

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

Form S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

BIOMX INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

2836

(Primary Standard Industrial
Classification Code Number)

82-3364020

(I.R.S. Employer
Identification Number)

7 Pinhas Sapir St., Floor 2
Ness Ziona, Israel 7414002
Telephone: (972) 72-394-2377

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Jonathan Solomon
Chief Executive Officer
7 Pinhas Sapir St., Floor 2
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: **As soon as practicable after the effective date of this registration statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

| <u>Title of each class of securities to be registered</u> | <u>Amount to be registered</u> | <u>Proposed maximum offering price per unit</u> | <u>Proposed maximum aggregate offering price</u> | <u>Amount of registration fee</u> |
|---|--------------------------------|---|--|-----------------------------------|
| Common stock, par value \$0.0001 per share | 15,741,829(1) | \$ 11.50(2) | \$ 181,031,033.50 | \$ 23,497.83 |
| Warrants to purchase common stock | 2,900,000(3) | —(4) | — | 0 |
| TOTAL | | | | \$ 23,497.83 |

- (1) Represents (i) 3,500,000 shares of its common stock, par value \$0.0001 per share (“Common Stock”) that may be issued upon the exercise of 7,000,000 warrants (the “Public Warrants”) originally sold as part of the units in the registrant’s initial public offering (the “IPO”), (ii) 2,900,000 shares of Common Stock that may be issued upon the exercise of the 2,900,000 warrants (the “Private Placement Warrants”, and together with the Public Warrants, the “Warrants”) sold in a private placement that closed simultaneously with the consummation of the IPO, (iii) 7,604,329 shares of Common Stock issued in a private placement in connection with the consummation of the Business Combination (as defined below) and (iv) 1,737,500 shares of Common Stock sold in one or more private placements prior to the IPO. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the “Securities Act”), there are also being registered such indeterminable additional shares of Common Stock as may be issued to prevent dilution as a result of stock splits, stock dividends or similar transactions, and the resale of such shares of Common Stock.
- (2) Based on the \$11.50 exercise price per share of a Warrant in accordance with Rule 457(g) under the Securities Act.
- (3) Represents the resale of the Private Placement Warrants underlying the Public Units sold in a private placement that closed simultaneously with the consummation of the IPO.
- (4) No fee pursuant to Rule 457(g) under the Securities Act.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting an offer to buy these securities, in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBER 13, 2019.

PROSPECTUS

BIOMX INC.



**Resale of 15,741,829 Shares of Common Stock and
2,900,000 Warrants to Purchase Common Stock**

This prospectus relates to the resale by the selling security holders named in this prospectus or their permitted transferees (the "Selling Securityholders") of up to 15,741,829 shares of our common stock, par value \$0.0001 per share ("Common Stock"), which consist of (a) 3,500,000 shares of Common Stock that may be issued upon the exercise of 7,000,000 warrants (the "Public Warrants") originally sold as part of the units offered in our initial public offering (the "IPO") and which entitle the holder to purchase one-half (1/2) of a share of Common Stock at an exercise price of \$11.50 per whole share of Common Stock, (b) 2,900,000 shares of Common Stock that may be issued upon the exercise of 2,900,000 warrants (the "Private Placement Warrants", and together with the Public Warrants, the "Warrants") issued in a private placement that closed simultaneously with the consummation of the IPO, which entitle the holder to purchase Common Stock at an exercise price of \$11.50 per share of Common Stock, (c) 7,604,329 shares of Common Stock issued in a private placement in connection with the consummation of the Business Combination (as defined below) and (iv) 1,737,500 shares of Common Stock sold in one or more private placements prior to the IPO.

The shares of Common Stock and the Private Placement Warrants that may be sold by the Selling Securityholders are collectively referred to in this prospectus as the "Offered Securities." We will not receive any of the proceeds from the sale by the Selling Securityholders of the Offered Securities. We will receive the proceeds from the exercise of the Warrants for cash, but not from the sale of the underlying shares of Common Stock. See "Use of Proceeds" beginning on page 48 of this prospectus. We will bear all costs, expenses and fees in connection with the registration of the Offered Securities, including with regard to compliance with state securities or "blue sky" laws. The Selling Securityholders will bear all commissions and discounts, if any, attributable to their sale of the Offered Securities, except as otherwise expressly set forth under "Plan of Distribution" beginning on page 104 of this prospectus.

This prospectus describes the general manner in which the Offered Securities may be offered and sold. If necessary, the specific manner in which the Offered Securities may be offered and sold will be described in one or more supplements to this prospectus. Any prospectus supplement may add, update or change information contained in this prospectus. You should carefully read this prospectus, and any applicable prospectus supplement, as well as the documents incorporated by reference herein or therein before you invest in any of our securities.

The Selling Securityholders may offer, sell or distribute Offered Securities publicly or through private transactions. If the Selling Securityholders use underwriters, dealers or agents to sell Offered Securities, we will name them and describe their compensation in a prospectus supplement. The price to the public of those securities and the net proceeds the Selling Securityholders expect to receive from that sale will also be set forth in a prospectus supplement.

Our Common Stock and Public Warrants are currently quoted on the NYSE American Stock Market ("NYSE American") under the symbols "PHGE" and "PHGE.W," respectively. On December 12, 2019, the last reported sale price of our Common Stock was \$9.04 per share and the last reported price of the Public Warrants was \$0.60 per warrant.

We are an "emerging growth company" under applicable federal securities laws and are subject to reduced public company reporting requirements. Investing in our securities involves a high degree of risk.

See "Risk Factors" beginning on page 5 for a discussion of information that should be considered in connection with the ownership of our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of the prospectus is .

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You should rely only on the information contained in this prospectus or a supplement to this prospectus. We have not authorized anyone to provide you with different information. This prospectus is not an offer to sell securities, and it is not soliciting an offer to buy securities, in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus or any supplement to this prospectus is accurate as of any date other than the date on the front cover of those documents.

PROSPECTUS SUMMARY

This summary only highlights the more detailed information appearing elsewhere in this prospectus. As this is a summary, it does not contain all of the information that you should consider in making an investment decision. You should read this entire prospectus carefully, including the information under “Risk Factors” and our financial statements and the related notes included elsewhere in this prospectus, before investing.

Unless otherwise stated in this prospectus, references to:

- “IPO” means our initial public offering of Public Units;
- “management” or “management team” means our executive officers and directors;
- “Private Placement Warrants” means the warrants issued to our Sponsor in a private placement that occurred simultaneously with the closing of the IPO;
- “Public Shares” means shares of our Common Stock sold as part of the Public Units;
- “Public Stockholders” means 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;
- “Public Units” means the units originally sold in our IPO;
- “Public Warrants” means the warrants sold as part of the Public Units;
- “Sponsor” means Chardan Investments, LLC, our sponsor; and
- “Warrants” means our redeemable warrants, which includes the Public Warrants as well as the Private Placement Warrants to the extent they are no longer held by the initial purchasers of the Private Placement Warrants or their permitted transferees.

Throughout the prospectus, which forms a part of this registration statement, 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, 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 prospectus 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 Combination, references to “BiomX” should be understood to reference BiomX Inc. Given that the Business Combination is accounted for as a reverse merger, as described in more detail below, and the accounting acquirer is BiomX Inc., the post-Business Combination financial statements included in this prospectus show the consolidated balances and transactions of the Company and BiomX as well as comparative financial information of BiomX (the acquirer for accounting purposes).

Our Company

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, the Sponsor purchased an 1,437,500 shares of 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 the IPO of 7,000,000 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 Public Share and one Public Warrant to purchase one-half of a share of Common Stock, 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, our Sponsor, 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 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 Public Stockholders, 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 October 28, 2019 (the “Closing Date”), the Company and BiomX Ltd., an Israeli company (“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 (“SRS”), 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.

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 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.

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.

Risk Factors

There are a number of risks related to our business and our Common Stock that you should consider before making an investment decision. You should carefully consider all the information presented in the section entitled “*Risk Factors*” beginning on page 5 of this prospectus and the other information contained and incorporated by reference in this prospectus.

Presentation of Financial and Operating Data

The Business Combination was accounted for as a “reverse merger” in accordance with generally accepted accounting principles in the United States (“GAAP”). Under this method of accounting, the Company was treated as the “acquired” company for financial reporting purposes. This determination was primarily based on the assumption that BiomX’s shareholders are holding a majority of the voting power of the Company, BiomX’s operations comprise the ongoing operations of the Company, BiomX’s designees comprise a majority of the governing body of the Company, and BiomX’s senior management comprise the senior management of the Company. Accordingly, for accounting purposes, the Business Combination is treated as the equivalent of a capital transaction in which BiomX is issuing stock for the net assets of the Company. The post-acquisition financial statements of the Company are included in this prospectus and show the consolidated balances and transactions of the Company and BiomX as well as comparative financial information of BiomX (the acquirer for accounting purposes).

