (as defined below), and together with its subsidiaries, BiomX Ltd. and RondinX Ltd. after the Recapitalization Transaction, 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. As a result, the historical financial statements of the Company were replaced with the financial statement of BiomX Israel for all periods presented.

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 12A).

The number of shares and instruments convertible into shares included within these financial statements have been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the Recapitalization Transaction.

On October 28, 2019, the Company was renamed BiomX Inc. and the Company's shares of Common Stock, units, and warrants began trading 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.

B. Risk factors:

To date, the Company has not generated revenue from its operations. As of December 31, 2020, the Company had a cash and cash equivalents and restricted cash balance of approximately $37,239 and short-term deposits of approximately $19,851, which management believes is sufficient to fund its operations for more than 12 months from the date of issuance of these condensed consolidated financial statements and sufficient to fund its operations necessary to continue development activities of its current proposed products.

NOTE 1 - GENERAL (Cont.)

B. Risk factors: (cont.)

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 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 all highly liquid investments, including unrestricted short-term bank deposits purchased with original maturities of three months or less, to be cash equivalents.

(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.

The Company uses foreign exchange contracts (mainly 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, 2020, the Company had outstanding foreign exchange contracts in the amount of approximately $1,555. As of December 31, 2019, the Company had no outstanding foreign exchange contracts.

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

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, 2020 and 2019, no impairment expenses were recorded.

H. Intangible assets:

Intangible research and development assets acquired in a business combination are 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 R&D efforts.

Indefinite-lived intangible assets are reviewed for impairment at least annually or whenever there is an indication that the asset may be impaired.

I. 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 bases 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, 2020 and 2019, the Company had a full valuation allowance against deferred tax assets.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

I. Income taxes: (cont.)

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, 2020 and 2019.

J. 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, 2020 and 2019.

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

J. Fair value of financial instruments: (Cont.)

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, 2020			
	Level 1	**Level 2**	**Level 3**	**Fair Value**
Assets:				
Cash equivalents:				
Money market funds	30,000	-	-	30,000
	30,000	**-**	**-**	**30,000**
Liabilities:				
Contingent liabilities	-	-	701	701
	-	**-**	**701**	**701**

	December 31, 2019			
	Level 1	**Level 2**	**Level 3**	**Fair Value**
Assets:				
Cash equivalents:				
Money market funds	-	-	-	-
	-	-	-	-
Liabilities:				
Contingent liabilities	-	-	585	585
	-	**-**	**585**	**585**

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.

K. 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 $567 and $381 for the years ended December 31, 2020 and 2019, 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, 2020 and 2019 the Company did not record any expenses for 401(k) match contributions.

L. 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.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

M. 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.

N. 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 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. 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.

The Company recognizes compensation expense for the fair value of non-employee awards over the requisite service period of each award.

In June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Stock-Based Payment Accounting," which simplifies the accounting for nonemployee stock-based payment transactions by aligning the measurement and classification guidance, with certain exceptions, to that for stock-based payment awards to employees. The amendments expand the scope of the accounting standard for stock-based payment awards to include stock-based payment awards granted to non-employees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance related to equity-based payments to non-employees. The Company adopted these amendments on January 1, 2019. The adoption of these amendments did not have a material impact on the consolidated financial statements and related disclosures.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

N. 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.

O. Leases:

ASU 2016-02, "Leases (Topic 842)" was issued by the FASB in February 2016. The Company adopted this ASU 2016-02 effective January 1, 2019 using the modified retrospective application, applying the new standard to leases in place as of the adoption date. Prior periods have not been adjusted. Leases existing for the reporting period beginning January 1, 2019 are presented under ASU 2016-02.

Arrangements that are determined to be leases at inception are recognized as long-term operating lease assets and lease liabilities in the consolidated balance sheet at lease commencement. Operating lease liabilities are recognized based on the present value of the future lease payments over the lease term at commencement date. As the rates implicit in the Company's leases are not reasonably determinable, the Company applies its incremental borrowing rate based on the economic environment at the commencement date in determining the present value of future lease payments. 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 elected to adopt a package of practical expedients under Topic 842 which removes the requirement to reassess whether expired or existing contracts contain leases and removes the requirement to reassess the lease classification for any existing leases prior to the adoption date of January 1, 2019. Additionally, 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.

P. Recent Accounting Standards:

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments – Credit Losses," to improve information on credit losses for financial assets and net investment in leases that are not accounted for at fair value through net income. ASU No. 2016-13 replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses. This guidance is effective for the Company beginning on January 1, 2023, with early adoption permitted. The Company does not expect that the adoption of this standard will have a significant impact on its consolidated financial statements and related disclosures.

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

P. Recent Accounting Standards: (Cont.)

In August 2018, the FASB issued ASU 2018-13, "Changes to Disclosure Requirements for Fair Value Measurements," which will improve the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements and was effective for the Company beginning on January 1, 2020. The adoption of ASU 2018-13 had no material impact on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18 ,"Collaborative Arrangements (Topic 808)," which clarifies the interaction between Topic 808 and Topic 606, "Revenue from Contracts with Customers." The Company adopted this standard on January 1, 2020. The adoption of ASU 2018-18 had no material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes" ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance was effective for the Company beginning on January 1, 2021, with early adoption permitted. The adoption of ASU 2019-12 had no material 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 in the consolidated statements of operations during the years for which the Company held short-term deposits.

As of December 31, 2020, the Company had deposits at Leumi Bank (Israel) and BHI USA that bore fixed annual interest between 0.51% and 1.58%. As of December 31, 2019, the Company has a deposit dominated in USD at BHI USA that bears fixed annual interest of 2.1%.

NOTE 4 - OTHER CURRENT ASSETS

	As of December 31,	
	2020	**2019**
Government institutions	276	244
Prepaid insurance	2,055	1,560
Other prepaid expenses	29	264
Lease incentive	1,075	-
Other	141	-
	3,576	2,068

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

NOTE 5 - PROPERTY AND EQUIPMENT, NET

	As of December 31,	
	2020	2019
Cost:		
Computers and software	483	350
Laboratory equipment	2,357	1,729
Equipment and furniture	120	159
Leasehold improvements	587	300
	3,547	2,538
Depreciation:		
Computers and software	310	199
Laboratory equipment	710	367
Equipment and furniture	36	5
Leasehold improvements	263	86
	1,319	657
	2,228	1,881

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 of up to $32,000 of the Company within ten years from the closing of the agreement and/or the entering of agreements with certain third parties or their affiliates that include a qualifying up-front fee and is entered into within three 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, 2020 and December 31, 2019.

The consolidated financial statements as of December 31, 2020 and 2019 include a liability with respect to this agreement in the amount of $83 and $260, respectively.

