

**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, 2019**

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

At June 30, 2019, 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 \$68,578,950 based on the closing sale price of the Registrant's shares of common stock on June 28, 2019 (the last trading day of the fiscal quarter) of \$9.79 per share.

The number of shares outstanding of the Registrant's shares of common stock as of March 25, 2020 was 22,911,142.

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 Annual Meeting of Stockholders to be held on June 3, 2020, are incorporated herein by reference for purposes of Items 10, 11, 12, 13 and 14 of 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, 2019.

BIOMX INC.
Annual Report on Form 10-K for the Year Ended December 31, 2019

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PART I

Throughout this Annual Report on Form 10-K (the “Annual Report”), we refer to the special purpose acquisition company, Chardan Healthcare Acquisition Corp. prior to the Closing Date (defined below), as the “Company.” Following consummation of the Business Combination (defined below), the “Company,” and references to “we,” “us,” or similar such references should be understood to be references to the combined company, BiomX Inc. When this Annual Report references “BiomX” and describes the business of BiomX, it refers to the business of BiomX Ltd., the Israeli entity, prior to the consummation of the Business Combination. Following the date of the Business Consummation, references to “BiomX” should be understood to reference BiomX Ltd. Given that the Business Combination is accounted for as a reverse merger, as described in more detail below, and the accounting acquirer is BiomX Ltd., the post-Business Combination financial statements included in this Annual Report show the consolidated balances and transactions of the Company and BiomX as well as comparative financial information of BiomX (the acquirer for accounting purposes).

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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended (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 and financial position.

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 of BiomX.” The risks and uncertainties include, but are not limited to:

- our limited operating history;
- 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 U.S. Food and Drug Administration’s (“FDA”) classification of our BX001 product candidate 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;
- the impact of unfavorable pricing regulations, third-party reimbursement practices or health care reform initiatives 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 16.

Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking 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. Accordingly, you should not rely on these forward-looking statements, which speak only as of the date of this report. 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 (“SEC”) after the date of this report.

ITEM 1. BUSINESS

BiomX

BiomX is an Israeli company formed on March 3, 2015. It is a clinical stage microbiome product discovery company developing products using both natural and engineered phage technologies designed to target and destroy bacteria that affect the appearance of skin, as well as harmful bacteria in chronic diseases, such as inflammatory bowel disease (“IBD”), liver disease and cancer. Bacteriophage or phage are 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, BiomX develops phage-based therapies intended to address large-market and orphan diseases.

BiomX’s approach is driven by the convergence of several factors: rapidly increasing understanding of phage, including the links between phage behaviors and their genomes; growing evidence that harmful bacteria are present and involved in chronic diseases, such as IBD, that could, in principle, be treated with phage; as well as by a growing number of anecdotal reports from different academic centers of successful compassionate use administration of phages to seriously ill patients who were unresponsive to other therapies. BiomX believes its phage therapeutic product candidates have the ability to treat conditions and diseases by precisely targeting pathogenic bacteria without disrupting other bacteria or the healthy microbiota.

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

Overview of BiomX

BiomX is developing BX001, its 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* (*C. acnes*, formerly taxonomically classified as *Propionibacterium acnes*, or *P. acnes*) on the skin. *C. acnes* is thought to be associated with acne vulgaris (“acne”), and the local inflammation of cells surrounding hair follicles in this condition. In October 2019, BiomX has initiated clinical testing to demonstrate the safety and tolerability of BX001 in 75 individuals with acne. Enrollment was completed in December 2019. BiomX is also examining exploratory endpoints of reduction of *C. acnes* and effects on the skin microbiome under this trial. An additional smaller single blinded, single application, placebo-controlled clinical trial to evaluate alternative methods of topical application of BX001 is also being conducted in parallel. BiomX expects results from these trials in the first quarter of 2020.

BX002 is BiomX’s therapeutic phage product candidate designed to treat IBD, targeting bacterial strains isolated from IBD patients that were shown to be pro-inflammatory in animal models and may have a role in the onset and aggravation of the disease. BX002 is a therapeutic phage cocktail product candidate targeting strains of *Klebsiella pneumoniae*, (“*K. pneumoniae*”), that are associated with the development of IBD. In BiomX’s BMX-IBD-006 study, BX002 led to rapid reductions in levels of these *K. pneumoniae* strains in a mouse model colonized with high titers (“levels”) of *K. pneumoniae*. There are up to 1.6 million patients in the United States with IBD. While there are multiple therapies that can relieve symptoms and induce remission in IBD, not all patients respond, and most of those who do respond experience periods of disease flares. BiomX expects to file an IND for BX002 in 2020.

BX003 is BiomX’s therapeutic phage product candidate targeting bacteria associated with PSC, a rare inflammatory liver disease. BX003 is a therapeutic phage cocktail product candidate that targets *K. pneumoniae* strains associated with the development of PSC, which is characterized by chronic inflammation leading to scarring of the bile ducts both inside and outside the liver and the accumulation of toxic levels of bile acids. PSC is a progressive disease for which there are no approved therapies, and which often eventually leads to liver failure. PSC is an underdiagnosed orphan disease with an estimated prevalence in the United States of approximately 30,000. BiomX expects to file an IND for BX003 in 2021.

BiomX is also developing synthetically engineered phage designed to target strains of bacteria found in CRC tumors. BiomX's CRC program incorporates its expertise in identifying and validating associations of specific strains of bacteria with human disease with BiomX's synthetic biology capabilities designed to deliver phage with therapeutic potential to tumors. Only a small percentage of the 141,000 new cases of CRC in the United States each year 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. BiomX has observed *in vitro* and *in vivo* that it can use phage to target strains of *Fusobacterium nucleatum*, a bacterial species that is highly enriched in colorectal tumors and is believed to be pathogenic. BiomX plans to use phage to deliver payload genes, such as those encoding immunostimulatory proteins, directly to tumors while also leading to eradication of these bacteria. BiomX plans to optimize the insertion and expression of these genes using synthetic engineering. BiomX then intends to examine the activity of the engineered phage in preclinical models. BiomX believes that this approach of using phage to deliver therapeutic payloads has the potential to deliver therapeutic benefit in additional cancer types as well as in a broad range of other diseases.

All of BiomX's therapeutic product candidates derive from its proprietary platform, which is first used to discover and validate the association of specific bacterial strains with human disease and is then used to develop rationally designed phage combinations ("cocktails"), that target these pathogenic bacteria. In BiomX's therapeutic discovery efforts, BiomX uses its proprietary platform both to identify naturally occurring phage and to create synthetically engineered phage that target pathogenic bacteria. BiomX then designs cocktails containing multiple phage with complementary functions and test these product candidates *in vitro* and *in vivo*. The use of specific combinations of phage is a critical and proprietary aspect of BiomX's approach, which is designed to maximize efficacy while minimizing the potential emergence of resistant bacterial strains. BiomX has observed that these therapeutic product candidates are able to selectively kill specific strains of bacteria, leading to alterations in the microbiome composition that BiomX believes will confer therapeutic benefit by impacting the patient's inflammatory response. BiomX believes that with appropriate and stringent phage selection and testing, BiomX can endow its therapeutic product candidates with disease-fighting properties that go well beyond those of any individual phage.

According to published studies, between 10 and 100 trillion symbiotic microorganisms, including bacteria and viruses, collectively referred to as the microbiome, are essential components of the human body. The microbiome contributes to metabolism, protects against pathogens and interacts with the immune system. Imbalance of the microbiome on the skin is associated with effects on the appearance of skin. Imbalance of the microbiome within the body is associated with multiple diseases. BiomX seeks to become a leader in restoring health to the microbiome by deploying phage to remove potentially harmful bacteria.

BiomX combines multiple technologies developed by its scientific founders and described in leading scientific journals. BiomX's scientific founder Rotem Sorek, a Professor in the Department of Molecular Genetics at the Weizmann Institute of Science, is a world leader in phage genomics and bacterial defense mechanisms. BiomX's scientific founder Eran Elinav, a Professor in the Department of Immunology at the Weizmann Institute of Science, is an expert in investigating the link between the microbiome and human health and disease. BiomX's 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 MIT. In addition, through the acquisition of the privately held Israel-based company, RondinX Ltd., in 2017, BiomX gained access to high throughput genomic analyses techniques developed by Prof. Eran Segal, a leading computational biologist from the Department of Computer Science and Applied Mathematics at the Weizmann Institute of Science. The combination of the technologies and expertise from these leaders in each of their respective fields is critical in enabling BiomX to focus on treating complex human diseases and conditions by precise manipulation of the microbiome.

As of December 31, 2019, BiomX had an accumulated deficit of \$44.6 million and expects that for the foreseeable future BiomX will continue to incur significant expenses as BiomX advances its product candidates from discovery through preclinical development and clinical trials and seeks regulatory approval of BiomX's product candidates. BiomX does not have any products approved or available for sale, BiomX's products are still in the preclinical and clinical development stages, and BiomX has not generated any revenue from product sales.

BiomX's Strategy

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

- Investigate the safety, tolerability and effect of BX001 and advance BX001 through clinical testing conducted with a leading multinational cosmetics company using the available regulatory pathways in the relevant jurisdictions and then commercialize BX001 with a partner;
- Develop BX002 and BX003 for the treatment of microbiome-related gastrointestinal immune disorders like IBD and PSC;
- Evaluate the preclinical efficacy of BiomX's synthetic engineering approach for delivering therapeutic payloads to bacteria that are resident within tumors followed by evaluation through clinical testing;
- Identify new targets for the indications BiomX is pursuing by expanding its internal database of clinical microbiome samples and its bioinformatics capabilities; and
- Develop and partner microbiome-based biomarker tests, based on BiomX's proprietary XMarker platform, that can be used for disease diagnosis or as companion diagnostics.

Pipeline

The chart below identifies each of product candidates and BiomX's biomarker test and their current status.



(1) BX001 is intended to be developed and commercialized as a cosmetic

Manufacturing

BiomX and a CRO have jointly developed a manufacturing process that utilizes state of the art industrial methods for the manufacture of BiomX's product candidates. This cGMP compliant process is designed to be scalable to meet BiomX's clinical study needs, and to fulfill the requirements of regulators for human studies. BiomX currently operates a manufacturing model that combines an in-house process development and manufacturing suite with outsourced third-party manufacturing services for the large scale production of BiomX's therapeutic phage cocktails for clinical use. As such, for BX001, BiomX has engaged one vendor to provide purified active ingredients (bacteriophages) and another to provide formulation and fill-finish services of BiomX's product candidates for clinical testing. For BX002, BiomX has also engaged an additional third-party provider to supplement BiomX's in house process development activities. BiomX has selected these organizations based on their experience, capability, capacity and regulatory status. Projects are managed by a specialist team of BiomX's internal staff, which is designed to promote compliance with the technical aspects and regulatory requirements of the manufacturing process.

BiomX maintains services agreements with multiple manufacturers. These services agreements generally are short-term in nature and capable of being extended or renewed. The production amounts identified in BiomX's current services agreements are sufficient to support BiomX's current clinical study needs.

In the third quarter of 2019, BiomX opened its own 550 square foot manufacturing facility at its headquarters in Ness Ziona, Israel. This facility has been designed with the capacity to produce clinical quantities of BiomX's product candidates required for future early stage clinical development of BX002.

While BiomX does not have a current need for commercial scale manufacturing capacity, at the appropriate time BiomX intends to evaluate building large scale cGMP internal manufacturing capabilities, which may include expansion of its operations.

Intellectual Property

BiomX strives to protect the proprietary technology that BiomX believes is important to its business, including seeking and maintaining patent protection in the United States and internationally for its product candidates and discovery platform. BiomX also relies on trademarks, trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain its proprietary position.

BiomX seeks to obtain U.S. and international patent protection, and endeavors to promptly file patent applications for new commercially valuable inventions. BiomX also relies on trade secrets and know-how to protect aspects of its business that are not amenable to, or that BiomX does not consider appropriate for, patent protection. BiomX plans to continue to expand its intellectual property estate by filing patent applications directed to formulations, related methods of treatment, methods of manufacture or identified from BiomX's ongoing development of its product candidates, as well as discovery based on BiomX's proprietary product platform. BiomX's success will depend on its ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to its business, defend and enforce any patents that BiomX may obtain, preserve the confidentiality of its trade secrets and know-how and operate without infringing the valid and enforceable patents and proprietary rights of third parties. The patent positions of life sciences companies like BiomX's are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent may be challenged in courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. BiomX cannot guarantee that its pending patent applications, or any patent applications that BiomX may in the future file or license from third parties, will result in the issuance of patents. BiomX cannot predict whether the patent applications it is currently pursuing will issue as patents in any particular jurisdiction or at all, whether the claims of any patent applications, should they issue, will cover its product candidates, or whether the claims of any issued patents will provide sufficient protection from competitors or otherwise provide any competitive advantage. BiomX cannot predict the scope of claims that may be allowed or enforced in its patents. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, BiomX may not obtain or maintain adequate patent protection for any of its programs and product candidates.