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 Telephone: (972) 72-394-2377. The website address is www.biomx.com. The information found on the website is not part of, and is not incorporated into, this prospectus.

THE OFFERING

We are registering (i) the resale by the Selling Securityholders of up to 15,741,829 shares of our Common Stock which may be issued upon the exercise of the Warrants and (ii) the resale from time to time by the Selling Securityholders of 2,900,000 Private Placement Warrants.

| | |
|--|--|
| Common Stock offered by the Selling Securityholders | We are registering 15,741,829 shares of Common Stock to be offered from time to time by the Selling Securityholders, which consists of: (i) 3,500,000 shares of Common Stock that may be issued upon the exercise of Public Warrants, (ii) 2,900,000 shares of Common Stock that may be issued upon the exercise of the Private Placement Warrants, (iii) 7,604,329 shares of Common Stock issued in a private placement in connection with the consummation of the Business Combination and (iv) 1,737,500 shares of Common Stock sold in one or more private placements prior to the IPO. |
| Private Placement Warrants offered by certain Selling Securityholders | We are registering 2,900,000 Private Placement Warrants to be offered from time to time by certain Selling Securityholders. Each Private Placement Warrant entitles the holder to purchase Common Stock at an exercise price of \$11.50 per share of Common Stock, subject to adjustment as set forth in the warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. |
| Terms of the offering | The Selling Securityholders will determine when and how they will dispose of the Common Stock and Warrants, registered under this prospectus for resale. For additional information concerning the offering, see "Plan of Distribution" beginning on page 104. |
| Risk factors | Before investing in our securities, you should carefully read and consider the information set forth in "Risk Factors" beginning on page 5. |
| Use of proceeds | We will not receive any of the proceeds from the sale of Offered Securities by the Selling Securityholders. However, we will receive proceeds of \$40,250,000 from the exercise of the Public Warrants if they are all exercised for cash at an exercise price of \$11.50 per share of Common Stock. If the Private Placement Warrants are no longer held by the initial purchasers or their affiliates, we will redeem such Private Placement Warrants and we will also receive proceeds of \$33,350,000 from the exercise of the Private Placement Warrants if they are all exercised for cash at an exercise price of \$11.50 per share of Common Stock. We intend to use any such proceeds for working capital and general corporate purposes. |
| Trading market and symbol | The Company's Common Stock and Warrants trade on the NYSE American under the symbols "PHGE" and "PHGE.W," respectively. |

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 our inception in 2015. As of September 30, 2019, our accumulated deficit was \$32.9 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 nine months ended September 30, 2019 and 2018, we had losses from operations of \$12.4 million and \$8.3 million, respectively. For the years ended December 31, 2018 and 2017, we had losses from operations of \$12.5 million and \$6.7 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 September 30, 2019, BiomX had cash, cash equivalents and short-term deposits of \$11.6 million and \$18.4 million respectively, and it has had recurring losses from operations and negative operating cash flows since inception in 2015. Additional cash amounting to approximately \$60 million was obtained from the Business Combination. 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 its 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 the 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;

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, we have devoted substantially all of our resources to developing product candidates with phage technology through our preclinical programs, building our intellectual property portfolio, developing our supply chain, planning our 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 *P. 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 5,000,000 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 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 2017, 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 2017, 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 Massachusetts Institute of Technology (“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 September 30, 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 September 30, 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 nine months ended September 30, 2019 and 2018, we recorded grants totaling \$299 thousand and \$646 thousand, from the IIA, respectively. The grants represented 3.4% and 9.6% of our gross research and development expenditures for the nine months ended September 30, 2019 and 2018, respectively. For the years ended December 31, 2018, 2017 and 2016, we recorded grants totaling \$0.6 million, \$0.7 million and \$0.3 million, from the IIA, respectively. The grants represented 6.6%, 13.6% and 20.8% of our gross research and development expenditures for the years ended December 31, 2018, 2017 and 2016, 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 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 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 20% of the outstanding Public Shares, our current directors, officers and affiliates own approximately 7% of the outstanding Public Shares, and our former stockholders own approximately 73% 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.

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 become exercisable on December 18, 2019, 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 prospectus, we had outstanding vested and unvested options to purchase 3,181,742 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 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.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The Company makes forward-looking statements in this registration statement, including in the statements incorporated herein by reference. Forward-looking statements provide our current expectations or forecasts of future events. 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 prospectus 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 prospectus 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 FDA’s 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 prospectus entitled “Risk Factors” beginning on page 5.

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 prospectus. Accordingly, you should not rely on these forward-looking statements, which speak only as of the date of this prospectus. We undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this prospectus 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 prospectus.

USE OF PROCEEDS

All of the shares of Common Stock offered by the Selling Securityholders pursuant to this prospectus will be sold by the Selling Securityholders for their respective accounts. We will not receive any of the proceeds from these sales. We will receive up to an aggregate of approximately \$40,250,000 from the exercise of Public Warrants, assuming the exercise in full of all of the Public Warrants for cash. If the Private Placement Warrants are no longer held by the initial purchasers or their affiliates, we will redeem such Private Placement Warrants and we will also receive proceeds of \$33,350,000 from the exercise of the Private Placement Warrants if they are all exercised for cash at an exercise price of \$11.50 per share of Common Stock. We expect to use the net proceeds from the exercise of the Warrants for general corporate purposes.

SELECTED HISTORICAL FINANCIAL INFORMATION

The following tables set forth selected historical financial information derived from the Company's audited consolidated financial statements as of December 31, 2018 and 2017 and for the three years in the period ended December 31, 2018, which are included elsewhere in this registration statement. The data below as of September 30, 2019 and 2018 and for the nine months ended September 30, 2019 and 2018, has been derived from the Company's unaudited consolidated financial statements for such periods, which are included in this registration statement. The Company has prepared the unaudited consolidated financial statements on the same basis as the audited consolidated financial statements and has included, in its opinion, all adjustments, consisting only of normal recurring adjustments considered necessary for a fair presentation of the financial information set forth in those statements. Historical results are not necessarily indicative of the results to be expected for future periods.

The information is only a summary and should be read in conjunction with our consolidated financial statements and related notes, and *Management's Discussion and Analysis of Financial Condition* contained elsewhere herein. The historical results included below and elsewhere in this prospectus are not indicative of the future performance of the Company.

| | Three months ended September 30, | | Nine months ended September 30, | |
|--|-------------------------------------|-------|------------------------------------|-------|
| | 2019 | 2018 | 2019 | 2018 |
| | USD In thousands | | | |
| Research and development expenses, net | 2,858 | 2,474 | 8,458 | 6,117 |
| Operating Loss | 4,655 | 3,251 | 12,445 | 8,329 |
| Net Loss | 4,260 | 3,205 | 11,263 | 8,583 |

Consolidated Balance Sheet Data

| | As of September 30, 2019 | As of December 31, | |
|-------------------------------|--------------------------------|--------------------|--------|
| | | 2018 | 2017 |
| | USD In thousands | | |
| Cash and cash equivalents | 11,570 | 8,604 | 6,898 |
| Total assets | 37,622 | 45,331 | 13,990 |
| Total current liabilities | 1,653 | 1,639 | 1,459 |
| Total non-current liabilities | 1,706 | 889 | 1,001 |
| Total liabilities | 3,359 | 2,528 | 2,460 |
| Total Shareholders' equity | 34,263 | 42,803 | 11,530 |

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 September 30, 2019, BiomX had received gross proceeds of approximately \$60.1 million from sales of its common and preferred shares. In addition, BiomX received approximately \$175 thousand from its collaboration agreements during 2018 and 2019 and recorded a reduction from research and development expenses of \$167 thousand during the nine months ended September 30, 2019.

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 \$12.7 million, \$6.4 million and \$1.9 million for the years ended December 31, 2018, 2017 and 2016, respectively. Our net losses were approximately \$11.3 million and \$8.6 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of \$32.9 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 following 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 September 30, 2019, we had cash and cash equivalents and short-term deposits of \$11.6 million and \$18.4 million respectively. In addition, BiomX also obtained approximately \$60 million from the Business Combination as of the Closing Date. 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 will show the consolidated balances and transactions of the Company and BiomX as well as comparative financial information of BiomX (the acquirer for accounting purposes).