NOTE 7 - IN-PROCESS RESEARCH AND DEVELOPMENT

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 in the financial statements. Amortization expenses recorded in the consolidated statements of operations were $1,518 for the year ended December 31, 2020. Based on management's analysis, there was no impairment for the year ended December 31, 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. As a part of the agreement, the Company provided a bank guarantee to the landlord in the amount of approximately $95 representing four monthly lease payments. As of December 31, 2020, the bank guarantee expired and was not renewed. Lease expenses recorded in the consolidated statements of operations were $217 and $201 for the years ended December 31, 2020 and 2019, respectively.

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. As a part of the agreement, the Company provided a bank guarantee to the landlord in the amount of approximately $63 representing four monthly lease and related payments. Lease expenses recorded in the consolidated statements of operations were $141 and $18 for the years ended December 31, 2020, and 2019, respectively.

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 is exempt from monthly payments under the new agreement until January 15, 2021. In addition, the lessor will reimburse 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. BiomX Israel undertook to obtain a bank guarantee in favor of the landlord in the amount of approximately $208, representing four monthly lease and related payments. Lease expenses recorded in the consolidated statements of operations were $45 for the year ended December 31, 2020.

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 is required to deposit $8 as a security, representing two monthly lease and related payments. Lease expenses recorded in the consolidated statements of operations were $13 for the year ended December 31, 2020.

(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, 2020
Cash payments for operating leases	416

As of December 31, 2020, the Company's operating leases had a weighted average remaining lease term of 9.9 years and a weighted average discount rate of 6%. The maturity analysis of operating leases as of December 31, 2020 were as follows:

	Operating Leases
2021	890
2022	806
2023	763
2024	763
2025	763
2026	763
2027	763
2028	763
2029	763
2030	699
Total operating lease payments	7,736
Less imputed interest	1,841
Total operating lease liability balance	5,895

NOTE 9 - OTHER ACCOUNT PAYABLES

	As of December 31,	
	2020	2019
Employees and related institutions	2,441	1,780
Accrued expenses	1,128	587
Government institutions	344	169
Deferred income	65	60
	3,978	2,596

NOTE 10 - BALANCES AND TRANSACTION WITH RELATED PARTIES

A. Balances with related parties

	As of December 31,	
	2020	2019
Additional paid in capital (treasury stock) (See 1 below)	(19)	(19)
Related party receivable (See 2 below)	-	50

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

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

B. Transactions with related parties

	Year ended December 31,	
	2020	**2019**
Research and development expenses (See 2 below)	-	(167)

1. BiomX Israel entered into loan agreements with certain shareholders who were subject to taxation in Israel in connection with the Recapitalization Transaction. The loans are for a period of up to two years from the time of the grant, are non-recourse, and are 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 any of such shareholders 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. As of December 31, 2020, one loan was granted in the amount of $19, and the aggregate amount of the remaining potential commitment as of December 31, 2020 is $89. All other shareholders waived their right to the loans. The number of shares of Common Stock in respect of which the $19 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.

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. According to the IIA directives, the IIA funded 85% of the approved budget and the rest of the budget was funded by certain shareholders.

In April 2019, the IIA approved an application for a total budget of NIS 4,221 (approximately $1,185). IIA funded 30% of the approved budget. The program was for the period beginning from July 2018 through June 2019. As of December 31, 2020, BiomX Israel has received all funds with respect to this program.

In December 2019, the IIA approved an application for a total budget of NIS 10,794 (approximately $3,123). IIA funded 30% of the approved budget. The program is for the period beginning from July 2019 through December 2019. As of December 31, 2020, BiomX Israel has submitted the final report to the IIA for this program.

NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)

During April 2020, the IIA approved a new application for a total budget of NIS 15,562 (approximately $4,287). The IIA committed to funding 30% of the approved budget. The program was for the period beginning January 2020 through December 2020. As of December 31, 2020, the Company received NIS 1,634 (approximately $450) from the IIA with respect to this program. BiomX Israel has not yet submitted the final report to the IIA for this program.

Refer to note 18C for more information regarding approved applications in 2021.

According to the agreement 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, 2020, therefore, no liability was recorded in these consolidated financial statements.

Total research and development income recorded in the consolidated statements of operations was $518 and $299 for the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, BiomX Israel had a contingent obligation to the IIA in the amount of approximately $2,300 including annual interest of LIBOR linked to the dollar.

B. 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. In July 2019, the Company and Yeda amended the 2015 License Agreement and the 2017 License Agreement (as defined below) with Yeda (the "Yeda Amendment"). See Note 11G regarding the Yeda Amendment. As the Company has not yet generated revenue from operations, no provision was included in the consolidated financial statements as of December 31, 2020 and 2019 with respect to the 2015 License Agreement.

NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)

C. 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, the Company is obligated to pay $10 over the term of the 2017 License Agreement, unless earlier terminated by either party, and granted Yeda 591,382 warrants to purchase shares of Common Stock. Refer to Note 12 below for the terms of the warrants granted. In addition, the 2017 License Agreement includes additional consideration contingent upon future sales or sublicensing revenue. As the Company has not yet generated revenue from operations, no provision was included in the financial statements with respect to the 2017 License Agreement as of December 31, 2020 and 2019.

In July 2019, the Company and Yeda amended the 2015 License Agreement and the 2017 License Agreement with Yeda. See Note 11G regarding the Yeda Amendment.

D. 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 ended 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. The consolidated financial statements as of December 31, 2020 and 2019 include a liability with respect to this agreement in the amount of $240 and $108, respectively.

In October 2020, the Company and MIT amended the 2017 Patent License Agreement (the "MIT Amendment"). See Note 11I regarding the MIT Amendment.

E. 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 on revenue of products. The consolidated financial statements as of December 31, 2020 and 2019 include a liability with respect to this agreement in the amount of $83 and $260, respectively. Refer to Note 6 regarding contingent liability with respect to the RondinX Ltd. acquisition.

F. 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 $3,210 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, 2020 and 2019 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 $32,10 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 $378 and $217 as of December 31, 2020 and 2019, respectively.

G. In July 2019, the Company and Yeda amended the 2015 License Agreement and the 2017 License Agreement with Yeda. 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.

H. 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 is 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). Unless terminated earlier, this agreement will remain in effect, until one year after the Effective Date or completion of the Project Plan (as defined in the agreement) and submission and approval of the Final Report. As of December 31, 2020, consideration of $150 had been received.

I. 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.

J. Refer to Note 8 for information regarding the Company's lease commitments.

K. Refer to Note 10B(1) for information regarding the Company's commitment to certain shareholders for taxes incurred in Israel as a result of the Recapitalization Transaction.

NOTE 12 - 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. As of December 31, 2020, the Company had 23,270,337 issued shares and 23,264,637 outstanding shares of Common Stock.

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").

Issuance of Share Capital:

During 2018 BiomX Ltd. issued an aggregate amount of 3,028,990 Preferred A Shares (pre-merger) for a total consideration of $13,000, in connection with various share purchase agreement with investors.