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, BiomX cannot be certain of the priority of inventions covered by pending patent applications. Accordingly, BiomX 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 BiomX may have to participate in interference proceedings or derivation proceedings declared by the USPTO, to determine priority of invention. For more information regarding the risks related to BiomX's intellectual property, see "*Risk Factors — Risks Related to BiomX's Licensed and Co-Owned Intellectual Property.*"

BiomX's licensed and co-owned technology is focused on microbiome product discovery to develop phage therapies to target and destroy harmful bacteria involved with chronic diseases. BiomX uses its licensed and proprietary platform technology to develop phage therapies that incorporate both naturally occurring phage and novel engineered phage created using synthetic biology. These phage therapies are directed to acne, IBD, PSC and CRC. BiomX then designs cocktails containing multiple phage (both naturally occurring and synthetic) with complementary functions.

Patent portfolio

BiomX's 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 BiomX's 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. BiomX solely owns one U.S. provisional patent application. BiomX co-owns one U.S. provisional patent application and one Patent Cooperation Treaty ("PCT") application with Keio University ("Keio"), one U.S. provisional, one PCT application and six national phase applications (US, Europe, Australia, Canada, China and Japan) with Yeda Research and Development Company Limited ("Yeda"), and one U.S. provisional application and one PCT application with both Keio and Yeda. BiomX has an exclusive license from Yeda and Keio for these co-owned applications. BiomX has exclusive licenses from Yeda, Keio, or the Massachusetts Institute of Technology ("MIT") for the rest of the patents and patent applications in its portfolio.

A significant portion of BiomX's portfolio is directed to its key product candidates, specifically: acne, IBD, PSC and CRC, as well as to BiomX's bacterial target discovery and bacteriophage discovery technology platforms. Prosecution has yet to commence for most of the pending patent applications covering BiomX's 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. BiomX expects this to be the case with respect to its licensed and co-owned patent applications, described briefly below.

Acne

BiomX co-owns with Yeda one U.S. provisional and one PCT application 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 U.S. patents issuing from the pending application covering BiomX's lead bacteriophage combination in this program are expected to expire in 2038. Patent term adjustments or patent term extensions could result in later expiration dates.

IBD

BiomX co-owns with one U.S. provisional application and one PCT application and co-owns with Keio and Yeda one U.S. provisional application, one PCT application and six national phase applications (US, Europe, Australia, Canada, China, 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 a bacterial strain discovered to cause or contribute to that disease. BiomX co-owns, solely with Keio, one U.S. provisional application with similar claims.

BiomX also has an exclusive license from Keio for a patent family including 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 U.S. patents issuing from the pending applications covering BiomX's lead bacteriophage combination in this program are expected to expire in 2037 or 2038. Patent term adjustments or patent term extensions could result in later expiration dates.

PSC

BiomX has an exclusive license to one U.S. national application, two U.S. provisional 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 U.S. patents issuing from the pending applications in this program are expected to expire in 2038 or 2039. Patent term adjustments or patent term extensions could result in later expiration dates.

CRC

BiomX has filed one U.S. provisional patent application containing claims directed to pharmaceutical compositions and formulations comprising combinations of bacteriophage (both synthetic and naturally occurring) useful to treat cancer. There is no assurance that a patent or claims will issue from this pending application or that, if a patent or claims issue, they will be of sufficient scope or strength to provide meaningful protection for our technology. Any U.S. patents issuing from the pending application covering BiomX's lead bacteriophage combination in this program are expected to expire in 2038. Patent term adjustments or patent term extensions could result in later expiration dates.

Technology Platform

BiomX is exclusively licensed to two U.S. issued patent, one allowed European Patent Convention patent, five U.S. national applications and seven foreign patent applications (Canada, China, Europe, and Israel). These licensed patent families include two issued U.S. patents and multiple pending patent applications, with claims directed to methods of analyzing the composition of the microbiome in a subject, polynucleotides that are useful as transcription terminators in bacteria and methods of identifying the same, 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 U.S. directed to BiomX's platform are expected to expire between 2034 and 2038. Patent term adjustments or patent term extensions could result in later expiration dates. For more information regarding the risks related to BiomX's intellectual property, see "*Risk Factors — Risks Related to BiomX's Licensed and Co-Owned Intellectual Property.*"

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 BiomX files, 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 U.S. 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 U.S. patent is shortened by terminal disclaimer that reduces its term to that of an earlier-expiring patent. The term of a U.S. 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 U.S. 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 BiomX's product candidates receive FDA approval, BiomX expects 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 BiomX's assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to BiomX's intellectual property, see "*Risk Factors — Risks Related to BiomX's Licensed and Co-Owned Intellectual Property*."

Trade secrets and know-how

In addition to patents, BiomX relies on trade secrets and know-how to develop and maintain its competitive position. BiomX typically relies on trade secrets to protect aspects of its business that are not amenable to, or that BiomX does not consider appropriate for, patent protection. BiomX protects trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with BiomX's 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 BiomX must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for BiomX or relating to BiomX's business and conceived or completed during the period of employment or assignment, as applicable, shall be BiomX's exclusive property. In addition, BiomX takes other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of its proprietary information by third parties.

Although BiomX takes steps to protect its proprietary information and trade secrets, including through contractual means with BiomX's employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to BiomX's trade secrets or disclose BiomX's technology. Thus, BiomX may not be able to meaningfully protect its trade secrets. For more information regarding the risks related to BiomX's intellectual property, see "*Risk Factors — Risks Related to BiomX's 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 BiomX believes that its technology, knowledge and experience provide BiomX with competitive advantages, BiomX faces 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. BiomX believes that the key competitive factors affecting the success of any of its product candidates will include efficacy, safety profile, method of administration, cost, level of promotional activity and intellectual property protection.

BiomX is aware of a number of biotechnology companies developing bacteriophage products to treat human diseases. To BiomX's knowledge, several biotechnology companies, as well as academic institutions, have discovery stage or clinical programs utilizing naturally occurring phages or synthetic biology approaches. In addition, BiomX is aware of several investigational and marketed products to treat the indications that BiomX is targeting with its product candidates, including, but not limited to:

- *C. acne*: Adapalene, Epiduo, Zineryt, erythromycin and Acnecide
- *Inflammatory bowel disease*: Humira, Stelara, Entyvio, Inflectra and Cimzia
- *PSC*: Obeticholic acid (Intercept clinical candidate), GS-9674 (Gilead clinical candidate), BTT1023, (Acorda Therapeutics candidate) and PLN-74809 (Pliant clinical candidate)

Many of BiomX's competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than BiomX does 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, BiomX's competitors may be more successful than BiomX may be in discovering product candidates, obtaining approval for such product candidates and achieving widespread market acceptance. BiomX's competitors' products may be more effective, or more effectively marketed and sold, than any product BiomX may commercialize and may render BiomX's product candidates obsolete or non-competitive before BiomX can recover the expenses of developing and commercializing any of BiomX's product candidates. BiomX anticipates that BiomX will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

These third parties compete with BiomX 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, BiomX's program.

In addition, for any cosmetics products that BiomX introduces, BiomX will face intense competition from a broader range of cosmetics companies with more resources than BiomX's.

Sales and Marketing

BiomX intends to pursue the commercialization of its drug product candidates either by building internal sales and marketing capabilities or through opportunistic collaborations with others if and when BiomX receives the requisite regulatory approvals.

BiomX seeks to distribute BX001 and is working in collaboration with a leading multinational cosmetics company in conducting trials, and does not plan to rely on its own sales and marketing capabilities, subject to negotiation and agreement of mutually acceptable terms (as to which there can be no assurance). BiomX also may select an alternate method for distribution.

Material Agreements

License Agreements

License Agreement with Yeda

BiomX entered into the License Agreement with Yeda, the technology transfer office of the Weizmann Institute of Science, pursuant to which BiomX 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 BiomX's 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 which BiomX funded.

In connection with this license, BiomX is obligated to pay a non-refundable license fee of \$10,000 per year. In addition, BiomX contributed an aggregate of approximately \$2.0 million to the research budget agreed upon in the license agreement. In addition, BiomX is required to pay tiered royalties in the low single digits on net sales of products and diagnostic kits covered by the 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 BiomX sublicenses its rights under this agreement BiomX 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. BiomX is obligated pay filing and maintenance expenses in respect of patents licensed under this license agreements. In connection with this license agreement, BiomX also issued an aggregate of 80,000 ordinary shares to Yeda. In the event of certain mergers and acquisitions by BiomX, BiomX is obligated to pay Yeda an amount equivalent to 1% of the consideration received under such transaction (the "exit fee"). On October 28, 2019 ("Closing Date"), the provisions of the License Agreement related to the exit fee were amended wherein the Company was obligated to pay Yeda a one-time payment as described in the amendment which will not exceed 1% of the consideration received under such transaction. Following the Closing, Yeda's shares were converted to 193,406 ordinary shares of the Company.

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 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 BiomX fails to observe certain diligence and development requirements and milestones as described in the agreement. BiomX 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, BiomX is required to grant to Yeda a non-exclusive, irrevocable, perpetual, fully paid-up, sublicensable, worldwide license in respect of BiomX's rights in know-how and research results as described in this agreement, provided that if Yeda subsequently grants a license to a third party that utilizes BiomX's rights, BiomX is 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 BiomX incurs in connection with this agreement.

BiomX consults with Yeda with respect to patent prosecution and maintenance decisions. Yeda is primarily responsible for prosecution and maintenance with respect to Licensed Information and BiomX is responsible for prosecution and maintenance with respect to Subsequent Results. BiomX and Yeda are both entitled to consultation rights. BiomX is responsible for costs associated with prosecution and maintenance of all patents and applications.

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

Exclusive Patent License Agreement with the MIT

On April 25, 2017, BiomX entered into an Exclusive Patent License Agreement with MIT, pursuant to which BiomX received an exclusive, royalty-bearing license to certain patents held by MIT covering methods to synthetically engineer phage in the field of treating, preventing or diagnosing IBD, cancer in humans, including CRC, or certain other specified indications, to utilize patents held by MIT. One of the inventors of the patents has an equity ownership in BiomX. Under this agreement, BiomX is required to expend minimum amounts on the research and development of the products that require the licensed patents or are manufactured by a licensed process until the first commercial sale of any product covered by this agreement. These minimum amounts start at \$50,000 for the first year of the agreement term and increase up to \$2.0 million per year after the fourth year. BiomX is also required to meet certain clinical and development milestones over the course of the agreement.

Under the terms of the agreement, BiomX paid MIT an initial license fee of \$25,000 and is obligated to pay certain license maintenance fees of up to \$250,000 in each subsequent year and following the commercial sale of licensed products. BiomX is also required to make payments to MIT upon the satisfaction of development and commercialization milestones totaling up to \$2.4 million in aggregate. BiomX is also required to pay MIT tiered royalties on a percentage of annual net sales of licensed products in the low single digits. In addition, BiomX is required to pay tiered royalties on a percentage of annual net sales of identified products ranging between approximately one-half percent and in the low single digits. If BiomX sublicenses its rights under this agreement, BiomX will be obligated to pay MIT sublicense royalties expressed as a percentage of sublicense income received as described in the agreement, including milestone payments and other payments, ranging between the low teens and the low twenties. BiomX's payments to MIT are subject to reductions as set forth in the agreement.

Unless earlier terminated, the agreement will continue until the expiration or abandonment of all issued patents or patent applications with the licensed patent rights, which is expected to be in 2038. BiomX may also terminate the agreement at any time with 90 days prior written notice and payment of all amounts due to MIT through the date of such termination. MIT may also terminate the agreement if BiomX ceases to carry on BiomX's business or if BiomX fails to pay any amounts due to MIT under the agreement. Either party may terminate the agreement upon material breach by the other party that is uncured.

MIT is responsible for prosecution and maintenance of the patents that fall under the patent rights. BiomX shares the costs of such prosecution and maintenance.

BiomX is entitled to enforce the patent rights under BiomX's own control and at its own expense, unless MIT is legally required to allow the action to be brought in its name. BiomX must consult with MIT before commencing any such action and cannot enter into settlements, consent judgments, or other dispositions that would adversely affect the patent rights without prior written consent of MIT. MIT reserves the right to bring its own enforcement actions if BiomX fails to do so within a reasonable time.

Exclusive Patent License Agreement with Keio and JSR for IBD

BiomX has entered into an Exclusive Patent License Agreement with Keio, and JSR, on December 15, 2017, as amended, pursuant to which BiomX was granted an exclusive, royalty-bearing, worldwide, perpetual sublicense by JSR to certain patent rights related to BiomX's 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.

BiomX paid JSR a license issue fee of \$10,000 and has agreed to pay annual fees ranging from \$15,000 to \$25,000 in each subsequent year. In addition to the license fees, BiomX has agreed to make payments upon the satisfaction of certain clinical and regulatory milestones up to an aggregate of \$3.2 million. BiomX is 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 BiomX sublicenses BiomX's rights under this agreement, BiomX 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. BiomX's 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 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. The counterparties may terminate this agreement if BiomX fails to pay the amounts due under this agreement, or upon BiomX's winding up, bankruptcy, insolvency, dissolution or other similar discontinuation of business, or if BiomX breaches the material terms of this agreement and such breach is uncured. BiomX may terminate this agreement at any time upon three months' advance written notice to JSR.