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:

| | Nine Months Ended September 30, | | Year Ended December 31, | | |
|---|------------------------------------|----------|----------------------------|----------|----------|
| | 2019 | 2018 | 2018 | 2017 | 2016 |
| | (in thousands) | | | | |
| BX001 | \$ 882 | \$ 1,191 | \$ 1,708 | \$ 821 | \$ 745 |
| BX002 | 1,072 | 1,146 | 1,430 | 480 | — |
| BX003 | 1,035 | 207 | 436 | — | — |
| CRC | 314 | 52 | 175 | 17 | — |
| Salaries and related benefits | 4,186 | 2,901 | 4,595 | 2,817 | 675 |
| Depreciation | 259 | 144 | 210 | 95 | 27 |
| Infrastructure & other unallocated R&D expenses | 1,176 | 1,122 | 1,227 | 606 | 4 |
| Less grants from the IIA & Income from collaborations | (476) | (646) | (646) | (660) | (302) |
| Total research and development expenses | \$ 8,458 | \$ 6,117 | \$ 9,135 | \$ 4,176 | \$ 1,149 |

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, director and officer 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 nine-month periods ended September 30, 2019 and 2018:

The following table summarizes our consolidated results of operations for the nine months ended September 30, 2019 and 2018:

| | Nine months ended September 30, | |
|--|--|-----------------|
| | 2019 | 2018 |
| | In thousands | |
| Research and development expenses, net | \$ 8,458 | \$ 6,117 |
| General and administrative expenses | 3,987 | 2,212 |
| Operating Loss | 12,445 | 8,329 |
| Financial expenses (income), net | (1,182) | 254 |
| Loss for the Period | \$ 11,263 | \$ 8,583 |

Research and development expenses, net, were \$8.5 million for the nine months ended September 30, 2019, compared to \$6.1 million for the nine months ended September 30, 2018. The increase of \$2.4 million, or 39.3%, in the nine months ended September 30, 2019, compared to the prior period is primarily due to significant expansion of our BX003 and CRC programs as well as an increase of \$1.3 million in salaries and related expenses, as a result of us increasing research and development headcount significantly in 2019 to support our growth.

General and administrative expenses were \$4.0 million for the nine months ended September 30, 2019, compared to \$2.2 million for the nine months ended September 30, 2018. The increase of \$1.8 million, or 80.2%, in the nine months ended September 30, 2019, compared to the prior period primarily reflected an increase of \$0.9 million of reverse merger transaction expenses as well as \$0.2 million in personnel-related costs.

Comparison of the Years Ended December 31, 2018 and 2017

The following table summarizes our consolidated results of operations for the years ended December 30, 2018 and 2017:

| | Year ended December 31, | |
|--|------------------------------------|-----------------|
| | 2018 | 2017 |
| | In thousands | |
| Research and development expenses, net | \$ 9,135 | \$ 4,176 |
| General and administrative expenses | 3,360 | 2,536 |
| Operating Loss | 12,495 | 6,712 |
| Revaluation of convertible security | — | — |
| Financial expenses, net | 225 | (279) |
| Loss for the Year | \$ 12,720 | \$ 6,433 |

Research and development expenses were \$9.1 million for the year ended December 31, 2018, compared to \$4.2 million for the year ended December 31, 2017. The increase of \$4.9 million, or 119%, in the year ended December 31, 2018, compared to the prior year is primarily due to significant expansion of our BX002 and BX001 programs in 2018, and launch of our BX003 and CRC programs, as well as an increase of \$2.1 million in salaries and related expenses, as a result of us increasing research and development headcount significantly in 2018.

General and administrative expenses were \$3.4 million for the year ended December 31, 2018, compared to \$2.5 million for the year ended December 31, 2017. The increase of \$0.9 million, or 32.5%, primarily reflected an increase of \$0.5 million in personnel-related costs and an increase of \$0.1 million in facilities related costs. These increases were mainly due to the hiring of additional personnel in our general and administrative, operations and business development functions.

Comparison of the Years Ended December 31, 2017 and 2016

The following table summarizes our consolidated results of operations for the years ended December 31, 2017 and 2016:

| | Year ended December 31, | |
|--|------------------------------------|-----------------|
| | 2017 | 2016 |
| | In thousands | |
| Research and development expenses, net | \$ 4,176 | \$ 1,149 |
| General and administrative expenses | 2,536 | 620 |
| Operating Loss | 6,712 | 1,769 |
| Revaluation of convertible security | — | 133 |
| Financial expenses, net | (279) | (2) |
| Loss for the Year | \$ 6,433 | \$ 1,900 |

Research and development expenses were \$4.2 million for the year ended December 31, 2017, compared to \$1.1 million for the year ended December 31, 2016. The increase of \$3.1 million, or 263%, in the year ended December 31, 2017 compared to the prior year, is primarily due to launch of our BX002 program in 2017, and advancing and expanding our BX001 program, including manufacturing activities, as well as an increase of \$1.4 million in employee-related expenses and an increase of \$0.6 million in other unallocated discovery and platform-related expense.

General and administrative expenses were \$2.5 million for the year ended December 31, 2017, compared to \$0.6 million for the year ended December 31, 2016. The increase of \$1.9 million, or 309%, primarily reflected increases of \$0.6 million in personnel related costs, \$0.2 million for non-cash share-based payments, \$0.2 million in facilities related costs, \$0.2 million for recruitment expenses and \$0.3 million in professional fees. These increases were due to the hiring of additional personnel in our general and administrative, operation and business development functions, as well as the lease of office and lab space.

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. Through September 30, 2019, we had received gross cash proceeds of approximately \$60.1 million from sales of our common and preferred shares. In addition, we received approximately \$175 thousand from our collaboration agreements in 2018 and 2019, and recorded a reduction from research and development expenses of \$167 thousand during the nine-month period ended September 30, 2019.

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:

| | Nine Months Ended September 30, | | Year Ended December 31, | | |
|--|--|-----------------|------------------------------------|-----------------|-----------------|
| | 2019 | 2018 | 2018 | 2017 | 2016 |
| | (in thousands) | | | | |
| Net cash used in operating activities | \$ (10,503) | \$ (7,804) | \$ (11,304) | \$ (4,100) | \$ (1,336) |
| Net cash provided by (used in) investing activities | 11,631 | 938 | (30,038) | (2,116) | (98) |
| Net cash provided by financing activities | 1,843 | 13,000 | 43,042 | 12,953 | 1,200 |
| Net increase (decrease) in cash and cash equivalents | \$ 2,971 | \$ 6,134 | \$ 1,700 | \$ 6,737 | \$ (234) |

Net cash used in operating activities for the nine months ended September 30, 2019 included our net loss of \$11.3 million, net cash provided by changes in our operating assets and liabilities of \$0.4 million and non-cash charges of \$1.2 million, which included share-based compensation expenses of \$0.9 million and depreciation of \$0.3 million. Net changes in our operating assets and liabilities for the nine months ended September 30, 2019 consisted primarily of a \$0.1 million decrease in trade account payables, a \$0.15 million decrease in related party transactions and a \$0.2 million decrease in other account payables.

Net cash used in operating activities for the nine months ended September 30, 2018 included our net loss of \$8.6 million, net cash used by changes in our operating assets and liabilities of \$0.1 million and non-cash charges of \$0.8 million, which included share-based compensation expenses of \$0.7 million and depreciation of \$0.1 million. Net changes in our operating assets and liabilities for the nine months ended September 30, 2018 consisted primarily of a \$0.4 million increase in other account payables, a \$0.2 million decrease in trade account payables and a \$0.1 million decrease in other receivables.

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 \$1.2 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.

Net cash used in operating activities for the year ended December 31, 2017 included our net loss of \$6.4 million, net cash used by changes in our operating assets and liabilities of \$0.9 million and non-cash charges of \$1.4 million, which included share-based compensation expenses of \$1.3 million and depreciation of \$0.1 million. Net changes in our operating assets and liabilities for the year ended December 31, 2017 consisted primarily of an increase in other account payables of \$0.8 million, mainly due to increase in payables to employees and related institutions, and an increase in trade account payables of \$0.4 million, mainly due to the increase in our activity and expenses, offset by an increase of \$0.2 million in other receivables.

Net cash used in operating activities for the year ended December 31, 2016 included our net loss of \$1.9 million, net cash provided by changes in our operating assets and liabilities of \$0.2 million and net non-cash charges of \$0.3 million, which included share-based compensation expenses of \$0.2 million and a non-cash revaluation of convertible security income of \$0.1 million. Net changes in our operating assets and liabilities for the year ended December 31, 2016 consisted primarily of an increase of \$0.1 million in other account payables and a decrease of \$0.1 million in other receivables.