In November 2018, the Company entered into a share purchase agreement (the "November 2018 SPA") with new and existing investors (the "November 2018 Investors"). In accordance with the November 2018 SPA, the Company issued to the November 2018 Investors a total of 5,478,985 Preferred B Shares at $0.0001 nominal value (the "Preferred B Shares") for total consideration of $31,955 as follows:

- On November 28, 2018 and on December 11, 2018, the Company issued to the November 2018 Investors 4,964,607 and 205,750 Preferred B Shares, respectively, for total consideration of $30,155 in accordance with the November 2018 SPA.

- On January 8, 2019, the Company issued to the November 2018 Investors an additional 308,628 Preferred B Shares for total consideration of $1,800 in accordance with the November 2018 SPA.

NOTE 12 - 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.

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, 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 recorded issuance expenses of $158.

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").

NOTE 12 - STOCKHOLDERS EQUITY (Cont.)

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, 2020, 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, 2020, there were 60,041 shares of Common Stock remaining for issuance under the 2019 plan. On January 1, 2021, the number of shares of Common Stock available to grant under the 2019 Plan was increased by 930,813.

Stock Options:

During 2019, the Board approved the grant of 704,669 options to 22 employees and 79,630 options to two consultants, without consideration. 527,716 of the options granted are to the executive officers of the Company. These options were granted under the 2015 Plan.

During 2019, 74,581 of these options were exercised to purchase shares of Common Stock at an average exercise price of $1.34 per share.

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

NOTE 12 - STOCKHOLDERS EQUITY (Cont.)

B. Stock-based compensation: (cont.)

Stock Options: (cont.)

Certain senior employees and 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 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 of Directors 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.

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:

	2020	2019
Underlying value of Common Stock ($)	5.59-6.44	1.7-10
Exercise price ($)	5.59-6.44	1.7-10
Expected volatility (%)	85.0	93.1
Term of the option (years)	6.11	6.11
Risk-free interest rate (%)	0.39-0.68	2.23

The cost of the benefit embodied in the options granted in 2020 and 2019 based on their fair value as at the grant date, is estimated to be $3,752 and $1,395, respectively. These amounts will be recognized in statements of operations over the vesting period.

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

NOTE 12 - STOCKHOLDERS EQUITY (Cont.)

B. Stock-based compensation: (cont.)

Stock Options: (cont.)

(1) 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, 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		

	For year ended December 31, 2019		
	Number of Options	Weighted average exercise price	Aggregate intrinsic value
Outstanding at the beginning of period	2,571,137	$ 1.34	$ 1,793
Granted	784,329	2.03	
Forfeited	(137,083)	1.90	
Exercised	(74,581)	1.34	
Outstanding at the end of period	3,143,802	$ 1.61	$ 25,733
Vested at end of period	1,482,098		
Weighted average remaining contractual life – years as of December 31, 2019	7.88		

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

NOTE 12 - STOCKHOLDERS EQUITY (Cont.)

B. Stock-based compensation: (cont.)

Warrants:

As of December 31, 2020, and 2019, the Company had the following outstanding warrants to purchase Common Stock as follows:

Warrant	Issuance Date	Expiration Date	Exercise Price Per Share (USD)	Number of Shares of Common Stock Underlying Warrants
Private Warrants issued to Yeda (see 1 below)	May 11, 2017	May 11, 2025	(*)	354,829
Private Warrants issued to Founders (see 2 below)	November 27, 2017		-	10,589
Private Placement Warrants (see 3 below)	IPO (December 13, 2018)	December 13, 2023	11.50	2,900,000
Public Warrants (see 4 below)	IPO (December 13, 2018)	October 28, 2024	11.50	3,500,000
				6,765,418

(*) less than $0.001.

1. In May 2017, in accordance with the 2017 License Agreement (see also Note 11C), 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.

For the year ended December 31, 2020, the Company recorded expense of $233. For the year ended December 31, 2019, the Company recorded income of $241. Expenses and income are included in R&D expenses, net in the consolidated statements of operations. See note 18B regarding the exercise of warrants.

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 cancelled following termination of the 2017 License Agreement,

b. 118,277 upon achievement of the earlier of the following milestone by the Company:

NOTE 12 - STOCKHOLDERS EQUITY (Cont.)

B. Stock-based compensation: (cont.)

Warrants: (cont.)

(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 cancelled 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 2020 and 2019.

3. 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. The Company filed a Registration Statement on Form S-1 for the resale of shares underlying the warrants on December 13, 2019, which was declared effective on January 3, 2020. Such Registration Statement was converted to Form S-3 in December 2020.

4. 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, 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 filed a Registration Statement on Form S-1 for the resale of shares underlying the warrants on December 13, 2019, which was declared effective on January 3, 2020. Such Registration Statement was converted to Form S-3 in December 2020.

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

NOTE 12 - STOCKHOLDERS EQUITY (Cont.)

B. Stock-based compensation: (cont.)

Warrants: (cont.)

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.

(2) 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,	
	2020	**2019**
Research and development expenses, net	1,815	450
General and administrative	1,075	488
	2,890	938

The Company recognized stock-based compensation expenses in connection with options granted to executive officers of the Company in the amount of $1,384 and $732 for the years ended December 31, 2020 and 2019, respectively.

The total unrecognized compensation expense was $2,657 and $2,308 as of December 31, 2020 and 2019, respectively. These expenses will be recognized over a period of approximately 2 years.

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

NOTE 13 - RESEARCH AND DEVELOPMENT EXPENSES, NET

	Year ended December 31,	
	2020	2019
Professional service and subcontractors	6,576	5,787
Salaries and related expenses	9,210	6,404
Stock-based compensation	1,815	450
Depreciation	652	317
Materials and supplies	1,094	997
Amortization	1,518	-
Rent and related expenses	664	-
Other	84	-
	21,613	13,955
Less income from collaboration agreements (see Note 11H,10B2)	(160)	(167)
Less grants from the IIA (see Note 11A)	(518)	(299)
	20,935	13,489

NOTE 14 - GENERAL AND ADMINISTRATIVE EXPENSES

	Year ended December 31,	
	2020	2019
Salaries and related expenses	2,757	1,746
Stock-based compensation	1,075	488
Professional services	1,648	3,434
Travel expenses	173	445
Recruitment expenses	170	333
Rent and related expenses	262	479
Insurance expenses	1,985	331
Other	1,253	1,462
	9,323	8,718

NOTE 15 - FINANCE INCOME (EXPENSES), NET

	Year ended December 31,	
	2020	2019
Exchange rate differences	511	(483)
Interest income from bank deposits	(641)	(921)
Revaluation of contingent liabilities	116	(304)
Bank fees and other	7	64
Income from foreign exchange contracts	(165)	-
	(172)	(1,644)

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

NOTE 16 - 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, 2020, the Company had total net operating losses in the U.S of approximately $3,425, 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 income tax returns since inception remain open and subject to examination. The statutory Israeli income tax rate is 23%.