BiomX and other joint owners are responsible for maintenance and prosecution of patents that fall under Joint Patent Rights. 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 BiomX is entitled to advise with respect to patent counsel, scope of claims, and other matters. BiomX is entitled to bring enforcement actions (in BiomX's name alone and at BiomX's own expense). BiomX is required to obtain JSR's prior written consent for each action BiomX brings with respect to the Patent Rights only.

Exclusive Patent License Agreement with Keio and JSR for PSC

BiomX has entered into an Exclusive Patent License Agreement with Keio and JSR on April 22, 2019, pursuant to which BiomX was granted an exclusive, royalty-bearing, worldwide, perpetual sublicense by JSR to certain patent rights related to BiomX's 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.

BiomX paid JSR a license issue fee of \$20,000 and has agreed to pay annual fees ranging from \$15,000 to \$25,000 in each subsequent year. In addition to the license fees, BiomX has agreed to make payments upon the satisfaction of certain clinical and regulatory milestones up to an aggregate of \$3.2 million. BiomX is 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 BiomX sublicenses BiomX's rights under this agreement, BiomX 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. BiomX's 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 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. The counterparties may terminate this agreement if BiomX fails to pay the amounts due under this agreement, or upon BiomX's winding up, bankruptcy, insolvency, dissolution or other similar discontinuation of business, or if BiomX breaches the material terms of this agreement and such breach is uncured. BiomX may terminate this agreement at any time upon three months' advance written notice to JSR.

BiomX and other joint owners are responsible for maintenance and prosecution of patents that fall under Joint Patent Rights. 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 BiomX is entitled to advise with respect to patent counsel, scope of claims, and other matters. BiomX is entitled to bring enforcement actions (in BiomX's name alone and at BiomX's own expense). BiomX is required to obtain JSR's prior written consent for each action BiomX brings with respect to the Patent Rights only.

Acquisition Agreement

RondinX Acquisition

In November 2017, BiomX entered into a share purchase agreement to acquire all of the outstanding share capital of RondinX Ltd., a company organized under the laws of Israel ("RondinX"). Under this agreement, BiomX issued to the shareholders of RondinX an aggregate of 250,023 Series A-1 preferred shares upon the closing of the acquisition. In addition, BiomX issued to warrant holders of RondinX warrants to purchase an aggregate of 4,380 Series A-1 preferred shares, which are exercisable for no additional consideration, as well as additional cash consideration.

In addition, BiomX is required to issue up to an additional 234,834 ordinary shares to the former securityholders of RondinX upon the achievement of certain milestones, including clinical, developmental, regulatory, commercial or strategic milestones relating to product candidates for treatment of PSC or entry into qualifying collaboration agreements with certain third parties. Furthermore, upon the achievement of such milestones, BiomX will be required to make payments of contingent consideration of up to \$32 million in the aggregate. Such contingent consideration may be made in cash, or in the most senior class of BiomX's shares authorized or outstanding as of the time the payment is due, or a combination of both. If BiomX issues shares for the payment of such contingent consideration, these shares will be issued based on the lowest price per share paid by any holder of such shares. In the event that any of BiomX's shares are traded on a public market, then the price per share calculated as part of such payment will be calculated as follows: (i) if the securities are then traded on a national securities exchange or the Nasdaq Stock Market (or similar national quotation system), then the value of the securities shall be deemed to be the average of the closing prices of the securities on such exchange or system over the thirty (30) trading-day period ending five (5) trading days prior to the distribution; or (ii) if the securities are actively traded OTC, then the value of the securities shall be deemed to be the average of the closing bid prices of the securities over the thirty (30) trading-day period ending five (5) trading days prior to the distribution.

Employees

As of December 31, 2019, BiomX had 73 full-time employees and consultants and 13 part time employees. Twenty-five of BiomX's employees have Ph.D. or M.D. degrees and 71 of BiomX's employees are currently engaged in research and preclinical development activities. None of BiomX's employees is represented by labor unions or covered by collective bargaining agreements. BiomX considers its relationship with its employees to be very strong.

Corporate Information

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.

Executive Officers

Name	Age	Position
Jonathan Solomon	43	Chief Executive Officer and Director
Assaf Oron	45	Chief Business Officer
Dr. Sailaja Puttagunta	51	Chief Medical Officer
Dr. Merav Bassan	54	Chief Development Officer
Marina Wolfson	36	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 Chief Executive Officer of BiomX from May 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 from January 2017 to October 2019. Prior to this position, he served in various roles at Evogene Ltd., 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 from December 2018 to October 2019. Prior to joining BiomX, 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 pharmaceutical company 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. Dr. Bassan joined as Chief Development Officer of BiomX in October 2019. Prior to this position, she served in various development roles at Teva Pharmaceutical Industries Limited since 2005, 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 Vice President of Finance and Operations of the Company since December 2019. 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) from 2010 to 2019 and a senior auditor at Ernst & Young, an international auditing and business advisory firm 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, specialty in finance) from Ben-Gurion University.

Corporate History

The Company 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, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses or entities, which we refer to as a "target business." Our efforts to identify a prospective target business were not limited to any particular industry or geographic location.

In March 2018, Chardan Investments, LLC ("Sponsor") purchased 1,437,500 shares of our common stock, par value \$0.0001 per share ("Common Stock") for an aggregate purchase price of \$25,000 in connection with the Company's organization. On September 14, 2018, we effected a 1.4 for 1 dividend in the nature of a stock split that resulted in there being an aggregate of 2,012,500 shares outstanding (resulting in a purchase price of approximately \$0.012 per share). Because these offers and sales were made to a single purchaser in a transaction not involving a public offering, the shares were issued in reliance on the exemption from registration contained in Section 4(a)(2) of the Securities Act.

On December 18, 2018, we consummated our 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 \$70,000,000. The Public Units each consists of one share of Common Stock ("Public Share") 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. Chardan Capital Markets, LLC acted as sole book-running manager of the IPO. The Public Units, Public Shares and Public Warrants were registered under the Securities Act on a registration statement on Form S-1 (No. 333-228533). The SEC declared the registration statement effective on December 13, 2018. We granted the underwriters a 45-day option to purchase up to 1,050,000 additional Public Units to cover over-allotments at the IPO price, less the underwriting discounts and commissions. The overallotment option expired unexercised on February 4, 2019.

Simultaneous with the consummation of the IPO, we consummated the private placement of an aggregate of 2,900,000 warrants ("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. The issuance was made pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act. These Private Placement Warrants are identical to the Public Warrants underlying the Public Units sold in the IPO, except that the Private Placement Warrants are not transferable, assignable or salable until after the completion of a business combination, subject to certain limited exceptions. Additionally, the Private Placement Warrants are exercisable on a cashless basis and are non-redeemable so long as they are held by the initial purchasers or their permitted transferees.

After deducting the underwriting discounts, offering expenses, and commissions from the IPO and the sale of the Private Placement Warrants, a total of \$70,000,000 was deposited into a trust account established for the benefit of the holders of our Public Shares, including our initial stockholders and members of our management team to the extent our initial stockholders and/or members of our management team purchased Public Shares (provided that each initial stockholder's and member of our management team's status as a "public stockholder" shall only exist with respect to such Public Shares), and the remaining proceeds became available to be used to provide for business, legal and accounting due diligence on prospective business combinations and continuing general and administrative expenses.

On the Closing Date, the Company and BiomX consummated a business combination pursuant to a merger agreement dated as of July 16, 2019 and amended as of October 11, 2019 (the “Merger Agreement”) by and among the Company, BiomX, CHAC Merger Sub Ltd., an Israeli company and wholly owned subsidiary of the Company (“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, with BiomX continuing as the surviving entity and a wholly-owned subsidiary of the Company (the “Business Combination”).

As of the Closing Date, all of the issued and outstanding shares and other equity interests in and of BiomX 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 the Company’s Common Stock or vested options or warrants to purchase Common Stock to BiomX vested security holders. Additional shares of Common Stock were reserved for issuance in respect of options to purchase ordinary shares of BiomX that were issued, outstanding and unvested immediately prior to the Closing Date.

In addition, the Company also agreed to issue the following number of additional shares of Common Stock, in the aggregate, to the BiomX shareholders on a pro rata basis, subject to the Company’s achievement of the conditions specified below following the Closing Date:

- 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.

ITEM 1A. RISK FACTORS

An investment in our securities carries a significant degree of risk. You should carefully consider the following risks, as well as the other information contained in this prospectus, including our historical financial statements and related notes included elsewhere in this prospectus, before you decide to purchase our securities. Any one of these risks and uncertainties has the potential to cause material adverse effects on our business, prospects, financial condition and operating results which could cause actual results to differ materially from any forward-looking statements expressed by us and a significant decrease in the value of our Common Shares and Warrants. Refer to “Cautionary Statement Regarding Forward-Looking Statements.”

We may not be successful in preventing the material adverse effects that any of the following risks and uncertainties may cause. These potential risks and uncertainties may not be a complete list of the risks and uncertainties facing us. There may be additional risks and uncertainties that we are presently unaware of, or presently consider immaterial, that may become material in the future and have a material adverse effect on us. You could lose all or a significant portion of your investment due to any of these risks and uncertainties.

Risks Related to Our Business, Technology and Industry

We are a development-stage company with limited operating history and has incurred losses since our inception. We anticipate that we will continue to incur increasing and significant losses for the foreseeable future.

We are a development-stage biopharmaceutical company with limited operating history. We have incurred losses in each year since BiomX's inception in 2015. As of December 31, 2019, our accumulated deficit was \$44.6 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, 2019 and 2018, BiomX had losses from operations of \$23.2 and \$12.5 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.

At December 31, 2019, the Company had cash, cash equivalents and short-term deposits of \$82.3 million, and it has 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. 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 for at least the next 24 months, 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 shareholders.

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 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. Additionally, we expect our financial condition and operating results to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. 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 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 U.S. Food and Drug Administration (“FDA”), the European Medicines Agency (“EMA”) or other equivalent foreign regulatory agencies to perform clinical trials and other studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable, or if we are unable to fund our continuing losses, our business, financial condition and results of operations may be materially adversely impacted.

We are seeking to develop product candidates 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 sold as a cosmetic or 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 have any other company, sold our product candidates as cosmetics or 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 the risk factors below.

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 a new drug application (“NDA”) or a Biologics License Application 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 (“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, 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 phages, given that their function is antibacterial, it is possible that the such agencies will decide that products containing phages 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 Food, Drug, and Cosmetic Act, 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 phages 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.

Regulatory requirements for development of our lead product candidate, BX001, 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 BX001.

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 phages 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-investigational new drug (“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. They however 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 phages 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 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 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.

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 colorectal cancer (“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.

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, 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 EMA's Committee for Advanced Therapies ("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 the Pediatric Research Equity Act ("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.

Results from preclinical studies of our product candidates BX001 and BX002 may not be predictive of the results of clinical trials or later stage clinical development.

Preclinical studies of our product candidates BX001 and BX002, including studies in animal disease models in the case of BX002 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 BX002, 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, 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 it is 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. For example, we plan to initiate Phase 1 clinical trials to explore the safety and tolerability of BX002 in 2020. However, 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 institutional review board 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 Common Stock 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 Institutional Review Boards (“IRBs”) or independent ethics committees at the institutions in which our studies are conducted, or the Data Safety Monitoring Board (“DSMB”) 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 evaluate our product candidates for safety and tolerability in the form of Phase 1 clinical trials. None of our product candidates have completed this testing to date, and we have initiated the first human studies of BX001 in November 2019. 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 phages 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 phages, or of adverse reactions to our phages 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 phages that target the desired bacteria for that product candidate. The selection of phages for any of our product candidates is based on a variety of factors, including, without limitation, the ability of the selected phages, in combination, to successfully kill the targeted bacteria, the degree of cross-reactivity of the individual phages with the same part of the bacterial targets, the ability of the combined phages to satisfy regulatory requirements, our ability to manufacture sufficient quantities of the phages, intellectual property rights of third parties, and other factors. While we have selected initial formulations of BX001 and BX002, 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 time lines, 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 phages may contain one or more integrated phages in their genomes that, if we are unable to remove, can present challenges in manufacturing of the produced phages. 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 opened our own current Good Manufacturing Process ("cGMP") manufacturing facility at its headquarters in Ness Ziona, Israel. Our facility must undergo ongoing inspections for compliance with cGMP regulations before the respective product candidates can be 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 subject to ongoing periodic inspection for compliance with European, FDA and cGMP regulations. Compliance with these regulations and standards is complex and costly, and there can be no assurance that we will be able to comply. Any failure to comply with applicable regulations could result in sanctions being imposed (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

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

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

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

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

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

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 phages 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 phages, the range of host bacteria that are affected by our phages, the variety of activity on different bacteria growth states, issues with toxicity in our phages, and the stability, robustness and ease of manufacturing of our product candidates. In addition, the designing of synthetically engineered phages may fail to result in the development of phages with the desired characteristics or behaviors that are suitable for use as viable therapies, or may result in phages 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 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.