Investing Activities

During the nine months ended September 30, 2019, net cash provided by investing activities was \$11.6 million, mainly as a result of a decrease in short-term deposits of \$12.6 million offset by purchases of property and equipment of \$1 million, which consisted primarily of laboratory and office equipment.

During the nine months ended September 30, 2018, net cash used by investing activities was \$0.9 million, mainly as a result of an investment in short-term deposits of \$1.1 million and purchases of property and equipment of \$0.1 million, which consisted primarily of laboratory and office equipment.

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.

During the year ended December 31, 2017, net cash used by investing activities was \$2.1 million, mainly as a result of investment in short-term deposits of \$1.2 million and purchases of property and equipment of \$0.9 million, which consisted primarily of laboratory and office equipment and leasehold improvements.

During the year ended December 31, 2016, net cash used by investing activities was \$0.1 million for purchases of property and equipment consisting primarily of laboratory equipment.

Financing Activities

During the nine months ended September 30, 2019, net cash provided by financing activities was \$1.8 million, consisting of net proceeds from the sale of our Series B preferred shares in January 2019.

During the nine months ended September 30, 2018, net cash provided by financing activities was \$13.0 million, consisting of net proceeds from the sale of our Series A preferred shares in February 2018.

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.

During the year ended December 31, 2017, net cash provided by financing activities was \$12.9 million, consisting of net proceeds from the sale of our Series A preferred shares in February 2017 and December 2017.

During the year ended December 31, 2016, net cash provided by financing activities was \$1.2 million, consisting of issuances of convertible securities.

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;
- expands BiomX's infrastructure and facilities to accommodate its growing employee base, including adding equipment and physical infrastructure to support its research and development; and
- operates as a subsidiary of a public company.

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.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of September 30, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

| | Payments Due by Period | | | | |
|---|------------------------|---------------------|-----------------|-----------------|----------------------|
| | Total | Less than 1 Year | 1 to 3 Years | 4 to 5 Years | More than 5 Years |
| | (in thousands) | | | | |
| Operating and related lease commitments | \$ 1,398 | \$ 270 | \$ 806 | \$ 322 | \$ - |
| License fee commitments | \$ 3,885 | \$ 115 | \$ 360 | \$ 400 | \$ 3,010 |
| Consultancy fee commitments | \$ 179 | \$ 150 | \$ 29 | - | - |
| Total | \$ 5,462 | \$ 535 | \$ 1,195 | \$ 722 | \$ 3,010 |

In addition, pursuant to our research and license agreements, we are required to make certain milestone and royalty payments to our licensors and collaborators. See “— License Agreements” and Financial Statements — Note 7 — Commitments and Contingent Liabilities for additional details regarding our payment obligations to these licensors.

Pursuant to the Share Purchase Agreement of RondinX, dated November 19, 2017 (the “RondinX SPA”), BiomX is required to issue its shares and/or cash, and/or the combination of cash and shares to the former shareholders of RondinX who are party to the RondinX SPA, upon the occurrence of certain milestones.

BiomX received grants from the IIA. According to the terms of such grants, BiomX will pay royalties of 3% to 3.5% of future sales up to the accumulated grant received including annual interest of LIBOR linked to the U.S. Dollar, provided however, that it shall not be obligated to repay such grants if no sales were generated. As of September 30, 2019, no sales were generated. BiomX may be obligated to pay additional royalties upon the occurrence of certain events as determined by the IIA that are within the control of BiomX.

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.

Quantitative and Qualitative Disclosures about Market Risks

Interest Rate Risk

As of September 30, 2019, we have cash and cash equivalents, restricted cash and short term bank deposits of \$11.6 million, \$0.1 million and \$18.4 million respectively.

Foreign Currency Exchange Risk

We are exposed to foreign exchange rate risk. Our headquarters are located in Israel, where the majority of our general and administrative expenses and research and development costs are incurred in Israeli new shekels. During each of the years ended December 31, 2018, 2017 and 2016, and each of the nine-month periods ended September 30, 2019 and 2018, our recognized foreign currency transaction income (loss) were \$(0.3), \$0.3, \$0.8, \$0.5 and \$(0.3) million, respectively. Our functional currency is the U.S. Dollar. These foreign currency transaction gains and losses were recorded in financial expenses, net in its consolidated statements of comprehensive loss. We believe that a 10% change in the exchange rate between the U.S. Dollar and Israeli new shekel would not have a material impact on our financial position or results of operations.

As we continue to grow our business, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk.

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.

BUSINESS

Overview of 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 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.

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 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 *Propionibacterium acnes* or *P. acnes* on the skin. *P. 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. BiomX is also examining exploratory endpoints of reduction of *P. acnes* and effects on the skin microbiome. BiomX expects results from this trial 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, 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, in 2017, BiomX gained access to high throughput genomic analyses techniques developed by 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 September 30, 2019, BiomX had an accumulated deficit of \$32.9 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 development stage, 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.
- Identify new targets for the indications BiomX is pursuing by expanding its internal database of clinical microbiome samples and its bioinformatics capabilities.
- 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.



The microbiome and human disease

The microbiome refers to the collection of microorganisms, including phage, that reside on the skin, line the gastrointestinal tract, and reside elsewhere in the body. The vast majority of these microorganisms are not pathogenic and instead exist in a symbiotic state, enabling the body to function normally by protecting against proliferation of pathogenic strains, educating the immune system and assisting in digestion. Imbalances in the composition of the microbiome have been found in multiple diseases. Many therapeutic and non-therapeutic approaches are designed to restore this balance. In some cases, these approaches involve supplementation with beneficial strains of bacteria. In others, treatments are being developed based on substances that are intended to shift the composition of the microbiome by restricting the growth of some microorganisms or promoting the growth of others or both.

Skin conditions including acne, changes such as hormonal changes, increased secretion of oil from sebaceous glands, or changes in the immune system result in imbalances in the skin microbiome. Changes in microbiome composition also have been linked to multiple diseases, including IBD; PSC; CRC; autoimmune diseases such as diabetes; nervous system diseases, such as autism and multiple sclerosis; and cardiovascular disease. While the importance of the microbiome in initiating or exacerbating some of these diseases has not been firmly established, there are a number of diseases in which inducing changes in microbiome composition has been observed to be associated with reductions in disease symptoms.

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

History of uses of phage

Bacteriophage or phage are viruses that infect bacteria. They were discovered in 1915 and used widely to treat infections in the early 1900s, a decade before antibiotics were discovered. Descriptions of the use of phage therapy in thousands of individuals, mostly in the former Soviet Union and Eastern Europe, have been published, but the effectiveness and safety of these therapies have not been definitively determined due, in part, to the lack of rigorously controlled clinical trials.

These early uses of phage were limited by the state of translational and clinical development at that time. Bacterial resistance quickly emerged to early phage therapies because of the limited ability to formulate effective cocktails. In turn, this limitation was due to a lack of know-how, such as the lack of a deep understanding of phage genomic composition. At the time, there were no known methods to control phage that had the propensity to infect bacteria without causing immediate lysis, a process now known as lysogeny. There were also technical hurdles to manufacturing phage of sufficient purity and stability to assure consistent results when put to therapeutic use. A consistent theme from these early trials, more recent, well-controlled trials, and cases of compassionate use is that phage therapy is generally well-tolerated, with a general lack of reports of serious adverse events. Phage have already been approved as both agricultural bacterial pest treatments by the USDA, as well as for use in cleaning food facilities and as a food additive for human consumption by the FDA and EMA. Phage have been approved in the past in food or food contact surface categories, and in these categories have met the criteria to be considered as “generally recognized as safe” (“GRAS”).

With the advent of antibiotics, the high selectivity of phage was seen as a disadvantage, especially for the empiric treatment of acute infections where the causative pathogen has not yet been identified. With the current understanding of the limitations and potential undesired effects of antibiotics, and with the advent of modern molecular biology tools, high throughput genomic sequencing and computational capabilities, BiomX seeks to convert endogenous properties of phage into product candidates that confer potential advantages and use genetic and process engineering to overcome historical hurdles, opening up a new era in the development of phage.

BX001 for the improvement of skin appearance

BX001 is BiomX’s topically administered product candidate intended to improve the appearance of oily and acne-prone skin. It contains a cocktail of phage that helps balance the skin microbiome by targeting *Propionibacterium acnes* (“*P. acnes*”), a bacteria associated with acne. BiomX has observed that BX001 is effective on more than 96 percent of clinical bacterial isolates tested *in vitro*, including variants that are resistant to antibiotics. In October 2019, BiomX has initiated clinical testing in a study enrolling 75 individuals with acne. The endpoint of both studies is safety and tolerability of BX001. Exploratory endpoints to evaluate the effect of BX001 on *P. acnes*, overall skin microflora and on skin appearance will also be assessed. BiomX anticipates data from these trials to be available in the first quarter of 2020.