C. As of December 31, 2020 and 2019, BiomX Israel had total net operating losses in Israel of approximately $62,927 and $25,883, respectively, which may be carried forward and offset against taxable income in the future for an indefinite period.

D. 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, 2020 and 2019. Management reevaluates the positive and negative evidence at each reporting period.

F. 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, 2020 and 2019.

	As of December 31,	
	2020	**2019**
Net operating loss carryforward BiomX Inc.	719	-
Net operating loss carryforward BiomX Ltd.	14,473	5,953
Total deferred tax assets	15,192	5,953
Valuation allowance	(15,192)	(5,953)
Net deferred tax assets	-	-

A reconciliation of the U.S. federal statutory tax rate and the effective tax rate is as follow:

	As of December 31,	
	2020	**2019**
Statutory U.S. federal income tax rate	(21)%	(21)%
U.S. vs foreign tax rate differential	(2)	(2)
Business Combination expenses	-	3.1
Change in deferred tax asset valuation allowance	23	19.9
Effective tax rate	-%	-%

Loss from operations, before taxes on income, consists of the following:

	As of December 31,	
	2020	**2019**
United States	3,273	1,589
Israel	26,813	18,974
	30,086	20,563

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

NOTE 17 - 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,	
	2020	**2019**
Net loss	30,086	20,563
Net loss per share	1.30	3.66
Weighted average number of Common Stock	23,062,216	5,615,856

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.

NOTE 18 - SUBSEQUENT EVENTS

A. On March 30, 2021, the Board of Directors approved the grant of 985,530 options to 104 employees, one consultant, five senior officers and six directors under the 2019 Incentive 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.

B. On March 10, 2021, Yeda exercised 362,444 warrants on a cashless basis, resulting in the issuance of 362,383 shares of Common Stock.

C. On March 25, 2021, the IIA approved two new applications for a total budget of NIS 19,444 (approximately $5,874). The IIA committed to funding 30% of the approved budget. The programs are for the period beginning January 2021 through December 2021.

D. From January 1, 2021 through March 25, 2021, we issued an aggregate of 600,644 shares of Common Stock pursuant to the ATM Agreement for aggregate net proceeds of $4,324.

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

BiomX Inc., or the Company, we, us or our, has three classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended, or the Exchange Act: (i) shares of Common Stock, $0.0001 par value per share, or common stock; (ii) Units, each consisting of one share of common stock and one warrant entitling the holder to receive one-half (1/2) of a share of common stock, or the units; and (iii) the warrants included as part of the units, or the warrants. Each of the Company's securities registered under Section 12 of the Exchange Act are listed on the NYSE American Stock Market.

DESCRIPTION OF SECURITIES

The following summary is a description of the material terms of our share capital. We encourage you to read our Amended and Restated Certificate of Incorporation, as amended, or our Certificate of Incorporation, and Amended and Restated By-laws, or our Bylaws, which have been filed with the Securities and Exchange Commission, as well as the applicable provisions of the General Corporation Law of the State of Delaware, or the DGCL, for more information.

Our authorized capital stock consists of 60,000,000 shares of common stock, and 1,000,000 shares of preferred stock, none of which shares of preferred stock are outstanding.

Common Stock

Our holders of record of our common stock are entitled to one vote for each share held on all matters to be voted on by stockholders. Our stockholders have no conversion, preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to the shares of common stock. There is no cumulative voting with respect to the election of directors. Our stockholders are entitled to receive ratable dividends when, as and if declared by our Board of Directors out of funds legally available therefor.

We have not paid any cash dividends on our common stock to date and do not intend to pay cash dividends in the foreseeable future. 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.

Preferred Stock

We have no shares of preferred stock outstanding. Our Certificate of Incorporation authorizes the issuance of 1,000,000 shares of preferred stock with such designation, rights and preferences as may be determined from time to time by our Board of Directors. Accordingly, our Board of Directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. In addition, the preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us. Although we do not currently intend to issue any shares of preferred stock, we reserve the right to do so in the future.

Warrants

Each warrant entitles the registered holder to purchase one-half (1/2) of a share of common stock at a price of $11.50 per whole share, subject to adjustment as discussed below, at any time commencing on December 18, 2019. A warrantholder may exercise its warrants only for a whole number of shares. This means that only an even number of warrants may be exercised at any given time by a warrantholder. However, no warrants will be exercisable for cash unless we have an effective and current registration statement covering the shares of common stock issuable upon exercise of the warrants and a current prospectus relating to such shares of common stock. The warrants will expire on October 28, 2024 at 5:00 p.m., New York City time.

We may call the outstanding warrants for redemption, in whole and not in part, at a price of $0.01 per warrant:

- at any time while the warrants are exercisable,
- upon not less than 30 days' prior written notice of redemption to each warrantholder,
- if, and only if, the reported last sale price of the shares of common stock equals or exceeds $16.00 per share, for any 20 trading days within a 30-day trading period ending on the third business day prior to the notice of redemption to warrantholders, 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.

The right to exercise will be forfeited unless the warrants are exercised prior to the date specified in the notice of redemption. On and after the redemption date, a record holder of a warrant will have no further rights except to receive the redemption price for such holder's warrant upon surrender of such warrant.

The redemption criteria for our warrants have been established at a price which is intended to provide warrantholders a reasonable premium to the initial exercise price and provide a sufficient differential between the then-prevailing share price and the warrant exercise price so that if the share price declines as a result of our redemption call, the redemption will not cause the share price to drop below the exercise price of the warrants.

If we call the warrants for redemption as described above, our management will have the option to require all holders that wish to exercise the warrants to do so on a "cashless basis." In such event, each holder would pay the exercise price by surrendering the warrants for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" (defined below) by (y) the fair market value. The "fair market value" shall mean the average reported last sale price of our common stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of warrants. Whether we will exercise our option to require all holders to exercise their warrants on a "cashless basis" will depend on a variety of factors including the price of our common stock at the time the warrants are called for redemption, our cash needs at such time and concerns regarding dilutive share issuances.

The warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. The warrant agreement provides that the terms of the warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval, by written consent or vote, of the holders of a majority of the then-outstanding warrants in order to make any change that adversely affects the interests of the registered holders.

The exercise price and number of shares of common stock issuable on exercise of the warrants may be adjusted in certain circumstances including in the event of a share dividend, extraordinary dividend or our recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for issuances of shares of common stock at a price below their respective exercise prices.

The warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of warrants being exercised. The warrantholders do not have the rights or privileges of holders of shares of common stock and any voting rights until they exercise their warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

Except as described above, no warrants will be exercisable for cash and we will not be obligated to issue shares of common stock unless at the time a holder seeks to exercise such warrant, a prospectus relating to the shares of Common Stock issuable upon exercise of the warrants is current and the shares of common stock have been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Under the terms of the warrant agreement, we have agreed to use our best efforts to meet these conditions and to maintain a current prospectus relating to the shares of common stock issuable upon exercise of the warrants until the expiration of the warrants. However, we cannot assure you that we will be able to do so and, if we do not maintain a current prospectus relating to the shares of common stock issuable upon exercise of the warrants, holders will be unable to exercise their warrants and we will not be required to settle any such warrant exercise. If the prospectus relating to the shares of common stock issuable upon the exercise of the warrants is not current or if the common stock is not qualified or exempt from qualification in the jurisdictions in which the holders of the warrants reside, we will not be required to net cash settle or cash settle the warrant exercise, the warrants may have no value, the market for the warrants may be limited and the warrants may expire worthless.

Warrantholders may elect to be subject to a restriction on the exercise of their warrants such that an electing warrantholder would not be able to exercise their warrants to the extent that, after giving effect to such exercise, such holder would beneficially own in excess of 9.9% of the shares of common stock outstanding.

No fractional shares will be issued upon exercise of the warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number of shares of Common Stock to be issued to the warrantholder.

Certain Anti-Takeover Provisions of Delaware Law and our Certificate of Incorporation and Bylaws

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

- a stockholder who owns 10% or more of our outstanding voting stock (otherwise known as an "interested stockholder");
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A "business combination" includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 do not apply if:

- our Board of Directors approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction;
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock; or
- on or subsequent to the date of the transaction, the business combination is approved by our Board of Directors and authorized at a meeting of our stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Special meeting of stockholders

Our Bylaws provide that special meetings of our stockholders may be called only by a majority vote of our Board of Directors, or by our chief executive officer.

Classified Board of Directors

Our Board of Directors is divided into three classes, each of which will generally serve for a term of three years with only one class of directors being elected in each year. This system of electing Directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the Directors.

Advance notice requirements for stockholder proposals and director nominations

Our Bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders must provide timely notice of their intent in writing. To be timely, a stockholder's notice to bring matters before our annual meeting of stockholders needs to be delivered to our principal executive offices not later than the close of business on the 90th day nor earlier than the opening of business on the 120th day prior to the scheduled date of the annual meeting of stockholders, and a stockholder's notice to nominate candidates for election as directors needs to be delivered to us not less than 120 days prior to any meeting of stockholders called for the election of directors. Our Bylaws also specify certain requirements as to the form and content of a stockholders' notice. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Exhibit 10.14

CERTAIN INDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO BIOMX LTD. IF PUBLICLY DICSLOSED. OMISSIONS ARE DENOTED IN BRACKETS THROUGHOUT THIS EXHIBIT.

Addendum to an Unprotected Lease Contract from 24th May 2017

prepared and signed in ____ on the _____ day of the month of _____ 2020

Between

1. **AFI Properties Ltd. (25.3%)**
of 4 Derech Hachoresh, Yehud

2. **Ef-Shar Ltd. (34.7%)**
of 4 Derech Hachoresh, Yehud

3. **Weizmann Institute of Science** (hereinafter – **the "Institute") (40%)** at the Weizmann Institute of Science Assets and Development (Mul Nof) Ltd. Beit Sagan, Weizmann Institute of Science, Herzl St 234, Rehovot By Afi Properties Ltd. and/or Ef-Shar Ltd. (hereinafter – **"AFI"**) By virtue of power of attorney signed by the Institute on 26th October 2015 (hereinafter together, distinctly from "jointly and severally" – **the** "**Lessor**")

The first party;

And

BiomX Ltd.
B.N: 515220556
(Hereinafter – **the "Lessee"**)

The second party;

Whereas an unprotected lease contract was signed between the Lessor and the Lessee on 24th May 2017 with its appendices and addendums (hereinafter together: **the "Lease"**), by virtue of which the Lessee leases from the Lessor an area of [**] (hereinafter: "**Area A"**) and [**] (hereinafter: **"Area B"**) in the Science Park in Ness Ziona (hereinafter respectively: **the "Lease", the "Leased Property" and the "Park"**); and

Whereas The Lessee has requested the termination of the lease in Area A and Area B (hereinafter: **the "Returned Area"**) from the Lessor on the determining date, as defined below; and

Whereas The Lessee has requested from the Lessor to rent an additional area [**] (hereinafter: **"Area C"**) and an additional area [**] (hereinafter: **"Area D"**) within the boundaries marked in red in the drawing attached to this addendum as **Appendix A** (Area C and Area D shall be referred to together below as **the "Additional Area"**); and

Whereas The Lessor has agreed to the Lessee's aforesaid requests, all in accordance with the details and conditions stipulated in this addendum below.

It is therefore agreed and stipulated between the parties as follows:

1. The preamble and the appendices to this addendum form an inseparable part thereof.

2. Each term appearing in this addendum shall have the meaning given to it in the Lease, unless expressly stated otherwise.

3. **Termination of the Lease in the Returned Area**

3.1 Subject to the fulfillment of the provisions of this addendum by the Lessee, the Lease of the Returned Area will be terminated on 31st March 2021 (hereinafter: **the "Determining Date"**) and the Lessee will be subject to all of the provisions of the Lease regarding vacating the Returned Area.

3.2 Notwithstanding the provisions of section 3.1 above, [**]. For the avoidance of doubt, the provisions of the Lease, including the termination of the Lease and the vacating of the Lessee, shall also apply in relation to [**].

3.3 The Lessee hereby declares and undertakes that until no later than the Determining Date [**], they will vacate the Returned Area, in accordance with the vacating provisions set forth in the Lease, when it is free from all persons and objects, as stated in the Lease.

3.4 The Lessee declares and hereby confirms that they are aware that as of the Determining Date, the Returned Area will be leased and handed over to a new lessee/new lessees (hereinafter: **the "New Lessee"**). The Lessee also declares that they are aware that any delay in their vacating of the Returned Area, for any reason, will cause a delay in the commencement of the New Lessee's lease in the Returned Area, for all that it entails. The Lessee hereby undertakes to indemnify the Lessor, at their first request in writing by law that has not been delayed, for any damage and/or expense incurred to them in connection with any delay in vacating the Returned Area, in whole or in part, for a reason dependent on the Lessee only.

4. **The Additional Area**

4.1 The Lessee hereby leases to the Lessee and the Lessee hereby leases from the Lessor, the Additional Area as defined above under the terms of the Lease, mutatis mutandis, subject to the conditions in this addendum above and below.

4.2 The area of Area C, for the purposes of payments according to the Lease and this addendum, [**]when it is clarified that this area includes the load due to the relative share of the Additional Area in the public areas in the building due to their joint use.

4.3 The area of Area D, for the purposes of payments according to the Lease and this addendum, [**], when it is clarified that this area includes the load due to the relative share of the Additional Area in the public areas in the building due to their joint use.