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.

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 have clinical trial insurance that covers our clinical trial for up to a \$3.0 million annual per claim and aggregate limit. In addition, we have a specific clinical trial insurance that covers our clinical trials in BX001 up to EUR 5 million aggregate limit. 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 obtain may not be adequate to cover potential claims or losses.

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 HIPAA (as defined below), as amended by HITECH (as defined below). 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, the General Data Protection Regulation (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 (“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 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.

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.

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 (“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.

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 (the “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 2019, 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 2019, the U.S. Dollar value of our Israeli expenses, mainly personnel and facility-related, will increase. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk. 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.

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.

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 BX002 and/or BX003. 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 available for our product candidates for therapeutic indications. We currently believe that BX003 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 ("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.

The orphan drug designation entitles the company 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 ("MAA"), 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 good clinical practice (“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 health care 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 Patient Protection and Affordable Care Act (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 current 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.

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 Research and License Agreement dated as of June 22, 2015, as amended (the “License Agreement”) with Yeda Research and Development Company Limited (“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 microbiome-based therapeutic product candidates would be delayed or terminated, and our business would be adversely affected.

Yeda undertakes to procure certain research and development activities under the License Agreement, including the 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 in vivo method for measuring immune induction capability (Th1) of bacteria, followed by testing several candidate IBD-inducing bacterial strains, during the research period, subject to the terms and conditions specified in the License Agreement. The License Agreement with Yeda 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 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 the MIT, pursuant to which we received an exclusive, royalty-bearing license to certain patents held by MIT covering methods to synthetically engineer phages in the field of treating, preventing or diagnosing IBD, cancer in humans, or certain other specified indications or specific bacterial targets to utilize patents held by MIT;
- with Keio University (“Keio”) and JSR Corporation (“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 phages 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 our primary sclerosing cholangitis (“PSC”) program. Specifically, these patent rights relate to bacterial targets that have been observed to be related to PSC and the phages 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, MIT, Keio and JSR. Our license agreement with Yeda provides 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 MIT, Keio and JSR provide licenses to patents related to, among other things, synthetic biology and our IBD, PSC 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. More information on our license agreements, see “*Material Agreements.*”

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 United States Patent and Trademark Office (“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 health care 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 (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 (“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 regulatory standards, commonly referred to as 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

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, 2019, we had received an aggregate of \$2.1 million in the form of grants from the Israeli Innovation Authority (“IIA”). We were 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 Israel Encouragement of Research and Development in Industries (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, 2019, the balance of the principal and interest in respect of our commitments for future payments to the IIA totaled approximately \$2.2 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.

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 IIA. We, therefore, must comply with the requirements of the Research Law. For the years ended December 31, 2019 and 2018, we recorded grants totaling \$0.3 and \$0.6 million, from the IIA, respectively. The grants represented 2.3% and 6.6% of our gross research and development expenditures for the years ended December 31, 2019 and 2018, 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. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries.

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, there has been an increase in unrest and terrorist activity, which began in October 2000 and has continued with varying levels of severity. For instance, beginning in July 2014, for approximately seven weeks, Israel experienced an armed conflict between Israel and Hamas, which included rocket strikes against civilian targets in various parts of Israel and disrupted day-to-day civilian activity in southern and central Israel. If renewed, such hostilities may negatively affect business conditions in Israel. 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. The civil unrest in Egypt, which borders Israel, resulted in the resignation of its president, Hosni Mubarak, and significant changes to the country’s government. In Syria, also bordering Israel, a civil war continues to take place. 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.

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 (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 named in this prospectus 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 Operations

We incur significant costs operating as a public company.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (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 (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.

Our management is required to devote substantial time to maintaining and improving our internal controls over financial reporting and the requirements of being a public company which may, among other things, strain our resources, divert management's attention and affect our ability to accurately report our financial results and prevent fraud.

We are be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules of the NYSE American. The Sarbanes-Oxley Act requires, among other things, that a company maintain effective disclosure controls and procedures ("DCP") and internal controls over financial reporting ("ICFR"). Our management and other personnel have limited experience operating as a public company, which may result in operational inefficiencies or errors, or a failure to improve or maintain effective ICFR and DCP necessary to ensure timely and accurate reporting of operational and financial results. Our existing management team will need to devote a substantial amount of time to these compliance initiatives, and may need to add personnel in areas such as accounting, financial reporting, investor relations and legal in connection with operations as a public company. Ensuring that the we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently. Our compliance with existing and evolving regulatory requirements will result in increased administrative expenses and a diversion of management's time and attention.

Pursuant to Sections 302 and 404 of the Sarbanes-Oxley Act ("Section 404"), we are required to furnish certain certifications and reports by our management on our ICFR, which, after we are no longer an emerging growth company and if we become an accelerated or large accelerated filer under SEC rules, must be accompanied by an attestation report on ICFR issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are documenting and evaluating our ICFR, which is both costly and challenging. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our ICFR, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable and timely financial reports and are important to help prevent fraud. Any failure by us to file our periodic reports in a timely manner may cause investors to lose confidence in our reported financial information and may lead to a decline in the price of our Common Stock.

In accordance with NYSE American rules, we are required to maintain a majority independent Board of Directors. The various rules and regulations applicable to public companies make it more difficult and more expensive to maintain directors' and officers' liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors' and officers' insurance, our ability to recruit and retain qualified officers and directors will be significantly curtailed.

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 under the JOBS Act. For so long as we are 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 of 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.

We could be an emerging growth company for up to five years from the end of our most recently completed fiscal year, although we may lose such status earlier, depending on the occurrence of certain events, including when we have generated total annual gross revenue of at least \$1.07 billion or when we are deemed to be a “large accelerated filer” under the Exchange Act, which means that the market value of our Common Stock that is held by non-affiliates exceeds \$700 million as of June 30 of the prior year, as determined each December 31, or when we have issued more than \$1.0 billion in nonconvertible debt securities during the prior three-year period.

We cannot predict if investors will find our securities less attractive or our company less comparable to certain other public companies because we rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities, and the trading prices of our securities may be more volatile.

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.

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.

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

Our Common Stock currently trades on the NYSE American. If our Common Stock is 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.

Having a minority share position may reduce the influence that our current stockholders have on our management.

Our current public stockholders own approximately 13% of the outstanding Public Shares, our current directors, officers and affiliates own approximately 45% of the outstanding Public Shares, and BiomX Ltd. former stockholders own approximately 76% of the outstanding Public Shares. The minority position of our public stockholders gives them limited influence over the management and operations of the company.

Risks Related to Our Common Stock

The price of our Common Stock is volatile like the stocks of other biotechnology companies.

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 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 recent outbreak of novel coronavirus (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 the Business Combination's benefits do not meet the expectations of investors or securities analysts, the market price of our securities may decline.

If the benefits of the Business Combination do not meet the expectations of investors or securities analysts, the market price of our securities may decline. Fluctuations in the price of our securities could contribute to the loss of all or part of your investment. Our securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline, which could have a material adverse effect on your investment in our securities.

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 the company. 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 the company 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.

We may fail to realize any or all of the anticipated benefits of the Business Combination.

The success of the Business Combination depends, in part, on our ability to successfully manage and deploy the cash received upon the consummation of the Business Combination. Although we intend to use the cash received upon the consummation of the Business Combination for the continued development of our product candidates, there can be no assurance that we will be able to achieve our intended objectives.

The price of our Common Stock is subject to increased volatility and the Rule 144 resale exemption is unavailable for our securities because the Business Combination resulted in a merger with a special purpose acquisition company.

The Business Combination resulted in our merging with a special purpose acquisition company (“SPAC”), which can cause additional volatility in the price of our Common Stock. We expect that the price of our Common Stock and of that of SPACs in general may be more volatile compared to the stock price of an operating company.

Rule 144 of the Securities Act provides a safe harbor under which holders of restricted securities and affiliates of an issuer may resell their securities into the public market. However, Rule 144 is unavailable for securities of former SPACs until, among other things, twelve months have elapsed since the former SPAC has filed “Form 10 information” with the SEC. After the completion of the Business Combination, our stockholders may not rely on Rule 144 for resales of their common stock for a minimum of one year, which can impair the ability to resell our Common Stock at a favorable return.

The current unavailability and potential future unavailability of the Rule 144 resale exemption for our Common Stock could have an adverse effect on the market price of 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.

Our outstanding Warrants are exercisable at a price of \$11.50 per share of Common Stock, subject to adjustment. Public Warrants may be exercised only for a whole number of shares of our Common Stock. Private Placement Warrants are exercisable on a cashless basis and are non-redeemable so long as they are held by the initial purchasers or their permitted transferees. 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 the date of this Annual Report, we had outstanding vested and unvested options to purchase 3,084,451 shares of our Common Stock and vested and unvested Warrants to purchase 601,971 shares of our Common Stock. To the extent any of these options or Warrants are exercised, additional Public Shares 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.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We maintain our principal executive offices at 7 Pinhas Sapir Street, Floor 2, Ness Ziona, Israel 7414002 and 2 Ilan Ramon Street, Floor 3, Ness Ziona, Israel 7414002. BiomX's corporate headquarters are located in Ness Ziona, Israel, where BiomX currently leases 18,620 square feet of laboratory and office space. The lease at 7 Pinhas Sapir Street expires in July 2022, subject to an option to extend for an additional five years. The lease in 2 Ilan Ramon Street expires in July 2024, subject to an option to extend the lease until July 2027. In the third quarter of 2019, BiomX opened its own 550 square foot manufacturing facility at its headquarters in Ness Ziona, Israel. This facility has been designed with the capacity to produce clinical quantities of BiomX's product candidates required for future early stage clinical development of BX002 and BX003.

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 legal proceedings brought against us. We are also not aware of any legal proceeding, investigation or claim, or other legal exposure that has a more than remote possibility of having a material adverse effect on our business, financial condition or results of operations.

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.

The Common Shares also began to trade on Tel Aviv Stock Exchange under the symbol "PHGE" on February 6, 2020.

Holders of Record

As of March 25, 2020, there were 21,923,846 issued and outstanding shares of our Common Stock held by 57 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.

Securities Authorized for Issuance Under Equity Compensation Plans

We have two equity incentive plans, the 2015 Employee Stock Option Plan (the "2015 Plan") and the 2019 Omnibus Incentive Plan (the "2019 Plan"). In October 2019, in connection with the Business Combination, the Board of Directors of the Company assumed the 2015 Plan with respect to each outstanding equity award thereunder. Although no shares are available for future issuance under the 2015 Plan, the 2015 Plan will continue to govern outstanding awards granted thereunder. As of December 31, 2019, options to purchase 3,143,805 shares of our Common Stock remained outstanding under the 2015 Plan.

The 2019 Plan was adopted by the Board of Directors and approved by the Company's stockholders in connection with the Business Combination and authorizes the issuance of 1,000 shares of our Common Stock. As of December 31, 2019, there were 1,000 shares available for issuance under the 2019 Plan. The aggregate number of shares available for issuance pursuant to the 2019 Plan will automatically increase on January 1 of each year, for a period of not more than ten (10) years, 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 outstanding on December 31 of the preceding calendar year.

For additional information regarding the 2015 Plan and the 2019 Plan, as of December 31, 2019, please see Part II – Item 8 – Financial Statements and Supplemental Data – Notes to consolidated financial statements – Note 9 – Stock-Based Compensation.

Equity Compensation Plan Information

Plan category	Equity Compensation Plan Information		
	Number of securities to be issued upon exercise of outstanding options and restricted stock (a)	Weighted-average exercise price of outstanding options and restricted stock (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,000	\$ —	1,000
Equity compensation plans not approved by security holders	3,143,805	1.979	—
Total	3,144,805	\$ 1.799	1,000

Recent Sales of Unregistered Securities

Except as previously reported on our Current Report on Form 8-K filed on November 1, 2019, we did not have any sales of unregistered equity securities during the three months ended December 31, 2019.

Use of Proceeds

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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 the 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 Statements Regarding Forward-Looking Statements" and "Risk Factors" in this Annual Report.

BiomX is a clinical stage microbiome product discovery company developing products using both natural and engineered phage technologies designed to target and destroy bacteria that affect the appearance of skin, as well as harmful bacteria in chronic diseases, such as IBD, liver disease and cancer. Bacteriophage or phage are viruses that target bacteria and are considered inert to mammalian cells. By developing proprietary combinations of naturally occurring phage and by creating novel phage using synthetic biology, BiomX develops phage-based therapies intended to address large-market and orphan diseases.

Since inception in 2015, BiomX has devoted substantially all its resources to organizing and staffing its company, raising capital, acquiring rights to or discovering product candidates, developing its technology platforms, securing related intellectual property rights, and conducting discovery, research and development activities for its product candidates. It does not have any products approved for sale, its products are still in the preclinical development stage, and it has not generated any revenue from product sales. As BiomX moves its product candidates from preclinical to clinical stage, it expects its expenses to increase. To date, BiomX has funded its operations with proceeds from sales of common and preferred shares. Through December 31, 2019, BiomX had received gross proceeds of approximately \$60.1 million from sales of its common and preferred shares. To date, BiomX received approximately \$224 thousand from its collaboration agreements and recorded a reduction from research and development expenses of \$167 thousand during the year ended December 31, 2019. Additional cash amounting to approximately \$60 million was obtained by BiomX from the Business Combination.