Background

BiomX believes that potential users of BX001 include individuals with oily skin, or those with skin conditions. One such condition is acne. Acne is one of the most common skin conditions in the world and is a chronic inflammatory condition characterized by the clogging of skin pores and associated local skin lesions. Acne lesions are believed to result from an interaction of multiple pathogenic factors, all of which can be associated with dysregulation of the skin microbiome resulting in the overgrowth of certain bacteria, in particular strains of *P. acnes*. Excessive proliferation of *P. acnes* along with excessive production of oily secretions and clogging, leads to inflammation of skin structures known as the pilosebaceous units that consist of a hair shaft, hair follicle, sebaceous gland, and pili muscle as shown below.

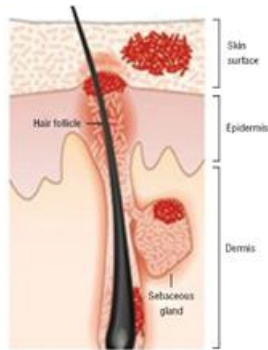


Figure 1. Structure of the pilosebaceous unit.

P. acnes induces inflammation through a number of mechanisms:

- Secretion of enzymes that degrade lipids in the hair follicle;
- Expression of surface proteins and secretion of lipid metabolites that promote inflammation;
- Expression of heat shock proteins that promote the innate immune system;
- Production of porphyrins that contribute to tissue damage and inflammation;
- Induction of T helper cells, stimulating the production of IL-17 and other inflammatory cytokines; and
- Formation of biofilms which increases bacterial adherence and contribute to antimicrobial resistance.

According to market studies, acne is estimated to affect 9.4 percent of the global population, making it the eighth most prevalent disease worldwide. There are an estimated 50 million people in the United States who suffer from acne each year, 85 percent of whom are between the ages of 12 to 24 years.

Depending on the regulatory framework in its jurisdiction, cosmetic or personal care products may be available to improve the appearance of blemishes and skin. In recent years, new cosmetic and personal care products are being introduced that contain skin microbiome modifying agents, such as probiotics or live organisms, that help promote the balance of the microbiome on, and thus the appearance of, the skin.

BX001 for acne prone skin

BX001 is a topically administered gel, containing natural phage, intended to improve the appearance of skin by helping to control *P. acnes* overgrowth and thus modulating the skin microbiome. Each of the natural bacteriophage in the formulation is strictly lytic in nature, has been isolated and purified from the environment and thoroughly characterized. BX001 has been shown to be active on antibiotic resistant *P. acnes* strains and does not target other bacteria on the skin. Furthermore, it has been observed to penetrate biofilms, a matrix secreted by the bacteria which surrounds them and makes them less accessible to substances such as antibiotics. Biofilms exist in the pilosebaceous unit, where undesirable bacteria such as *P. acnes* are found. These natural bacteriophage have been observed to be well-tolerated using accepted methods in internationally recognized models of human skin.

Development plan

In October 2019, BiomX has initiated clinical testing of BX001 consisting of a multiple application study in individuals with acne.

The study is a four-week randomized, double-blind, dose-finding, placebo controlled single center trial in which BiomX enrolled 75 individuals with mild to moderate acne. These individuals were divided into three cohorts: a placebo cohort and two cohorts with BX001, each receiving a different amount of phage. The primary endpoints were safety and tolerability and the exploratory endpoints examined the reduction in *P. acnes* levels and changes in the skin microbiome. BiomX anticipates data from these trials to be available in the first quarter of 2020.

If BiomX observes promising results from its initial clinical testing, BiomX intends to conduct an eight-week placebo-controlled clinical test of BX001 in which BiomX expects to enroll 100 patients divided into a placebo cohort and a cohort with BX001. The primary endpoints are safety and efficacy, as measured by parameters related to changes in the skin microbiome. BiomX expects to initiate this clinical test in the second quarter of 2020, with results available by the end of 2020.

Preclinical data

BiomX conducted preclinical studies on *in vitro* and *ex vivo* systems. First, BiomX assembled a panel of *P. acnes* bacterial isolates that BiomX used to screen a library of phage isolates obtained from clinical and environmental sources. Using this method, tens of phages that could inhibit the growth of strains of *P. acnes* in BiomX's panel were identified. BiomX made two important observations in these initial screens. First, although all the tested bacterial strains were variants of *P. acnes*, there was sufficient variation among them to prevent any individual phage from having equal potency against all the bacterial strains. Second, there was sufficient variation among naturally occurring phage such that there was at least one phage with high potency against each strain of bacteria. The table below shows relevant data.

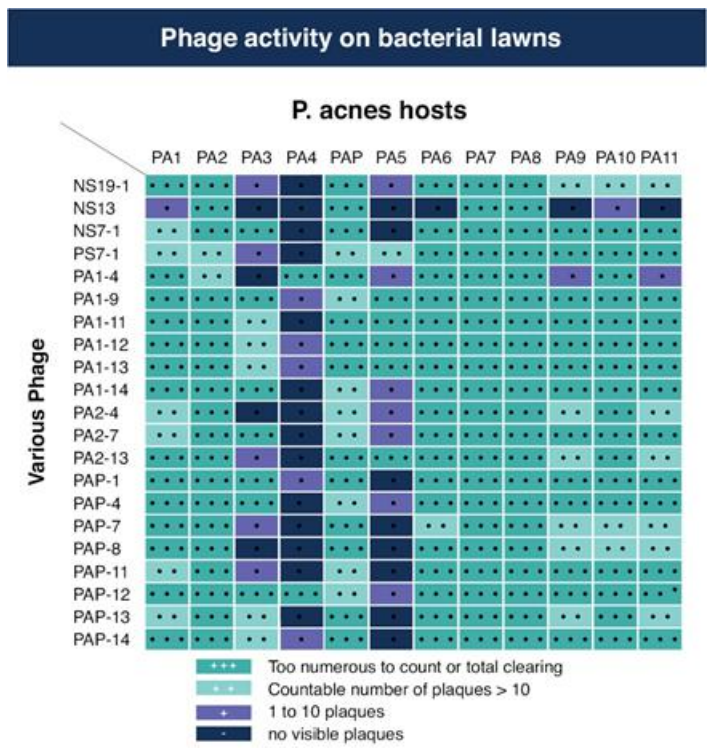


Figure 2. Example of data from screening of a library of phage against a panel of *P. acnes* strains measuring the level of sensitivity to exposure to phage.

Together these results suggest that a phage product with the potential for broad efficacy would require the use of more than one phage and that a limited number of phage may be sufficient to address the variation in *P. acnes* sensitivity. BiomX incorporated three different phage into BiomX's BX001 topical product candidate after extensive qualification of individual phage for factors including potency across different *P. acnes* strains, ability to penetrate biofilm, manufacturability and stability. In addition, BiomX assessed the ability of these phage to function in combination without interfering with each other. The combination of phage BiomX chose was found to exhibit activity across an independent panel of clinical isolates of *P. acnes*. In extended *in vitro* assays, treatment with BX001 was associated with the complete eradication of one *P. acnes* strain with no appearance of resistant mutant strains. Following exposure of an additional *P. acnes* strain *in vitro*, initial eradication was followed by the appearance only of growth compromised resistant strains with very low growth potential.

BX001 eradicates *P. acnes* (no mutants arising)

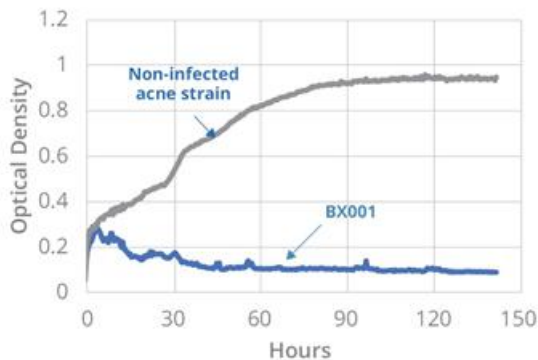


Figure 3. BX001 was associated with eradication of *P. acnes* and no resistant strains emerged on the target strain PA1. The figure shows the growth of *P. acnes* bacteria, as measured by optical density or OD, in a liquid *in vitro* culture with and without addition of the BX001 cocktail. Without BX001, the number of bacteria increases with time (higher OD density) while, in the presence of BX001, initial growth is observed followed by immediate killing and then no recovery of growth for the length of the study.