The Lessee declares that as of the date of signing this addendum, they are not aware of any defect or fault in the Additional Area.

5. **The Lease Period in the Additional Area**

5.1 The lease period in the Additional Area will begin on 1st September 2020 (hereinafter: **the "Delivery Date"**) and will end [**] (hereinafter: **the "Lease Period in the Additional Area"**).

The Additional Area will be handed over to the Lessee on the Delivery Date in its condition as is without the Lessor making any work and/or adjustments to it. The Lessee declares that as of the date of signing this addendum, they are not aware of any defect or fault in the Additional Area.

Delay in the delivery of the Additional Area due to reasons dependent on the Lessor and/or those on their behalf will delay and postpone the actual Date of Delivery but not the Lessee's obligations from the Date of Delivery stated above and hereafter, including regarding their obligations to pay rent and management fees, etc. and payments in respect of the Additional Area, in accordance with the provisions of the lease and this addition (without prejudice to section 8 below). The parties agree that insofar as there is an impediment in receiving the Additional Area on the Date of Delivery for a reason dependent on the Lessor or Transferor, as stated in the tripartite agreement attached as Appendix ___, the Date of Delivery and the Determining Date will be postponed accordingly until the impediment is removed. To the extent that there is a delay in handing over possession of the Additional Area for a reason dependent on the said Lessee or transferor, the parties agree that the Lessee will continue to lease the occupied area and seize possession of it, in accordance with the provisions of the Lease and all the dates stated in this addendum will be postponed accordingly. In addition, to the extent that the delay in handing over possession of the Additional Area for a reason dependent on the Lessor or transferor is more than [**], each of the parties will be entitled to cancel this addendum by giving written notice at the end of the [**]and on that date only. If no notice is given on this date by any of the parties, this will constitute a waiver by the parties of the possibility of cancellation in these circumstances as stated.

In the event of cancellation of the said addendum, the Lessee will continue to lease the Returned Area and will continue to occupy it until the end of the Lease and will continue to fulfill all their obligations in relation to the Returned Area, including making payments, all in accordance with the Lease.

6. **Additional Lease Period in the Additional Area**

Subject to the fulfillment of the conditions listed below, [**]

1. If the Lessee has not breached during the Lease Period in the Additional Area any of his obligations under this contract, a breach which has not been remedied on the date stipulated in this agreement, insofar as such date has been stipulated in the agreement, including and without derogating from the aforesaid generality, all payments applicable to them under this agreement shall be paid, in full and on time.

2. There are no legal proceedings or arbitration proceedings or disagreements between the parties regarding the fulfillment of the Lessee's obligations under the lease agreement and this addendum.

3. The Lessor did not receive, at least three (3) months before the end of the Lease Period in the Additional Area, a letter by registered mail from the Lessee, informing [**].

4. [**]all the insurances and collateral under this contract, and presented them to the Lessor, [**].

(The Lease Period in the Additional Area [**] will be referred to together hereinafter as **the "Lease Period"**).

At the end of the Lease Period in the Additional Area and/or the end of the Lease Period, [**]the Lessee's Lease in the Additional Area will come to an end and the provisions of the Lease regarding the termination of the Lease and the vacating of the Lessee will apply.

7. **Rental and Service Fees**

7.1 The rent to be paid by the Lessee for the Additional Area during the Lease Period in the Additional Area and the Additional Lease Period will be [**]of the Additional Area per month, plus VAT, with this amount linked to the consumer price index published on 15 May 2020 in respect of April 2020 (hereinafter: **the "Basic Index"**).

7.2 The service fee to be paid by the Lessee for the additional area will be customary from time to time in the building, and will be paid plus VAT and linked to the Basic Index in the acceptable manner in the building. Without derogating from the aforesaid, it should be noted that [**].

7.3 The rental and service fees for the Additional Area will be paid on the dates and in the manner specified in the Lease.

7.4 For the avoidance of doubt, it is clarified that all other obligations and payments applicable to the Lease under the lease agreement, including (but not limited to) property taxes, electricity, water and any payment to any third party, will also apply to the Additional Area, all in accordance with the Lease.

8. **[**]**

[**].

[**].

The Lessor hereby notifies the Lessee that they have a banker's lien and have registered in their favor a first lien in respect of the land on which the Leased Property is built. The aforesaid shall not derogate from the rights of the Lease under this agreement.

9. **Construction Budget**

It is agreed that the Lessor will participate in the cost of carrying out construction work in the Additional Area only and up to a total amount of [**] (hereinafter: **the "Lessor's Participation in the Construction"**), which will be paid to the Lessee in the manner and conditions accepted by the Lessor, [**], in return for presenting a legal tax invoice prepared in the name of the Lessor. The Lessee undertakes to bear alone any additional cost that may be required as part of the construction work on the Leased Property. The parties agree that the responsibility for carrying out the construction work on the Leased Property, for all that it entails, including planning and coordination with any relevant party required, will rest solely on the Lessee and the lessor undertakes to sign any documents regarding the construction work as required, as part of their signature as owner in the additional area, provided that this does not impose any financial and/or other obligation on them. It is hereby clarified and agreed that the Lessor's participation in the construction work on the Leased Property as specified above does not impose on the Lessor any liability and/or responsibility in connection with the planning and/or execution of the works on the Leased Property, and the Lessee hereby declares that they will be solely responsible for any approval and/or permit required by law, and will also be responsible for the execution and planning of the construction work on the Leased Property. The Lessee hereby declares and confirms that they do not have and will not have any claim and/or demand and/or lawsuit against the Lessor in this context, except in the case of malice and/or negligence on behalf of the Lessor.

For the avoidance of doubt, the Lessor is not required to carry out any adjustment and/or renovation and/or construction work on the Leased Property themselves.

For the avoidance of doubt, it is hereby clarified that the construction budget as defined below, is determined [**] (and without detracting from the Lessor's rights in this case in case of breach of contract by the Lessee), an amount equal to [**]of the construction budget [**].

Construction budget refund:

During the first Lease Period, the Lessee will pay, at a monthly rate, the construction budget reimbursement, at a rate of [**] (hereinafter: **the "Construction Budget Reimbursement"**)

It is agreed that the collateral provided by the Lessee to the Lessor in accordance with the provisions of this agreement will also be used to secure the Lessee's undertakings in respect of the aforesaid, all without prejudice to any other relief and/or remedy reserved to the Lessor under this contract and/or any applicable law.

It is clarified that the above does not constitute consent and/or approval to shorten the Lease Period for any purpose.