Since inception, BiomX has incurred significant operating losses. BiomX's ability to generate product revenue 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 BiomX's product candidates. Our net losses were approximately \$20.6 million and \$12.7 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of \$44.6 million and expect that for the foreseeable future we will continue to incur significant expenses as BiomX advances its product candidates from discovery through preclinical development and clinical trials and seek regulatory approval of its product candidates. In addition, if BiomX obtains regulatory approval for any of its product candidates, we would 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. In November 2017, BiomX entered into a share purchase agreement to acquire all of the outstanding share capital of RondinX Ltd., a company organized under the laws of Israel. We may incur expenses in the future in connection with similar acquisitions.

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. We anticipate that our general and administrative expenses will increase as a result of the completion of the Business Combination because of the increased costs associated with being a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. 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.

At December 31, 2019, we had cash and cash equivalents and short-term deposits of \$82.2 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 for at least the next 24 months, as discussed further below under "— Liquidity and Capital Resources"

Accounting Treatment

The Business Combination was treated as a “reverse merger” in accordance with GAAP. For accounting purposes, BiomX was considered to have acquired the Company. Therefore, for accounting purposes, the Business Combination was treated as the equivalent of a capital transaction in which BiomX issued stock for the net assets of the Company. The net assets of the Company were stated at historical cost, with no goodwill or other intangible assets recorded. The post-acquisition financial statements of the Company had shown the consolidated balances and transactions of the Company and BiomX as well as comparative financial information of BiomX (the acquirer for accounting purposes).

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 2018 fiscal year consists of the year ended December 31, 2018, and our 2019 fiscal year consists of the year ended December 31, 2019. In view of this change, this Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” (“MD&A”) includes a discussion and analysis of our financial statements for fiscal years ended December 31, 2019 and 2018.

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.

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. These expenses include:

- license maintenance fees and milestone fees incurred in connection with various license agreements;
- expenses incurred under agreements with CROs, CMOs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials;
- employee-related expenses, including salaries, related benefits, travel and share-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
- depreciation and other expenses.

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

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

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

	Year Ended December 31,	
	2019	2018
	In thousands	
BX001	\$ 1,160	\$ 1,708
BX002	2,590	1,430
BX003	1,468	436
CRC	374	175
Salaries and related benefits	6,492	4,595
Depreciation	318	210
Infrastructure & other unallocated R&D expenses	1,553	1,227
Less grants from the IIA & Income from collaboration agreement	(466)	(646)
Total research and development expenses, net	<u>\$ 13,489</u>	<u>\$ 9,135</u>

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 share-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 share-based compensation expenses for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, consulting, accounting and audit services.

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 incur increased 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 substantially increase our general and administrative expenses. 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.

Consolidated Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

The following table summarizes our consolidated results of operations for the years ended December 31, 2019 and 2018:

	Year ended December 31,	
	2019	2018
	In thousands	
Research and development (“R&D”) expenses, net	\$ 13,489	\$ 9,135
General and administrative expenses	8,718	3,360
Operating loss	22,207	12,495
Finance expenses (income), net	(1,644)	225
Income tax	-	-
Net Loss	\$ 20,563	\$ 12,720

Research and development expenses were \$13.5 million for the year ended December 31, 2019, compared to \$9.1 million for the year ended December 31, 2018. The increase of \$4.4 million, or 48%, in the year ended December 31, 2019 compared to the prior year, is primarily due to the manufacturing of BX001 and BX002, the Company’s product candidates for acne prone skin, and IBD, respectively, and due to initiation of the BX001 clinical study.

General and administrative expenses were \$8.7 million for the year ended December 31, 2019, compared to \$3.4 million for the year ended December 31, 2018. The increase of \$5.3 million, or 156%, is primarily due to expenses related to the Business Combination and construction of the in-house manufacturing facility.

Liquidity and Capital Resources

Since inception, we have not generated any revenue 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 and preferred shares, and through the Business Combination. Through December 31, 2019, we had received gross cash proceeds of approximately \$60 million from sales of our common and preferred shares. In addition, in 2018 and 2019 we received approximately \$175 thousand and \$ 945 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.

Cash Flows

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

	Year Ended December 31,	
	2019	2018
	In thousands	
Net cash used in operating activities	\$ (17,577)	\$ (11,304)
Net cash provided by (used in) investing activities	19,740	(30,038)
Net cash provided by financing activities	61,554	43,042
Net increase in cash and cash equivalents	\$ 63,717	\$ 1,700

Net cash used in operating activities for the year ended December 31, 2019 included our 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, which included share-based compensation expenses of \$0.9 million and depreciation of \$0.3 million, 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, increase in other account payables of \$0.8 million and increase in operation leasing liability of \$0.1 million, offset by an increase of \$1.8 million in other receivables and a decrease of \$0.1 million in related parties.

Net cash used in operating activities for the year ended December 31, 2018 included our net loss of \$12.7 million, net cash used by changes in our operating assets and liabilities of \$0.4 million and non-cash charges of \$1 million, which included share-based compensation expenses of \$1.0 million and depreciation of \$0.2 million, offset by non-cash revaluation of contingent liabilities expenses of \$0.1 million. Net changes in our operating assets and liabilities for the year ended December 31, 2018 consisted primarily of an increase in other account payables of \$0.4 million and a decrease of \$0.2 million in other receivables, offset by a decrease of \$0.2 million in trade account payables.

Investing Activities

During the year ended December 31, 2019, net cash provided by investing activities was \$19.7 million, mainly as a result of decrease in investment in short-term deposits of \$21.0 million and purchase of property and equipment of \$1.3 million, which consisted primarily of investment in laboratory equipment and leasehold improvements.

During the year ended December 31, 2018, net cash used by investing activities was \$30.0 million, mainly as a result of investment in short-term deposits of \$29.9 million and purchases of property and equipment of \$0.1 million, which consisted primarily of laboratory and office equipment.

Financing Activities

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

During the year ended December 31, 2018, net cash provided by financing activities was \$43.0 million, consisting of net proceeds from the sale of our Series A Preferred Shares in February 2018 and the sale of our Series B Preferred Shares in November and December 2018.

Funding Requirements

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. In addition, we expect to incur additional costs associated with operating as the subsidiary of a public company. Our expenses will also increase as BiomX:

- continues the development of its product candidates, including its lead product candidate, BX001;
- completes IND-enabling activities and prepares to initiate clinical trials for BiomX's other product candidates;
- initiates additional clinical trials and preclinical studies for BiomX's product candidates in its pipeline;
- seeks to identify and develop or in-license or acquire additional product candidates and technologies;
- seeks regulatory approvals for BiomX's product candidates that successfully complete clinical trials, if any;

- establishes a sales, marketing and distribution infrastructure to commercialize any product candidates for which it may obtain regulatory approval;
- hires and retains additional personnel, such as clinical, quality control, commercial and scientific personnel; and
- expands BiomX's infrastructure and facilities to accommodate its growing employee base, including adding equipment and physical infrastructure to support its research and development.

We believe that our existing cash and cash equivalents, together with our existing resources, which include approximately \$60 million we obtained from the Business Combination, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. 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 and other outside funding sources. 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with 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.

Share-Based Compensation

We apply ASC 718-10, "Share-Based Payment," which requires the measurement and recognition of compensation expenses for all share-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 share-based award forfeitures as they occur, rather than estimate by applying a forfeiture rate.

In June 2018, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2018-07, “Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting,” which simplifies the accounting for nonemployee share-based payment transactions by aligning the measurement and classification guidance, with certain exceptions, to that for share-based payment awards to employees. The amendments expand the scope of the accounting standard for share-based payment awards to include share-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 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. BiomX 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 our operations.

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.

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 R&D efforts.

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

The Company is an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and it 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 United States Securities Act of 1933, as amended, 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 (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than \$1.0 billion of non-convertible debt securities over a three-year period.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our audited consolidated financial statements.

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

Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2019, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial and accounting officer have concluded that during the period covered by this Annual Report, our disclosure controls and procedures were effective.

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment, or an attestation by our registered public accounting firm regarding management's assessment, of internal control over financial reporting. Management did not have sufficient time following the Business Combination to complete a comprehensive assessment of internal control over financial reporting. In making this determination, we considered the effects of the Business Combination, which is treated as a "reverse merger" in accordance with GAAP and after which, substantially all of the business of the Company was that of BiomX. Management has begun to take steps to strengthen the Company's internal control over financial reporting, including the hiring of experienced accounting and finance staff, and adopting new policies and procedures, and intends to take additional steps during the 2020 fiscal year. Management intends to complete its assessment for inclusion in our 2020 Annual Report.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item regarding the Company's directors and corporate governance, including information with respect to our corporate governance guidelines, Code of Business Conduct and Ethics and beneficial ownership reporting compliance, will appear in the Proxy Statement we will deliver to our stockholders in connection with our 2020 Annual Meeting of Stockholders. Such information is incorporated herein by reference. Information relating to our executive officers is included in Item 1 of Part I, "Business—Executive Officers."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will appear in the Proxy Statement we will deliver to our stockholders in connection with our 2020 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

The information required by this Item regarding security ownership of certain beneficial owners and management will appear in the Proxy Statement we will deliver to our stockholders in connection with our 2020 Annual Meeting of Stockholders. Such information is incorporated herein by reference. Information relating to securities authorized for issuance under the Company's equity compensation plans is included in Part II of this Annual Report under "Item 5—Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities."

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

The information required by this Item will appear in the Proxy Statement we will deliver to our stockholders in connection with our 2020 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item will appear in the Proxy Statement we will deliver to our stockholders in connection with our 2020 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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 registrant's Current Report on Form 8-K filed by the registrant on July 17, 2019)
2.2	Amendment Agreement to the Merger Agreement (Incorporated by reference to Exhibit 2.1 to the registrant's Current Report on Form 8-K filed by the registrant on October 11, 2019)
3.1	Amended and Restated Certificate of Incorporation of the Company, effective on December 11, 2018 (Incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019)
3.2	Certificate of Amendment of Certificate of Incorporation of the Company, effective on October 28, 2019 (Incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019)
3.3	Amended and Restated Bylaws of the Company, effective as of October 28, 2019 (Incorporated by reference to Exhibit 3.3 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019)
4.1	Specimen Unit Certificate (Incorporated by reference to Exhibit 4.1 to the registrant's Registration Statement on Form S-1 filed by the registrant on December 4, 2018)
4.2	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.2 to the registrant's Registration Statement on Form S-1 filed by the registrant on December 4, 2018)
4.3	Specimen Warrant Certificate (Incorporated by reference to Exhibit 4.3 to the registrant's Registration Statement on Form S-1 filed by the registrant on December 4, 2018)
4.4	Warrant Agreement, dated December 13, 2018 between Continental Stock Transfer & Trust Company and the registrant (Incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K filed by the registrant on December 18, 2018)
10.1	Registration Rights Agreement dated October 28, 2019 (Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019)
10.2	Escrow Agreement dated October 28, 2019, among Chardan Healthcare Acquisition Corp., Shareholder Representative Services LLC and Continental Stock Transfer & Trust Company (Incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019)
10.3	Voting Agreement dated October 28, 2019 (Incorporated by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019)
10.4	Form of Indemnification Agreement with each director and officer (Incorporated by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019)
10.5*	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 registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019)
10.6*	Exclusive Patent License Agreement dated April 25, 2017, between BiomX Ltd. and the Massachusetts Institute of Technology (Incorporated by reference to Exhibit 10.6 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019)
10.7*	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 registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019)