A critical challenge for any microbiome balancing product is the need to penetrate biofilms. BiomX has observed that *P. acnes* phage are able to penetrate the biofilm secreted by *P. acnes*. In *in vitro* experiments, phage reduced the number of viable bacteria within biofilm by 100,000 fold within 24 hours resulting in undetectable levels after 48 hours. Under the same conditions, erythromycin, a common antibiotic, reduced bacterial levels by approximately 100 fold after 48 hours.

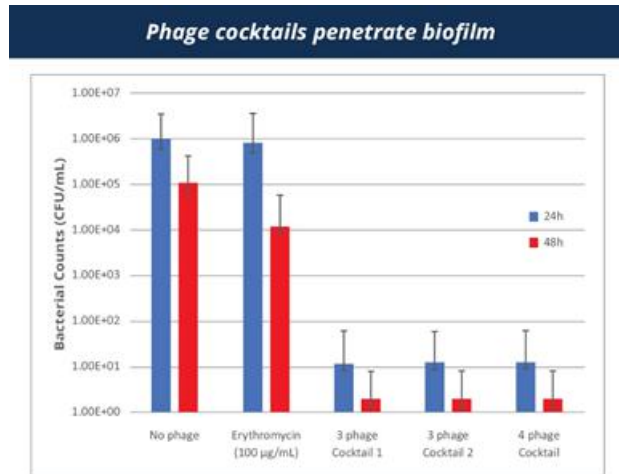


Figure 4. Phage show potent antibacterial activity even in the presence of biofilms.

BX001 showed microbiome balancing activity when exposed to clinical isolates of *P. acnes* strains showing that 96 percent of these strains were highly sensitive, including strains that were resistant to antibiotics. BiomX then tested the ability of BX001 to inhibit proliferation of *P. acnes* in an *ex vivo* model of artificial human skin infected with the bacteria. In this model, applying BX001 gel topically resulted in significant reduction of bacterial counts following one application and the complete elimination of *P. acnes* following two applications.

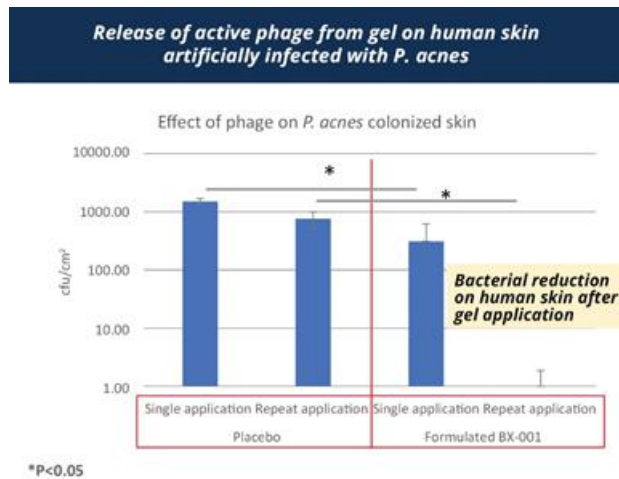


Figure 5. BX001 was effective in reducing the level of *P. acnes* colonized on human skin.

The safety of BX001 has been evaluated using OECD-recognized models of irritation, currently used in the cosmetics and pharmaceutical industry for topical products. In the EpiDerm™ model of human skin and the EpiOcular™ eye irritation test, no irritation occurred even when BX001 was applied at very high concentration, or approximately 100-fold the maximal planned dose, suggesting that BX001 is not likely to be an irritant to the skin or eyes. The studies were carried out under strict Good Laboratory Practice (“GLP”) procedures. A GLP permeation study using human skin tissue showed a very low amount of phage, 0.0039% of the total amount applied, apparently penetrated the skin. An additional study with a synthetic membrane accepted in the industry as representative of human epidermis, showed no permeation through this layer.

BX002 for the treatment of IBD

BX002 is a therapeutic phage cocktail product candidate BiomX is developing for the treatment of IBD, a disease that is strongly linked to specific alterations in the microbiome. In BiomX's BMX-IBD-006 study, BX002 led to sustained reductions in levels of pathogenic target bacteria in mouse models. BiomX plans to conduct a pre-IND meeting with the FDA and anticipate filing an IND for BX002 in 2020. Following initiation of a Phase 1 clinical trial of BX002, BiomX expects to receive results in the second half of 2020. If BiomX observes promising results from Phase 1 clinical testing, BiomX plans to initiate a Phase 2 clinical trial of BX002 in the first half of 2021, with interim results from this trial expected in the second half of 2021.

IBD disease background

IBD is a group of chronic autoimmune and inflammatory conditions of the colon and small intestine, which is characterized by abdominal pain, diarrhea, weight loss, fatigue and anemia. Ulcerative colitis ("UC") and Crohn's disease ("CD") are the principal sub-types of IBD. Both UC and CD can have periods of varying intensity ranging from severe inflammation or flares causing patients to be symptomatic, to periods of remission where patients are free of most symptoms. According to a report by the Crohn's and Colitis Foundation, IBD affects as many as 1.6 million people in the United States, most of whom are diagnosed before the age of 30.

Current treatment of IBD consists mainly of immunosuppressive therapies. Treatment options depend on the patient's disease severity and responsiveness to therapy. Medications that treat mild to moderate IBD are generally well tolerated. However, as the severity of IBD increases, the potential toxicities of the medications required to manage the disease also increase. For example, treatment of mild-to-moderate patients typically starts with topical agents, such as 5-aminosalicylic acid ("5-ASA"). For those IBD patients who do not respond to 5-ASAs, or those with more severe disease, corticosteroids are generally used to induce clinical remission. However, studies report that sustained remissions are only obtained by approximately 40% of patients receiving corticosteroids. Long-term treatment with corticosteroids is associated with multiple adverse effects. Patients with moderately to severely active IBD who become nonresponsive or intolerant to corticosteroids are treated with either biologics such as anti-TNF antibodies or small molecule immunomodulators such as 6-mercaptopurine or azathioprine. Immunomodulators generally show a delay in onset of action of one to three months, and can result in neutropenia, pancreatitis, nephrotoxicity and hepatotoxicity. The treatment of IBD patients with moderately to severely active inflammation is dominated by anti-TNF biologics given their improved efficacy and side effect profile relative to immunomodulators.

The microbiome's role in IBD

Conventional medical wisdom defines IBD as purely an inflammatory disease. However, similar to other indications such as gastric ulcers where both a bacterial cause and an anti-bacterial solution were found, scientific attention is turning to infection of the gut or dysfunction in gut bacteria as potential causes for IBD. The hypothesis that IBD was a result of a gastrointestinal infection started in the early 20th century, when IBD patients were sometimes treated with early anti-infective compounds such as potassium permanganate. After the discovery of antibiotics, broad antibacterial therapies were used until further studies identified IBD as an inflammatory disease. The hypothesis that the development of IBD was related to changes in the gut microbiome, however, continued. A recent development in the treatment of IBD and related disorders is the use of therapies directed against the gastrointestinal microbiome, such as fecal transplants, which induce a significant increase in remission in UC. While the effectiveness of fecal transplants may be variable, in one trial published in the *Journal of the American Medical Association* in 2019, 32 percent of patients receiving pooled fecal transplants from healthy individuals were in steroid-free remission three months post-treatment compared to 9 percent of controls who received autologous fecal transplants. Over 40 percent of the initial pooled transplant responders were still in steroid-free remission after twelve months. BiomX believes these results support the hypothesis that targeting the microbiome can result in therapeutic benefit in patients with IBD while highlighting the opportunity to develop improved microbiome-directed therapies.

Recent studies have identified specific strains as potential pathogenic organisms leading to IBD. Among them, specific strains of *Klebsiella* bacteria stand out. Elevated levels of *Klebsiella* are associated with IBD in microbiome samples from patients compared to healthy controls. In an analysis of two cohorts of IBD patient registries, one from Massachusetts General Hospital (“MGH”), Prospective Registry in IBD Study at MGH (“PRISM”) and the other from the University of Pennsylvania (“UPenn”), prospective cohort of pediatric CD patients, the aggregated relative abundance of *Klebsiella* strains was significantly higher in patients with IBD than healthy controls as shown in the table below.