10. **Parking Spaces**

10.1 From the Date of Delivery and during the Lease Period in the Additional Area, the Lessee may use, for parking purposes only, [**]to be allocated by the Lessor [**] (hereinafter respectively: **the "Parking Spaces" and the "Parking Lot"**). The Lessor will be entitled to change, subject to 3 days' prior notice to the Lessee, from time to time, the location of the Parking Spaces, at their sole discretion, subject to providing notice to the Lessee and provided it is done in coordination with the Lessee, without the Lessee having any claim and/or lawsuit and/or demand in connection in this regard.

10.2 In respect of each of the Parking Spaces, the Lessee will pay the Lessor a sum in the amount of [**], with this amount linked to the Basic Index plus VAT (hereinafter: **the "Parking Fee"**).

11. **Bank Guarantee**

To ensure the fulfillment of all obligations of the Lessee according to this addendum and according to the Lease, and as a precondition for delivery of possession in the Additional Area by the Lessee, the Lessee will provide the Lessor, no later than the Date of Delivery in the Additional Area, an autonomous bank guarantee in the amount of ___ NIS (hereinafter: **the "Supplementary Guarantee"**) which will join the existing bank guarantee at the hands of the Lessor. It is clarified that all the provisions of the lease agreement regarding the bank guarantee will apply, respectively, to the Supplementary Guarantee, including the manner of realization, the date and the conditions for returning the guarantee to the Lessee. The sum of the Supplementary Guarantee will be linked to the Basic Index. If the Supplementary Guarantee is not issued on such date, this addendum shall be considered null and void and the Lessee will not have any claim and/or demand and/or lawsuit in connection therewith. The Supplementary Guarantee will be used by the Lessor together with the balance of the collateral deposited with the Lessor to secure the Lessee's obligations in accordance with the Lease and in accordance with this addendum.

Without derogating from the aforesaid, and insofar as the Lessor chooses not to cancel this addendum, then failure to deposit the Supplementary Guarantee on the date stated in this section above will postpone the date of delivery of possession in the Additional Area but not the Lessee's charges under this addendum and under the Lease.

12. The validity of the Lessee's insurance under the Lease will be extended in accordance with this addendum so that they apply to the additional Area throughout the Lease Period in the Additional Area, the Lessee undertakes to present to the Lessor, until the date of commencement of the Lease Period in the Additional Area, the insurance certificates attached to the Lease when they are signed by their insurer.

13. It is agreed that a breach of this addendum will constitute a breach of the Lease for all intents and purposes and that a breach of the Lease will constitute a breach of this addendum.

14. Except for the matters specified and regulated explicitly in this addendum, all the provisions of the Lease will continue to apply to the Lessor in the Leased Property and in the Additional Area.

15. Each term mentioned in this addendum shall have the meaning given to it in the Lease, unless otherwise expressly provided in this addendum.

In witness whereof the parties have signed:

/s/ Jonathan Solomon, CEO /s/ Marina Wolfson, SVP Finance and Operations	/s/ Ariel Goldstein /s/ Avi Barzilay
Biomx Ltd. **The Lessee**	**Ef-Shar Ltd.** **AFI Properties Ltd.** **The Lessor**

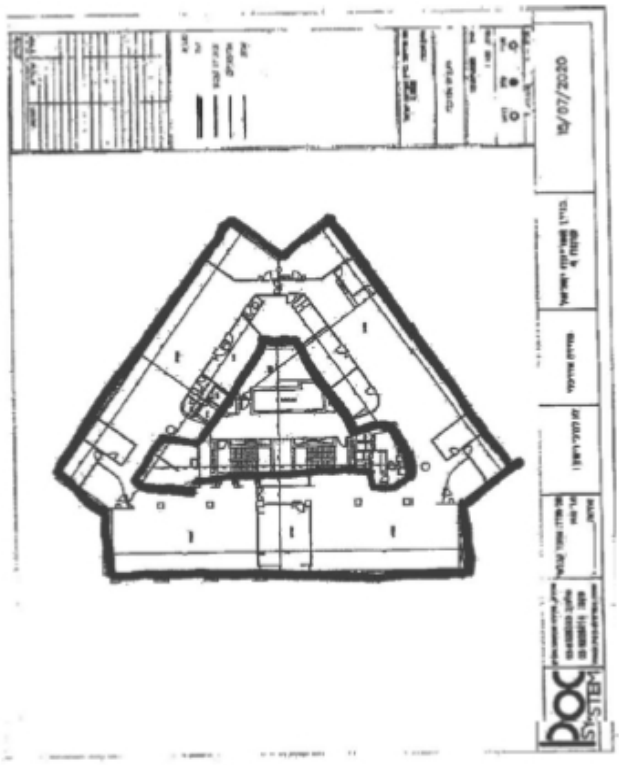


Exhibit 10.15

CERTAIN INDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO BIOMX INC. IF PUBLICLY DICSLOSED. OMISSIONS ARE DENOTED IN BRACKETS THROUGHOUT THIS EXHIBIT.

Agreement

prepared and signed on the 7th day of the month of **September** 2020

Between

1. **AFI Properties Ltd. (25.3%)**
   of 4 Derech Hachoresh, Yehud

2. **Ef-Shar Ltd. (34.7%)**
   of 4 Derech Hachoresh, Yehud

3. **Weizmann Institute of Science** (hereinafter – **the "Institute") (40%)** at the Weizmann Institute of Science Assets and Development (Mul Nof) Ltd. Beit Sagan, Weizmann Institute of Science, Herzl St 234, Rehovot By Afi Properties Ltd. and/or Ef-Shar Ltd. (hereinafter – **"AFI"**) By virtue of power of attorney signed by the Institute on 26th October 2015 (hereinafter together, distinctly from "jointly and severally" – **the** "**Lessor**")

The first party;

And

Nova Measuring Instruments Ltd.
B.N: 511812463
(Hereinafter – **the "Transferor"**)

The second party;

And

BiomX Ltd.
B.N: 515220556
(Hereinafter – **the "Transferee"**)

The third party;

Whereas An unprotected lease was drawn up between Ef-Shar and the Transferor on September 19, 1995, with its appendices and addendums (hereinafter: **the "Lease with the Transferor"**), by virtue of which the Transferor leases from the Lessor an area [**] in the Science Park in Ness Ziona as marked in red in the blueprint attached to this agreement as Appendix A (hereinafter respectively: **the "Lease", the "Leased Property" and the "Park"**); and

Whereas The Transferor and the Transferee requested from the Lessor that the Transferor's lease be terminated and to commence the Transferee's lease under the terms of the addendum to the Lease with the Transferee at the same time as signing this agreement (hereinafter: **the "Lease Addendum with the Transferee"**); and

Whereas The Lessor complied in principle with the transfer of possession of the Leased Property of the Transferor and the Transferee, in accordance with and subject to the full observance of the provisions of this agreement by the Transferor and the Transferee, including all the conditions set out below; and

Whereas The Transferee requested from the Lessor [**]; and

Whereas The Lessor complied with the Transferor's request [**].