- 10.8* [Exclusive Patent License Agreement, dated April 22, 2019, among BiomX Ltd., Keio University and JSR Corporation \(Incorporated by reference to Exhibit 10.8 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019\)](#)
- 10.9* [Share Purchase Agreement, dated November 19, 2017, among BiomX Ltd., RondinX Ltd. and Guy Harmelin, as the Shareholders' Representative \(Incorporated by reference to Exhibit 10.9 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019\)](#)
- 10.10** [Chardan Healthcare Acquisition Corp. 2019 Equity Incentive Plan \(Incorporated by reference to Exhibit 10.10 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019\)](#)
- 10.11** [2015 Employee Stock Option Plan for Key Employees of BiomX Ltd., as amended \(Incorporated by reference to Exhibit 99.1 to the registrant's Registration Statement on Form S-8 filed by the registrant on January 2, 2020\)](#)
- 10.12 [Waiver Agreement, dated October 28, 2019 \(Incorporated by reference to Exhibit 10.11 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019\)](#)
- 10.13 [Purchase Agreement, dated October 28, 2019, between Cornix LLC and Chardan Healthcare Acquisition Corp. \(Incorporated by reference to Exhibit 10.12 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019\)](#)
- 10.14 [Waiver Letter to Voting Agreement \(Incorporated by reference to Exhibit 10.13 to the registrant's Current Report on Form 8-K filed by the registrant on November 4, 2019\)](#)
- 10.15 [Letter Agreements, dated December 13, 2018, among the registrant and each of the initial stockholders, officer and directors of the registrant \(Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed by the registrant on December 18, 2018\)](#)
- 10.16 [Stock Escrow Agreement, dated December 13, 2018, between the registrant, Continental Stock Transfer & Trust Company and the initial stockholders \(Incorporated by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K filed by the registrant on December 18, 2018\)](#)
- 10.17 [Registration Rights Agreement, dated December 13, 2018, among the registrant and the initial stockholders and Chardan Capital Markets, LLC. \(Incorporated by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K filed by the registrant on December 18, 2018\)](#)
- 10.18 [Form of Subscription Agreement, dated December 13, 2018, among the registrant, the initial stockholders and Chardan Capital Markets, LLC \(Incorporated by reference to Exhibit 10.5 to the registrant's Registration Statement on Form S-1 filed by the registrant on December 4, 2018\)](#)
- 10.19 [Form of Non-Qualified Stock Option Agreement \(U.S. Awards to Non-Executives\)](#)
- 10.20 [Form of Non-Qualified Stock Option Agreement \(U.S. Awards to Executive Officers\)](#)
- 10.21 [Form of Option Agreement \(Israeli Awards\)](#)
- 21.1 [Subsidiaries of Registrant \(Incorporated by reference to Exhibit 21.1 to the registrant's Current Report on Form 8-K filed by the registrant on November 1, 2019\)](#)
- 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\(a\), promulgated under the Securities and Exchange Act of 1934, as amended.](#)
- 31.2 [Certification of Chief Financial Officer pursuant to Rule 13a-14 and Rule 15d-14\(a\), promulgated under the Securities and Exchange Act of 1934, as amended.](#)
- 32 [Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)

* 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 registrant if publicly disclosed.

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

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 26, 2020

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each of the undersigned constitutes and appoints Mr. Jonathan Solomon, Ms. Marina Wolfson and Dr. Sailaja Puttagunta, and each or any one of them, as the undersigned's true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for the undersigned and in the undersigned's name, place and stead, in any and all capacities, to sign any and all amendments (including pre-effective and post-effective amendments) to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto such attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that such attorneys-in-fact and agents, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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 registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Dr. Russell Greig</u> Dr. Russell Greig	Chairman of the Board of Directors	March 26, 2020
<u>/s/ Jonathan Solomon</u> Jonathan Solomon	Chief Executive Officer (Principal Executive Officer) and Director	March 26, 2020
<u>/s/ Marina Wolfson</u> Marina Wolfson	Vice President of Finance and Operations (Principal Financial Officer and Principal Accounting Officer)	March 26, 2020
<u>/s/ Dr. Gbola Amusa</u> Dr. Gbola Amusa	Director	March 26, 2020
<u>/s/ Yaron Breski</u> Yaron Breski	Director	March 26, 2020
<u>/s/ Erez Chimovits</u> Erez Chimovits	Director	March 26, 2020
<u>/s/ Jonas Grossman</u> Jonas Grossman	Director	March 26, 2020
<u>/s/ Lynne Sullivan</u> Lynne Sullivan	Director	March 26, 2020
<u>/s/ Dr. Robbie Woodman</u> Dr. Robbie Woodman	Director	March 26, 2020

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP)

CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP)

CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders 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, 2019 and 2018, the related consolidated statements of comprehensive loss, changes in shareholders’ equity and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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 FASB’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.

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

Tel Aviv, Israel
March 26, 2020

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)

		As of December 31,	
	Note	2019	2018
<u>ASSETS</u>			
Current assets			
Cash and cash equivalents		72,256	8,604
Restricted cash		154	89
Short-term deposits	2D	10,003	31,055
Related parties	9	50	-
Other current assets	3	2,068	140
Total current assets		<u>84,531</u>	<u>39,888</u>
Non-current assets			
Lease deposit		5	-
Operating lease right-of-use asset	7	1,148	-
Property and equipment, net	4	1,881	887
In-process research and development (“R&D”)	6	4,556	4,556
Total non-current assets		<u>7,590</u>	<u>5,443</u>
		<u>92,121</u>	<u>45,331</u>

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)

		As of December 31,	
	Note	2019	2018
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>			
Current liabilities			
Trade account payables		3,253	193
Current portion of lease liabilities	7	375	-
Other account payables	8	2,596	1,396
Related parties	9	-	50
Total current liabilities		<u>6,224</u>	<u>1,639</u>
Non-current liabilities			
Lease liabilities – net of current portion	7	856	-
Contingent liabilities	10	585	889
Total non-current liabilities		<u>1,441</u>	<u>889</u>
Commitments and Contingent Liabilities	10		
Shareholders' equity			
Common stock shares, \$0.0001 par value ("Ordinary Shares"); Authorized 60,000,000 and 33,954,304 shares as of December 31, 2019 and 2018, respectively. Issued and outstanding 22,862,835 and 2,307,871 as of December 31, 2019 and 2018, respectively.		2	(*)
Preferred A shares (pre-merger - BiomX Ltd.) ("Preferred A Shares"); NIS 0.01 par value; Authorized 16,430,668 shares as of December 31, 2018. Issued and outstanding 7,543,831 shares as of December 31, 2018.		-	1
Preferred B shares (pre-merger - BiomX Ltd.) ("Preferred B Shares"); NIS 0.01 par value; Authorized 6,858,371 shares as of December 31, 2018. Issued and outstanding 5,170,357 shares as of December 31, 2018.		-	1
Additional paid in capital		126,626	64,410
Accumulated deficit		(42,172)	(21,609)
Total shareholders' equity		<u>84,456</u>	<u>42,803</u>
		<u>92,121</u>	<u>45,331</u>

(*) Less than \$1 thousand.

** Number of shares has been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the reverse 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 COMPREHENSIVE LOSS
(USD in thousands, except share and per share data)

		Year ended December 31,	
	Note	2019	2018
Research and development (“R&D”) expenses, net	12	13,489	9,135
General and administrative expenses	13	8,718	3,360
Operating loss		22,207	12,495
Finance expenses (income), net	14	(1,644)	225
Loss before income tax		20,563	12,720
Income tax	15	-	-
Net Loss		20,563	12,720
Basic and diluted loss per Ordinary Shares	16	3.66	7.62
Weighted average number of Ordinary Shares outstanding, basic and diluted		5,615,856	2,002,464

** Number of shares has been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the reverse 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 SHAREHOLDERS' EQUITY
(USD in thousands, except share and per share data)

	Common stock		Ordinary A Shares (pre-merger - BiomX Ltd.),		Preferred A Shares (pre-merger - BiomX Ltd.),		Preferred B Shares (pre-merger - BiomX Ltd.),		Additional paid	Accumulated	Total shareholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	in capital	deficit	(deficit)
Balance as of January 1, 2018	1,580,159	(*)	696,774	(*)	4,514,841	(*)	-	-	20,419	(8,889)	11,530
Issuance of shares (**)	-	-			3,028,990	(*)	5,170,357	1	43,040	-	43,042
Conversion of Ordinary to Ordinary A Shares	696,774	(*)	(696,774)	(*)	-	-	-	-	-	-	-
Share-based payment	-	-	-	-	-	-	-	-	951	-	951
Exercise of options	30,938	(*)	-	-	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	(12,720)	(12,720)
Balance as of December 31, 2018	2,307,871	(*)	-	-	7,543,831	1	5,170,357	1	64,410	(21,609)	42,803
Issuance of shares (***)	-	-	-	-	-	-	308,628	(*)	1,800	-	1,800
Effect of reverse recapitalization transaction	20,486,082	2	-	-	(7,543,831)	(1)	(5,478,985)	(1)	59,397	-	59,397
Acquisition of treasury stock	(5,700)	(*)	-	-	-	-	-	-	(19)	-	(19)
Share-based payment	-	-	-	-	-	-	-	-	938	-	938
Exercise of options	74,582	(*)	-	-	-	-	-	-	100	-	100
Net loss	-	-	-	-	-	-	-	-	-	(20,563)	(20,563)
Balance as of December 31, 2019	<u>22,862,835</u>	<u>2</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>126,626</u>	<u>(42,172)</u>	<u>84,456</u>

(*) Less than \$1 thousand.

(**) Net of issuance expenses in amount of \$73 thousand.

(***) Net of issuance expenses in amount of \$114 thousand.

** Number of shares has been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the reverse 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,	
	2019	2018
<u>CASH FLOWS – OPERATING ACTIVITIES</u>		
Net loss	(20,563)	(12,720)
Adjustments required to reconcile net loss to cash flows used in operating activities		
Depreciation	318	210
Share-based compensation	938	951
Revaluation of contingent liabilities	(304)	(112)
Changes in operating assets and liabilities:		
Other current assets	(1,845)	187
Trade account payables	3,060	(228)
Other account payables	836	358
Operating lease liabilities	83	-
Related parties	(100)	50
Net cash used in operating activities	<u>(17,577)</u>	<u>(11,304)</u>
<u>CASH FLOWS – INVESTING ACTIVITIES</u>		
Increase (decrease) in short-term deposits	21,052	(29,901)
Purchase of property and equipment	(1,312)	(137)
Net cash used (provided by) in investing activities	<u>19,740</u>	<u>(30,038)</u>
<u>CASH FLOWS – FINANCING ACTIVITIES</u>		
Issuance of preferred shares, net of issuance costs	1,800	43,042
Cash acquired in connection with the reverse recapitalization transaction, net	59,673	-
Acquisition of treasury stock	(19)	-
Exercise of stock options	100	(*)
Net cash provided by financing activities	<u>61,554</u>	<u>43,042</u>
Increase in cash and cash equivalents and restricted cash	63,717	1,700
Cash and cash equivalents and restricted cash at the beginning of the year	<u>8,693</u>	<u>6,993</u>
Cash and cash equivalents and restricted cash at the end of the year	<u><u>72,410</u></u>	<u><u>8,693</u></u>

(*) Less than \$1 thousand.

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

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2019	2018
	USD In thousands	
<u>SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES:</u>		
Recognition of right-of-use asset and lease liability upon adoption of ASU 2016-02	662	-
Assets acquired under operating leases	690	-
<u>Assets acquired (liabilities assumed) in reverse recapitalization transaction:</u>		
Current assets (excluding cash and cash equivalents)	(88)	-
Current liabilities	364	-
Reverse recapitalization effect on equity	59,397	-
Cash acquired in connection with reverse recapitalization transaction	59,673	-

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

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - GENERAL

A. General information:

BiomX Inc. (together with its subsidiaries, BiomX Ltd. and RondinX Ltd., the “Company” or “BiomX” and formerly known as Chardan Healthcare Acquisition Corp.) 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, share 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 (“SRS”), 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 acquired 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 reverse recapitalization. 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 \$60.1 million held in a trust account, after redemptions of IPO shares held by certain shareholders (refer to Note 11A).

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.

The Commons Stock of the Company began trading on the NYSE American stock exchange on October 28, 2019 and the Company was renamed BiomX Inc.

Commencing October 29, 2019, the Company’s shares of Common Stock, units, and warrants are traded 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, 2019, the Company had unrestricted cash and cash equivalent balance of approximately \$72 million and short-term deposits of approximately \$10 million, which management believes is sufficient to fund its operations for more than 12 months from the date of issuance of these financial statements and sufficient to fund its operations necessary to continue development activities of its current proposed products.

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - GENERAL (Cont.)

B. Risk factors: (cont.)

Consistent with its continuing R&D 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 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 the Company.

C. Use of estimates in the preparation of financial statements:

The preparation of financial statements in conformity with generally accepted accounting principles 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.

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. 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 comprehensive loss as financial income or expenses, as appropriate.

C. 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.

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

D. 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 comprehensive loss during the years for which the Company held short-term deposits.

As of December 31, 2019, the Company has a deposit dominated in USD at BHI USA that bears fixed annual interest of 2.1%. As of December 31, 2018, the Company had deposits at Leumi Bank (Israel) and BHI USA that bore fixed annual interest between 2.8% and 3.6%.

E. 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. We have no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements.

F. 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	6-7 years
Computers and software	3 years
Equipment and furniture	6-7 years
Leasehold improvements	Shorter of lease term or useful life

In accordance with ASC 360-10, 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, 2019, and 2018, no impairment expenses were recorded.

G. Intangible assets:

Intangible R&D assets acquired in a business combination (IPR&D) 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.

H. 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 of the deferred tax assets will not be realized. As of December 31, 2019 and 2018, the Company had a full valuation allowance against deferred tax assets.

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP.)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

H. 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, 2019 and 2018.

I. 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, 2019 and 2018.

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 (USD in thousands):

		December 31, 2019			
		Level 1	Level 2	Level 3	Fair Value
Liabilities					
Contingent liabilities		-	-	585	585
		December 31, 2018			
		Level 1	Level 2	Level 3	Fair Value
Liabilities					
Contingent liabilities		-	-	889	889

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.