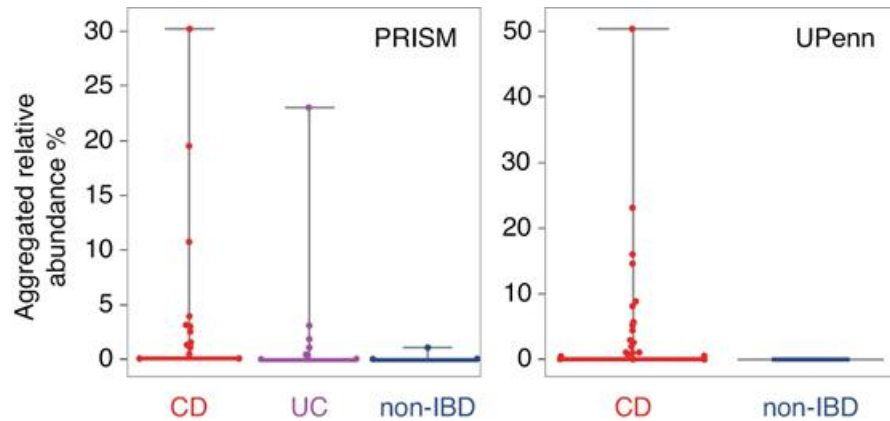


Figure 6. The relative abundance of strains of *Klebsiella* were shown to be elevated in the microbiome of patients with either CD or UC compared to patients without IBD.

Since the early 1990s, researchers have been reporting elevated levels of antibodies to *Klebsiella* in IBD patients. Furthermore, patients with IBD have levels of circulating Immunoglobulin G (“IgG”) antibodies against *K. pneumoniae* that are significantly higher than those found in healthy controls. Pointing the finger even more strongly at *K. pneumoniae* as a potential causative factor in IBD, similar analyses have failed to identify significant differences in IgG antibody levels between healthy controls and IBD patients for other bacterial strains commonly found in the gastrointestinal tract, including *E. coli*, *E. faecalis* and *B. fragilis*.

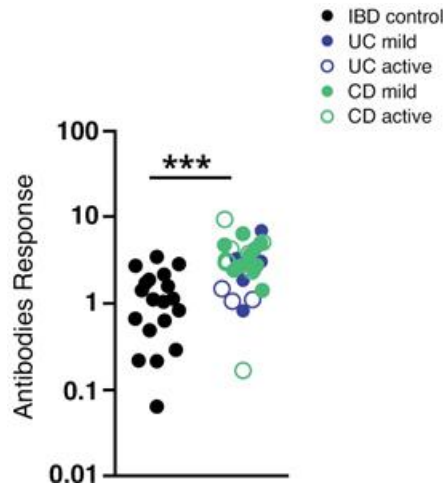


Figure 7. Increased titers of high affinity anti-microbiota antibodies that bind to Klebsiella have been detected in patients with IBD.

In a study published in the journal *Science* in 2017, germ-free mice inoculated with bacteria from a patient with CD had approximately three-fold higher levels of Th1 immune response as measured by an elevated population of CD4 T-cells producing interferon gamma. Imbalances of T cell subsets including Th1 in the intestinal mucosa are hallmarks of IBD. Other experiments reported in this publication identified a particular strain of *K. pneumoniae* as a key pathogenic bacteria in these patient samples.

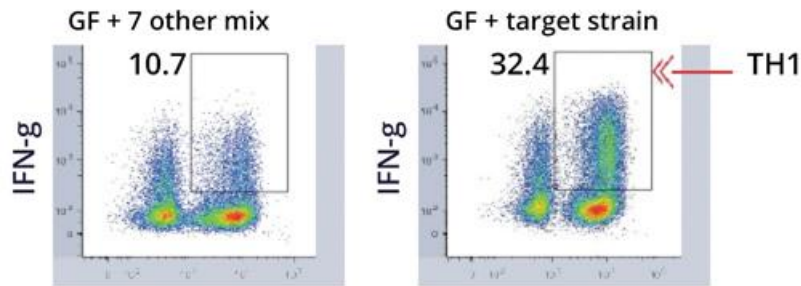


Figure 8. Microbiome samples from IBD patients with either a 7 bacteria mix (left) or only the single *K. pneumoniae* strain causing TH1 cell proliferation in germ free mice.

K. pneumoniae is a species of bacteria that colonizes the mucosal layer of the gastrointestinal system in mammals and may be pathogenic. There are multiple variants of *K. pneumoniae* with some estimates of up to 82 types that can be distinguished by their surface antigens. Different characteristics of *K. pneumoniae* may be associated with their pathogenic potential. These include surface antigens and virulence factors, factors that enhance bacterial strains' ability to survive and thrive, due to their role in allowing the bacteria to escape destruction by the immune system, or the ability to secrete a genotoxic molecule, such as colibactin, upon colonization of the gastrointestinal tract.

BX002, BiomX's IBD solution

BiomX is developing BX002, a cocktail of phage that target specific strains of *K. pneumoniae* that were observed to induce a Th1 response in animal models, as a means of directly and specifically altering the gut microbiome in patients with IBD. BiomX believes that reducing the levels of these pathogenic bacteria may lower the levels of inflammatory signals that propagate the disease.

As part of BiomX's evidence supporting the link between *K. pneumoniae* and IBD BiomX analyzed microbiome samples from approximately 250 patients with IBD across multiple geographies. BiomX found that the prevalence of the specific pathogenic *K. pneumoniae* was approximately 30 percent in IBD patients across three different geographies. In a subset of French patients for which clinical metadata was available, higher abundance of the pathogenic *K. pneumoniae* was found in IBD patients in flare versus remission. BiomX corroborated the results shown in the *Science* paper from 2017 by assessing the ability of specific *K. pneumoniae* strains to cause gastrointestinal inflammation by transplanting germ-free mice with strains of *K. pneumoniae* isolated from IBD patients. Mice receiving these strains of bacteria had statistically significant higher levels of IFN-gamma expressing CD4 expressing Th1 cells than those receiving placebo.

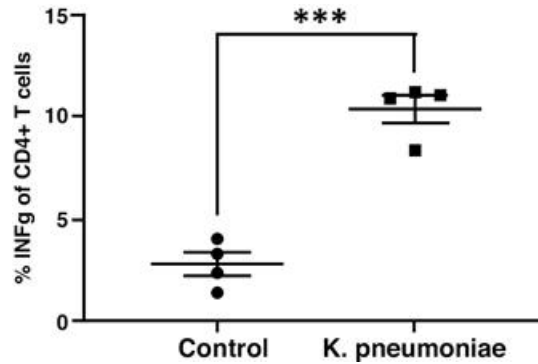


Figure 9. A *K. pneumoniae* strain displaying induced IFN-gamma producing T cells. *P<0.001**

BiomX screened a broad library of phage sources derived from environmental and clinical samples for phage capable of targeting patient-derived strains of *K. pneumoniae* that are related to the strain shown to induce a pro-inflammatory response in the germ-free animal model. BiomX examined the potency of each phage that was isolated on all clinical bacterial isolates and also ranked the lead candidate phage from these screens based on stability, manufacturability and lack of potential safety concerns. BiomX then further characterized combinations of these phage for their lack of interference while prioritizing diversity. BiomX observed that when used in animal models, combinations of phage were associated with the rapid reduction of the bacterial load of the pathogenic *K. pneumoniae* strains, though, in some cases, resistant strains emerge after several days. Combining phage that recognize the bacteria by different mechanisms of action is designed to impair this development of resistance, resulting in sustained reductions in the level of bacteria which fall below the level of detection after three doses of BX002. Bacteria are eliminated both from the fecal material and from the mucosal lining where they usually reside.

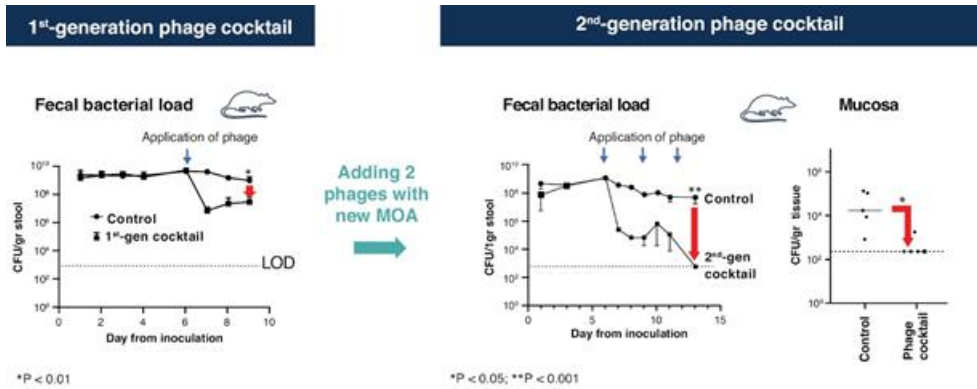


Figure 10. Combinations of phage were associated with sustained antibacterial activity in mouse models. BX003 for the treatment of PSC

BX003 is a phage cocktail that BiomX is developing for the treatment of PSC. A majority of PSC patients also suffer from IBD and it has been found that the development of PSC is associated with a subset of strains of *K. pneumoniae*. BiomX has identified phage that target these strains and anticipate holding a pre-IND meeting with the FDA in the first half of 2020, with an anticipated IND filing for BX003 in 2021. Following initiation of a Phase 1/2 clinical trial of BX003, BiomX expects to receive interim results in 2021. BiomX anticipates initiating clinical-scale manufacturing for BX003 in the second half of 2020.