It is therefore agreed and stipulated between the parties as follows:

1. The preamble and the appendices to this agreement form an inseparable part thereof.

2. Subject to the prior existence of all the cumulative conditions set forth in section 4 below, the Transferor's lease term shall terminate on 31st August 2020 (hereinafter: **the "Determining Date"**), and the provisions of the Lease with the Transferor regarding the termination of the Lease and the vacating of the Leased Property by the Transferor, subject to the provisions of this agreement below, and the Transferee's lease shall commence under the terms of the addendum with the Transferee and this agreement in such a manner as from the Determining Date shall apply to the Transferee all obligations specified in the Lease agreement and addendum.

3. The Transferor will continue to bear towards the Lessor their full obligations towards them in relation to the period up to the Determining Date and/or the charges that arose before the aforesaid date even if the demand for payment is received at a later stage and bears any payment and/or liability and/or responsibility in this regard, without this agreement derogating from any such obligations and/or constituting any waiver on behalf of the Lessor in connection therewith.

4. An essential and precondition for the entry into force of this agreement is that the Transferor will present to the Lessor all the documents and perform all the actions as detailed below no later than 14 days from the date of signing this agreement or by the Determining Date, whichever is earlier:

   4.1 The Transferee will sign the Lease Addendum with the Lessor and will provide the Lessor with all the collateral required for the Leased Property in accordance with the provisions of the Lease Addendum with the Transferee.

   4.2 The Transferee will present to the Lessor the letter of authorization to debit the Lessee's account as required by the provisions of the Lease with the Transferee.

   4.3 The Transferee will fulfill in full and on time the provisions of the Lease with the Transferee and the addendum relating to the preparation of insurance in respect of the Leased Property and will proved a certificate to that effect from their insurer to the Lessor.

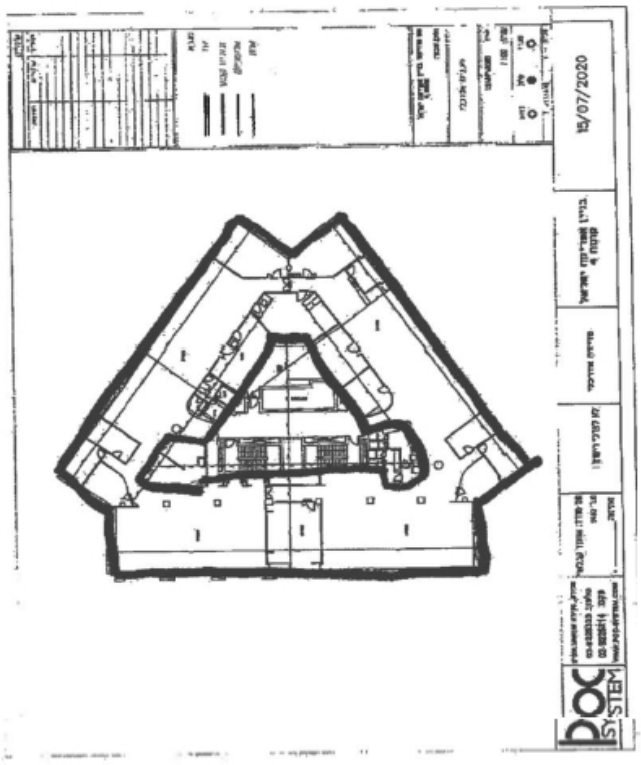
5. The Transferor hereby declares and undertakes that they are solely responsible to the Transferee for the delivery of the Leased Property to the Transferor on the Determining Date. The Transferee declares that they are aware that the Transferor is solely responsible to them in relation to the delivery of the said Leased Property and they remove responsibility from the Lessor for the delivery of the Leased, without detracting from the aforesaid addendum of the Lease with the Transferee. In this regard, the Transferor and the Transferee declare and undertake that they will not make any demand and/or claim and/or lawsuit against the Lessor in connection with the delivery of the Lease to the Transferee as stipulated in this agreement, including and without derogating from the above with regard to the return of the Transferor's investments of any kind in the Leased Property, as long as they exist.

6. The Transferor and the Transferee declare that they will not be permitted to make any demand and/or claim and/or lawsuit against the Lessor in case of any defects and/or faults in the Leased Property, and that they agree to hand over the transferred area to the Transferee as is on the Determining Date without the Lessor performing any adjustment and/or construction work of any kind and they waive any claim and/or demand and/or lawsuit against the Lessor in connection with this section, and they waive any claim and/or demand and/or lawsuit against the Lessor in connection with what is stated in this section, without derogating from what is stated in the Lease Addendum with the Transferee.

7. **In addition to the stipulation in section 4 above, it is expressly stated that the validity of this agreement is conditional on a condition under which this agreement will not enter into force unless the "Addendum with the Transferee" is signed between the Lessor and the Transferee by no later than the Determining Date.**

8. Except as provided herein and in the Addendum to the Lease, no change will be made to the provisions of the Lease with the Transferee.

/s/ Jonathan Solomon, CEO /s/ Marina Wolfson, SVP Finance and Operations	/s/ Ariel Goldstein /s/ Avi Barzilay	/s/ **Avishai Shahaf,** **Procurement manager** /s/**Gabi Sharon, VP Operations**
BiomX Ltd. **The Transferee**	**Afi Properties Ltd.** **Ef-Shar Ltd.** **The Lessor**	**Nova Measuring Instruments Ltd.** **The Transferor**



[Stamp]: Ef-Shar Ltd. [signature]

[Stamp] Afi Properties Ltd. [signature]

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement on Form S-8 (File No. 333-235777), Registration Statement on Form S-3 (File No. 333-251151) and Post-Effective Amendment on Form S-3 to Registration Statement on Form S-1 (File 333-235507) of our report dated March 31, 2021, relating to the financial statements of BiomX Inc. as of December 31, 2020 and 2019 and for each of the two years in the period ended December 31, 2020, appearing in this Annual Report on Form 10-K of BiomX Inc. for the year ended December 31, 2020.

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

Tel Aviv, Israel
March 31, 2021

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934

I, Jonathan Solomon, certify that:

1. I have reviewed this Annual Report on Form 10-K of BiomX Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2021

/s/ Jonathan Solomon
Jonathan Solomon
Chief Executive Officer
(Principal executive officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934

I, Marina Wolfson, certify that:

1. I have reviewed this Annual Report on Form 10-K of BiomX Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2021

/s/ Marina Wolfson
Marina Wolfson
Senior Vice President for Finance and Operations
(Principal financial officer)

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Annual Report of BiomX Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), each of the undersigned, in the capacities and on the dates indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, that to his or her knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

/s/ Jonathan Solomon
Jonathan Solomon
Chief Executive Officer
(Principal executive officer)

Date: March 31, 2021

/s/ Marina Wolfson
Marina Wolfson
Senior Vice President for Finance and Operations
(Principal financial officer)

Date: March 31, 2021