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

J. R&D costs:

R&D costs are charged to statements of comprehensive loss as incurred.

Royalty-bearing grants from the Israel Innovation Authorities ("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

K. Basic and diluted loss per share:

Basic loss per share is computed by dividing net loss by the weighted average number of ordinary shares outstanding during the year. Diluted loss per share is computed by dividing net loss by the weighted average number of ordinary shares outstanding during the year, plus the number of ordinary shares that would have been outstanding if all potentially dilutive ordinary shares had been issued, using the treasury stock method, in accordance with ASC 260-10 "Earnings per Share." Potentially dilutive ordinary shares 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.

L. Defined contribution plans:

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

Payments in accordance with Article 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 comprehensive loss as and when the services are received from the Company's employees. Total expenses with respect to these contributions were \$381 thousand and \$283 thousand for the years ended December 31, 2019 and 2018, respectively.

M. Stock compensation plans:

The Company applies ASC 718-10, "Share-Based Payment," ("ASC 718-10") which requires the measurement and recognition of compensation expenses for all share-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 share-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 comprehensive loss. The Company recognizes share-based award forfeitures as they occur rather than estimate by applying a forfeiture rate.

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

M. Stock compensation plans: (cont.)

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 Share-Based Payment Accounting”, which simplifies the accounting for nonemployee share-based payment transactions by aligning the measurement and classification guidance, with certain exceptions, to that for share-based payment awards to employees. The amendments expand the scope of the accounting standard for share-based payment awards to include share-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.

The Company estimates 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). 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.

N. 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 expense for operating leases are recognized on a straight-line basis over the lease term.

BIOMX INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

N. Leases: (cont.)

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.

O. Recent Accounting Standards:

In June 2016, the FASB issued ASU 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. The ASU replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses. The Company plans to adopt this ASU in the first quarter of 2020. The Company does not expect the adoption of this ASU will have a material impact on its consolidated financial statements.

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 is effective for the Company beginning on January 1, 2020. The Company does not expect that this standard will have a material effect 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. This standard is not expected to have a material impact on the Company’s consolidated financial statements and related disclosures.

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 is effective for the Company beginning on January 1, 2021, with early adoption permitted. The Company does not expect that the adoption of this standard will have a significant impact on the consolidated financial statements and related disclosures.

NOTE 3 - OTHER CURRENT ASSETS

	As of December 31,	
	2019	2018
	USD In thousands	
Government institutions	244	129
Prepaid insurance	1,560	2
Other prepaid expenses	264	9
	2,068	140

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 4 - PROPERTY AND EQUIPMENT, NET

	As of December 31,	
	2019	2018
	USD In thousands	
Cost:		
Computers and software	350	272
Laboratory equipment	1,729	608
Equipment and furniture	159	132
Leasehold improvements	300	214
	<u>2,538</u>	<u>1,226</u>
Depreciation:		
Computers and software	199	125
Laboratory equipment	367	165
Equipment and furniture	5	4
Leasehold improvements	86	45
	<u>657</u>	<u>339</u>
	<u>1,881</u>	<u>887</u>

NOTE 5 - ACQUISITION OF SUBSIDIARY

On November 19, 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 US\$4.5 million. 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 ordinary shares 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 authorized or outstanding as of the time the payment is due, or a combination of both of up to \$32 million 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.

BiomX Israel completed the RondinX Ltd. acquisition on November 27, 2017.

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, 2019 and December 31, 2018.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 5 - ACQUISITION OF SUBSIDIARY (Cont.)

The change in the fair value of the contingent consideration as of December 31, 2019 and 2018 was as follows (USD in thousands):

	<u>Contingent consideration</u>
As of December 31, 2018	889
Revaluation of contingent consideration	<u>(629)</u>
As of December 31, 2019	260
	<u>Contingent consideration</u>
As of December 31, 2017	1,001
Revaluation of contingent consideration	<u>(112)</u>
As of December 31, 2018	889

NOTE 6 - IN-PROCESS RESEARCH AND DEVELOPMENT

Intangible assets acquired in the RondinX Ltd. acquisition (see Note 5) were determined to be in-process 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. Once the R&D efforts are complete, the Company will determine the useful life of the R&D assets and will amortize these assets accordingly in the financial statements. As of December 31, 2019, the in-process R&D efforts had not yet been completed nor abandoned. Based on management's analysis, there were no impairment indicators present as of December 31, 2019 and 2018.

NOTE 7 - 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 \$17 thousand. As a part of the agreement, the Company provided a bank guarantee to the property owner in the amount of approximately \$95 thousand representing four monthly lease payments. Lease expenses recorded in the consolidated statements of comprehensive loss were \$201 thousand and \$198 thousand for the years ended December 31, 2019, and 2018, 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 \$10 thousand. As a part of the agreement, the Company provided a bank guarantee to in the amount of approximately \$59 thousand representing four monthly lease payments. Lease expenses recorded in the consolidated statements of comprehensive loss were \$18 thousand for the year ended December 31, 2019.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7 - LEASES (Cont.)

Supplemental cash flow information related to operating leases was as follows (USD in thousands):

	Year ended December 31, 2019
Cash payments for operating leases accounted under ASU 2016-02	219

As of December 31, 2019, the Company's operating leases had a weighted average remaining lease term of 4 years and a weighted average discount rate of 3%. The maturity analysis of operating leases as of December 31, 2019 were as follows (USD in thousands):

	Operating Leases
2020	\$ 381
2021	380
2022	272
2023	143
2024	98
Total operating lease payments	1,274
Less imputed interest	(43)
Total operating lease liability balance	\$ 1,231

NOTE 8 - OTHER ACCOUNT PAYABLES

	As of December 31,	
	2019	2018
	USD In thousands	
Employees and related institutions	1,780	807
Accrued expenses	587	411
Government institutions	169	120
Deferred income	60	58
	<u>2,596</u>	<u>1,396</u>

NOTE 9 - BALANCES AND TRANSACTION WITH RELATED PARTIES

A. Balances with related parties

	As of December 31,	
	2019	2018
	USD In thousands	
Additional paid in capital (treasury stock) (See 1 below)	(19)	-
Related party receivable (payable) See 2 below	50	(50)

BIOMX INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 9 - BALANCES AND TRANSACTION WITH RELATED PARTIES (Cont.)

B. Transactions with related parties

	Year ended December 31,	
	2019	2018
R&D expenses (See 2 below)	(167)	-
General and administration expenses (See 3 below)	-	28

1. BiomX Israel committed to enter 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, are non-recourse and are secured by Company shares issued to them that have a value that equals three times the loan amount. If any of such shareholders defaults on such loan, the Company will have the right to forfeit or sell such number of shares as have a value equal to the amount of the loan (plus interest accrued thereon) not timely repaid, based on their market price at the time of such forfeiture or sale. As of December 31, 2019, one loan was granted in the amount of \$19 thousand. The aggregate amount of the remaining potential commitment is \$89 thousand. All other shareholders waived their right to the loans. The numbers 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 relating 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 amount.
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 thousand in instalments of \$50 thousand within 60 days of signing of the agreement, \$17 thousand upon completion of data processing, and two instalments of \$50 thousand 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 thousand had been received. The remaining \$50 thousand consideration was received in January 2020.
3. In June 2015, an incubator company formation and financing agreement (the "Incubator Agreement") was signed between BiomX Israel and other investors. According to the Incubator Agreement, the role of the Incubator (as defined within the Incubator Agreement) was to provide BiomX Israel with offices, labs, administrative, finance, legal and other services. In return for these services, the Incubator was entitled to receive fees at amount equal to 20% of BiomX Israel's payroll expenses. Starting from July 2018, BiomX Israel no longer received these services from the Incubator. The Company recorded total expenses of \$28 thousand for the year ended December 31, 2018, with respect to this agreement.
4. BiomX Israel entered into indemnification agreement with the Incubator on December 13, 2017. According to the agreement, the aggregate amount of the indemnification shall not exceed an aggregate of NIS 2,295 thousand (approximately \$664 thousand). In addition, the indemnification is limited only to matters in connection with the Company's compliance with the IIA regulations and that such indemnification undertakings will not derogate from any other indemnification undertakings to which BiomX Israel is bound.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 - COMMITMENTS AND CONTINGENT LIABILITIES

- A. During 2015, 2016 and 2017, BiomX Israel submitted three requests to the IIA for a R&D project for the technological incubators program. The approved budget per year was NIS 2.7 million (approximately \$781 thousand) 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.

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, 2019, therefore, no liability was recorded in these consolidated financial statements.

Total research and development income recorded in the consolidated statements of comprehensive loss was \$299 thousand and \$646 thousand for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, BiomX Israel had a contingent obligation to the IIA in the amount of approximately \$2.3 million including annual interest of LIBOR linked to the dollar.

In December 2019, the IIA approved a new application for a total budget of NIS 10.8 million (approximately \$3.1 million). IIA will fund 30% of the approved budget. The program is for the period beginning from July 2019 through December 2019. BiomX Israel has not yet submitted the final report to the IIA for this program. As of December 31, 2019, no income was recorded with respect to this application.

During December 2019 BiomX Israel submitted three additional applications to the IIA, for a total budget of NIS 41.1 million (approximately \$11.9 million). These applications are being reviewed by the IIA.

- B. In June 2015, BiomX Israel entered into a Research and License Agreement (the "2015 License Agreement") as amended with Yeda Research and Development Company Limited ("Yeda"), according to which Yeda undertakes to conduct research. The research includes 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 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, the Company contributed an aggregate of approximately \$1.8 million to the research budget agreed upon in the 2015 License Agreement. In addition, Yeda granted the Company with an exclusive worldwide license for the development, production and sale of the products (the "License"), as defined in the 2015 License Agreement and subject to the terms and conditions specified in the 2015 License Agreement. In return for the License, the Company will pay Yeda annual license fees of approximately \$10 thousand and royalties on revenues as defined in the 2015 License Agreement. As the Company has not yet generated revenue from operations, no provision was included in the financial statements with respect to the 2015 License Agreement as of December 31, 2019 and 2018.

BIOMX INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 - 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 BiomX Israel. As consideration for the license, the Company paid \$10 thousand for the term of the 2017 License Agreement, unless earlier terminated by either party and granted Yeda 591,382 warrants to purchase Ordinary Shares of the Company at \$0.0001 nominal value. Refer to Note 11 below for the terms of the warrants granted. In the event of certain mergers and acquisitions by BiomX Israel, 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 agreement. 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, 2019 and 2018.

In July 2019, the Company, Yeda and BiomX Israel amended the 2015 License Agreement and the 2017 License Agreement with Yeda (the “Amendment”). Pursuant to the Amendment, following the closing of the Recapitalization Transaction, the provisions of the 2015 License Agreement and the 2017 License Agreement related to the exit fee were amended so that, in the event of any merger or acquisition involving BiomX, the Company is obliged to pay Yeda a one-time payment as described in the Amendment which will not exceed 1% of the consideration received under such transaction.

- D. As successor in interest to RondinX Ltd., BiomX Israel is a party to a license agreement dated March 20, 2016 with Yeda, pursuant to which the Company has a worldwide exclusive license to Yeda’s know-how, information and patents related to the Company’s meta-genomics target discovery platform. As consideration for the license, the Company will pay license fees of \$10 thousand 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 will pay a royalty in the low single digits on revenue of products. As the Company has not yet generated revenue from operations, no provision was recorded in the financial statements as of December 31, 2019 and 2018 with respect to the agreement.
- F. In April 2017, BiomX Israel signed an exclusive 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 thousand during the year ended 2017 and is required to pay certain license maintenance fees of up to \$250 thousand 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 \$2.4 million in aggregate, as well as royalty payments on future revenues. The consolidated financial statements include a liability with respect to this agreement in the amount of \$108 thousand as of December 31, 2019. There was no liability recorded with respect to this agreement as of December 31, 2018.
- G. 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 BiomX Israel inflammatory bowel disease program. In return, BiomX Israel will pay annual license fees of between \$15 thousand to \$25 thousand subject to the terms and conditions specified in the agreement. Additionally, the Company is obligated to pay contingent consideration based upon the achievement of clinical and regulatory milestones up to an aggregate of \$3.2 million and royalty payments based on future revenue.

In April 2019, BiomX Israel signed 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, BiomX Israel is required (i) to pay a license issue fee of \$20 thousand and annual license fees ranging from \$15 thousand to \$25 thousand; (ii) make additional payments based upon the achievement of clinical and regulatory milestones up to an aggregate of \$3.2 million (“milestone payments”); and (iii) make tiered royalty payments, in the low single digits based on future revenue.

BIOMX INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 - COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)

G. (cont.)

The consolidated financial statements include liabilities with respect to this agreement in the amount of \$217 thousand as of December 31, 2019. The amount was determined using the expected cash flow approach. There was no liability recorded with respect to this agreement as of December 31, 2018.

H. Refer to Note 7 for information regarding the Company's lease commitments.

I. Refer to Note 9B(1) for information regarding the Company's commitment to certain shareholders for taxes incurred in Israel as a result of the Recapitalization Transaction.

J. Refer to Note 5 regarding contingent liability with respect to RondinX Ltd. acquisition.

NOTE 11 - SHAREHOLDERS EQUITY

A. Share Capital:

Common Stock:

The Company is authorized to issue 60,000,000 shares of Common Stock with a par value of \$0.0001 per share. Holders of the Company's Common Stock are entitled to one vote for each share. As of December 31, 2019, the Company had 22,862,835 issued and outstanding Common Stock shares.

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 \$70,000,000. The Public Units each consists 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 the \$60.1 million 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 thousand, 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 thousand 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 thousand 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 thousand in accordance with the November 2018 SPA.

Share Exchange:

As detailed in Note 1, as part of the Recapitalization Transaction on October 28, 2019, the Company issued 15,069,058 Common Shares 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 have been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the Recapitalization Transaction.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 11 - SHAREHOLDERS EQUITY (Cont.)

A. Share Capital: (cont.)

Share Exchange: (cont.)

In addition, the Company also agreed to issue the following number of additional shares of Common Stock, in the aggregate, to shareholders 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 shares traded on the NYSE):

- 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.

Preferred Stock:

The Company is authorized to issue 1,000,000 shares of preferred stock with a par value of \$0.0001 per share. As of December 31, 2019, no preferred stock has been issued.

B. Share-based compensation:

Equity Incentive Plan:

In 2015, the board of directors of BiomX Israel approved a plan (original option plan) for the allocation of options to employees, service providers, and officers (the "2015 Plan"). The options represented a right to purchase 1 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 Israeli Internal Revenue Code.

The original option plan was adjusted in 2019 following the Recapitalization Transaction on October 28, 2019. Following the Recapitalization Transaction, each outstanding option entitles its holder to purchase 1 Common Stock share 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 option plan. The number of outstanding options and exercise prices in this Note have been restated to reflect the adjusted option plan.

As of December 31, 2019, there are no shares remaining for issuance under the original option plan.

The Company adopted a new incentive plan in 2019 (the "2019 Plan") to grant 1,000 options, exercisable to Common Stock, par value \$0.0001 per share. As of December 31, 2019, no options were granted under the 2019 plan.

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 Common Stock outstanding on December 31 of the preceding calendar year. Notwithstanding the foregoing, the Board of Directors 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 Common Stock than provided herein.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 11 - SHAREHOLDERS EQUITY (Cont.)

B. Share-based compensation: (cont.)

Stock Options:

All options granted during 2018 and 2019 were made under the 2015 Plan.

During 2018, the Board approved the grant of 785,775 non-tradable options without consideration to 27 employees and 199,481 non-tradable options without consideration to 2 consultants.

- 876,504 options were granted at an exercise prices of between \$1.97-\$2.03 per share. 25% of the options vest and become exercisable on the first anniversary of the vesting commencement date. Thereafter, the options vest and become exercisable in 12 equal quarterly instalments of 6.25% each.
- 108,752 options were granted at an exercise price of \$1.69 per share and vest on variable vesting dates.

During 2018, 30,938 options were exercised to purchase ordinary shares at an exercise price of \$0.001 per share.

During 2019, the Board approved the grant of 704,669 options without consideration to 22 employees and 79,630 options without consideration to 2 consultants. 527,716 of the options granted are to the executive officers of the Company.

During 2019, 74,581 options were exercised to purchase ordinary shares at an exercise price of \$1.34 per share.

Certain senior employees are entitled to full acceleration of their unvested options upon the occurrence of cumulative two certain events.

The fair value of each option was estimated as of the date of grant or reporting period using the Black-Scholes option-pricing model.

The fair value of options was estimated at the date of grant using the following assumptions:

	<u>2019</u>	<u>2018</u>
Underlying value of ordinary share (\$)	1.7-10	1.7-2
Exercise price (\$)	1.7-10	1.7-2
Expected volatility (%)	93.1	93.1
Term of the option (years)	6.25	6.25
Risk-free interest rate (%)	2.23	2.25-3.05

The cost of the benefit embodied in the options granted in 2019 and 2018 based on their fair value as at the grant date, is estimated to be \$1,406 thousand and \$1,451 thousand, respectively. These amounts will be recognized in statements of comprehensive loss over the vesting period.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 11 - SHAREHOLDERS EQUITY (Cont.)

B. Share-based compensation: (cont.)

(1) A summary of options granted to purchase the Company's Ordinary Shares under the Company's share option plan is as follows:

For year ended December 31,						
2019						
	Employees			Consultants		
	Number of Options	Weighted average exercise price	Aggregate intrinsic value	Number of Options	Weighted average exercise price	Aggregate intrinsic value
Outstanding at the beginning of year	1,868,749	1.58	849	702,388	0.69	944
Granted	704,699	2.03		79,630	2.03	
Forfeited	(137,682)	1.90		-		
Exercised	(74,581)	1.34		-		
Outstanding at the end of year	2,361,185	1.87	19,185	782,018	0.82	6,588
Vested at year end	1,011,862			470,236		
Weighted average remaining contractual life – years as of December 31, 2019	8.16			7.29		

For year ended December 31,						
2018						
	Employees			Consultants		
	Number of Options	Weighted average exercise price	Aggregate intrinsic value	Number of Options	Weighted average exercise price	Aggregate intrinsic value
Outstanding at the beginning of year	1,278,900	1.29	840	518,442	0.21	915
Granted	801,310	1.98		183,946	2.03	
Forfeited	(180,523)	1.63		-		
Exercised	(30,938)	(*)		-		
Outstanding at the end of year	1,868,749	1.58	849	702,388	0.69	944
Vested at year end	653,201			323,111		
Weighted average remaining contractual life – years as of December 31, 2018	8.65			8.1		

(*) Less than \$0.01.

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NOTE 11 - SHAREHOLDERS EQUITY (Cont.)

B. Share-based compensation: (cont.)

- (2) The following table sets forth the total share-based payment expenses resulting from options granted, included in the statements of operation:

	Year ended December 31,	
	2019	2018
	USD In thousands	
R&D	450	623
General and administrative	488	328
	<u>938</u>	<u>951</u>

The Company recognized share-based compensation expenses in connection with options granted to executive officers of the Company in the amount of \$732 thousand and \$405 thousand for the years ended December 31, 2019 and 2018, respectively.

The total unrecognized compensation expense was \$2,308 thousand and \$3,026 thousand as of December 31, 2019 and 2018, respectively. These expenses will be recognized over a period of approximately 4 years.

Warrants:

As of December 31, 2019, and 2018, the Company had the following outstanding warrants to purchase Common Stock as follows:

Warrant	Issuance Date	Expiration Date	Exercise Price Per Share	Number of Shares of Common Stock Underlying Warrants
Private Warrants issued to Yeda(see 1 below)	May 11, 2017	May 11, 2025	(*)	591,382
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
				<u>7,001,971</u>

(*) less than \$0.001.

1. In May 2017, in accordance with the 2017 License Agreement (see also Note 10C), the Company issued to Yeda, for nominal consideration, 591,382 warrants to purchase Common Stock at \$0.0001 nominal value. For the year ended December 31, 2019, the Company recorded income of \$241 thousand. For the year ended December 31, 2018 the Company recorded an expense of \$584 thousand. Expenses and income are included in R&D expenses, net in the consolidated statements of comprehensive loss.

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,

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NOTE 11 - SHAREHOLDERS EQUITY (Cont.)

B. Share-based compensation: (cont.)

- b. 118,277 upon achievement of the earlier of the following milestone by the Company:
- (i) execution of an agreement with a pharmaceutical company with respect to the commercialization of any of the Company's licensed technology or the Consulting IP or a Product (both defined in the 2017 License Agreement) or
 - (ii) the filing of a patent application covering any Discovered Target (as defined in the 2017 License Agreement) or a Product.
- c. 59,139 upon completion of a Phase 1 clinical trial in respect of a Product.
2. In November 2017, the Company 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 have no exercise price. No compensation expenses were recorded in the financial statements during 2019 and 2018.
3. The Private Placement Warrants are identical to the Public Warrants underlying the Units sold in the Initial Public Offering 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.
4. The Public Warrants became exercisable upon Closing of the Reverse Recapitalization. No fractional shares will be issued upon exercise of the Public Warrants. Therefore, Public Warrants must be exercised in multiples of two warrants. The Company filed a Registration Statement for the shares underlying the warrants on December 13, 2019 (effective on January 3, 2020). The Public Warrants will expire five years after the completion of the Reverse Recapitalization or earlier upon redemption or liquidation.

The Company may redeem the Public Warrants:

- in whole and not in part;
- at a price of \$0.01 per warrant;
- at any time during the exercise period;
- upon a minimum of 30 days' prior written notice of redemption;
- if, and only if, the last sale price of the Company's common stock equals or exceeds \$16.00 per share for any 20 trading days within a 30-trading day period ending on the third business day prior to the date on which the Company sends the notice of redemption to the warrant holders; and
- if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants at the time of redemption and for the entire 30-day trading period referred to above and continuing each day thereafter until the date of redemption.

If the Company calls the Public Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a "cashless basis," as described in the warrant agreement. The exercise price and number of shares of Common Stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, or recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for issuance of Common Stock at a price below its exercise price. Additionally, in no event will the Company be required to net cash settle the warrants.

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NOTE 12 - R&D EXPENSES, NET

	Year ended December 31,	
	2019	2018
	USD In thousands	
Professional service and subcontractors	4,295	4,365
Salaries and related expenses	7,896	3,972
Share-based compensation	450	623
Depreciation	317	210
Materials and supplies	997	611
	<u>13,955</u>	<u>9,781</u>
Less Income from Collaboration Agreement (see Note 8)	(167)	-
Less Grants from the IIA (see Note 10A)	(299)	(646)
	<u><u>13,489</u></u>	<u><u>9,135</u></u>

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NOTE 13 - GENERAL AND ADMINISTRATIVE EXPENSES

	Year ended December 31,	
	2019	2018
	USD In thousands	
Salaries and related expenses	1,746	1,369
Incubator overhead	-	28
Share-based compensation	488	328
Professional services	3,765	284
Travel expenses	445	258
Office expenses	286	189
Recruitment expenses	333	209
Rent and rent related expenses	374	333
Other	1,281	362
	<u>8,718</u>	<u>3,360</u>

NOTE 14 - FINANCE INCOME (EXPENSES), NET

	Year ended December 31,	
	2019	2018
	USD In thousands	
Exchange rate differences	(483)	420
Interest income from bank deposits	(921)	(103)
Revaluation of contingent liabilities	(304)	-
Bank fees and other	64	9
	<u>(1,644)</u>	<u>225</u>

NOTE 15 - INCOME TAXES

- A. The Company files income tax returns in the U.S. federal jurisdiction 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. Statutory U.S. federal income tax rate is 21%.
- B. BiomX Ltd. And RondinX Ltd. file income tax returns in Israel. Their income tax returns since inception remain open and subject to examination. Statutory Israeli income tax rate is 23%.
- C. As of December 31, 2019 and 2018, BiomX Ltd. had total net operating losses in Israel of approximately \$25,883 thousand and \$10,556 thousand, respectively, which may be carried forward and offset against taxable income in the future for an indefinite period.
- D. BiomX Ltd is still in its development stage and has not yet generated revenue, therefore, it is more likely than not that sufficient taxable income will not be available for the tax losses to be utilized in the future. Therefore, a valuation allowance was recorded to reduce the deferred tax assets to its recoverable amounts.
- E. BiomX Inc is still in its development stage, therefore, it is more likely than not that sufficient taxable income will not be available for the tax losses to be utilized in the future. Therefore, a valuation allowance was recorded to reduce the deferred tax assets to its recoverable amounts.

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NOTE 15 - INCOME TAXES (Cont.)

	As of December 31,	
	2019	2018
	USD In thousands	
Net operating loss carry-forward Biomx Inc.	-	-
Net operating loss carry-forward Biomx Ltd.	5,953	2,430
Total deferred tax assets	5,953	2,430
Valuation allowance	(5,953)	(2,430)
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,	
	2019	2018
	USD In thousands	
Statutory U.S. federal income tax rate	21%	21%
U.S. vs foreign tax rate differential	2	2
Business Combination expenses	(3.1)	-
Valuation allowance	(19.9)	(23)
Effective tax rate	0%	0%

NOTE 16 - 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 (USD in thousands, except share and per share data):

	For the year ended December 31,	
	2019	2018
Net loss	20,563	12,720
Net loss attributable to holders of Preferred shares (pre-merger – BiomX Ltd.)	-	2,533
Net loss used in the calculation of basic net loss per share	20,563	15,253
Net loss per share	3.66	7.62
Weighted average number of Common Stock	5,615,856	2,002,464

As the inclusion of Common Stock share 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 17 - SUBSEQUENT EVENTS

On March 25, 2020, the Board of Directors approved the grant of 814,700 options to 67 employees, one consultant, four senior officers (one of whom is a consultant) and six directors under the 2019 Incentive Plan. 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 cumulative two certain events.