PSC background

PSC is a rare progressive liver disorder affecting approximately 30,000 patients in the United States according to published studies. PSC is characterized by inflammation and fibrosis within the bile ducts, which transport bile within the liver and from the liver to the intestines. This fibrosis often results in the obstruction or interruption of bile flow from the liver, a condition known as cholestasis. Symptoms associated with PSC include fatigue and itching, or pruritus, followed by jaundice, characterized by yellowing of the skin, mucous membranes, and whites of the eyes. In some cases, the liver may also become abnormally enlarged. Scarring of the liver, or cirrhosis, eventually develops and many individuals will ultimately require a liver transplant. PSC patients suffer from increased risk of cancer in the bile ducts and colon. Over 70 percent of individuals with PSC also have UC, a form of IBD.

Without a liver transplant, patients with PSC have a median survival after diagnosis of nine to eighteen years. There is currently no FDA-approved treatment. A number of immunosuppressive and anti-inflammatory agents have been studied in patients with PSC, but none has been conclusively proven to alter the natural history of this disorder. Liver transplantation is the treatment of choice for PSC patients with advanced liver disease with forty percent of PSC patients eventually receiving a transplant. Between 1988 and 2015, six percent of all liver transplantations in the United States were due to PSC, a number BiomX believes to be remarkable given the rarity of this disease. However, in up to twenty percent of patients, even a liver transplant is not curative and PSC reoccurs.

Role of the microbiome in PSC

The strong linkage between the microbiome and IBD and the overlap in patients with both PSC and IBD suggest that the microbiome may also influence the development of PSC, especially given that most of the blood leaving the intestine flows immediately to the liver. Compromises in the intestinal barrier caused by alterations in the microbiome may expose the liver to altered levels of toxins, metabolites, and bacteria, which in turn may trigger aberrant bile duct responses.

The gut-liver axis in the pathogenesis of PSC

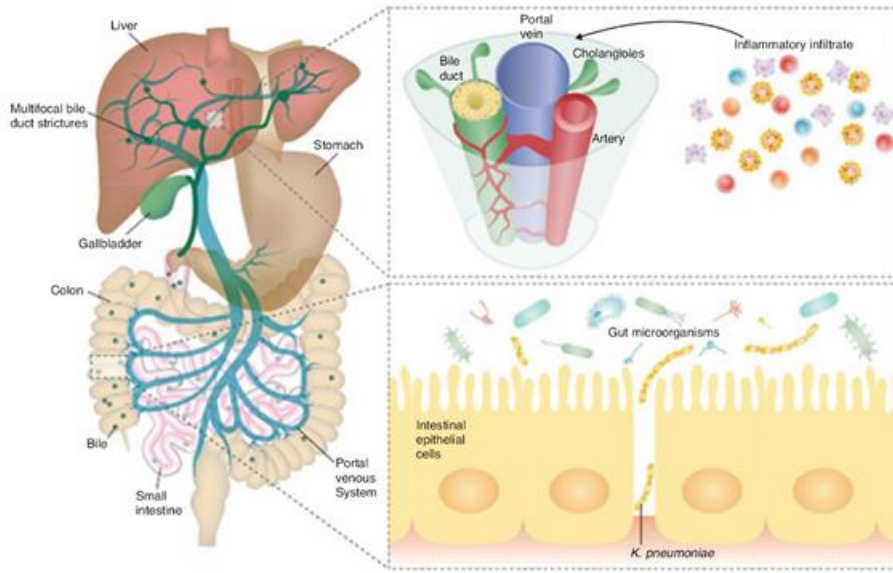


Figure 11. Schematic representation the gut-liver axis in the pathogenesis of PSC. Left, PSC is a chronic inflammatory and progressive liver disease, which primarily affects large- and medium-sized bile ducts with strictures and dilatations (bile ducts shown in green) due to inflammatory cells invading the portal system (top right). Pore-forming *K. pneumoniae* increase gut permeability (bottom right) and trigger an inflammatory response in the liver.

Additional evidence to support the role of the microbiome comes from experiments done in germ-free mice. These mice were transplanted with three groups of human fecal samples: from healthy controls; from PSC patients who also had UC; and from patients who had UC without having PSC. Mice transplanted with samples from PSC+UC patients had significant increases in the number of IL17 expressing CD4 T cells in the liver. Fecal samples from UC patients or healthy controls failed to induce Th17 response in the liver.

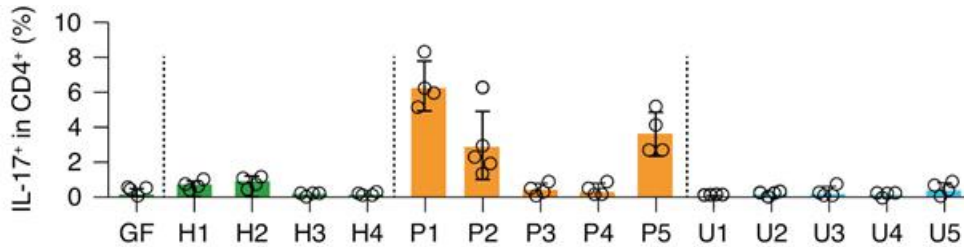


Figure 12. Fecal samples from PSC patients (P), but not healthy controls (H) or UC patients without PSC (U), transplanted into mice increased the number of IL-17-expressing CD4 cells.

Specific strains of *K. pneumoniae* were identified and cultured from the mesenteric lymph-nodes of the colonized mice, confirming their capability to migrate through the epithelial wall of the gut, resulting in gut barrier dysfunction. Further analysis of human PSC fecal samples showed that strains of *K. pneumoniae* were enriched in samples from PSC patients. These results indicated that *K. pneumoniae* may be a pathogen in the development of PSC.

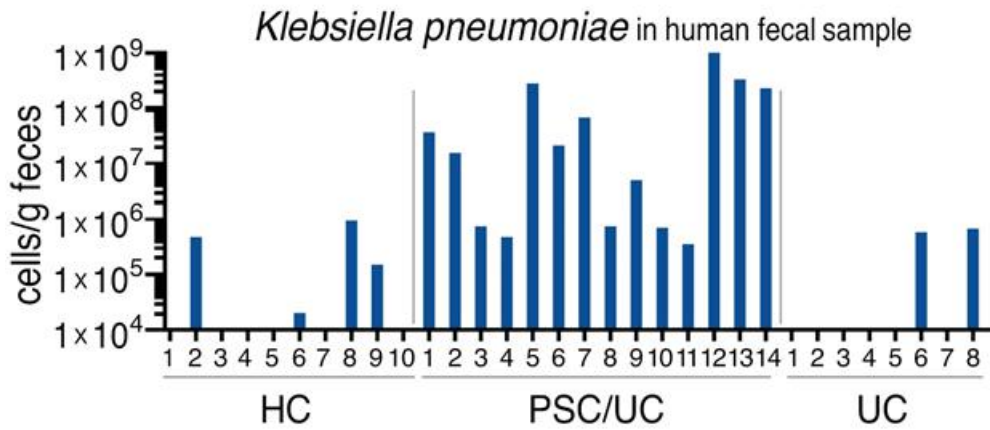


Figure 13. *K. pneumoniae* was found to be enriched in fecal samples from PSC patients.

In the same study, using a human primary intestinal organoid culture system, *K. pneumoniae* administered on the apical epithelial surface induced the formation of pores through the monolayer culture. These pores were only formed by strains of *K. pneumoniae* isolated from PSC patients. Similar pores were shown to be responsible for the breakdown of the epithelial barrier in animal models and were linked to activation of Th17 cells.

BX003, BiomX's PSC solution

BiomX has analyzed over 200 human fecal samples from patients with PSC across multiple geographies, as well as healthy controls and patients with UC from the same regions — in all, over 600 samples. Through this analysis BiomX confirmed the high prevalence of *K. pneumoniae* in PSC patients and discovered an association of *K. pneumoniae* with the disease severity and duration. Certain clinical *K. pneumoniae* isolates BiomX cultured from human PSC fecal samples confirmed that these strains induce Th17 immune responses and are able to induce epithelial permeability in cellular monolayers and in animals. BiomX believes that its findings support the development of a phage therapy for PSC.

BX003 is a cocktail of *K. pneumoniae* specific phage that BiomX is optimizing for their ability to function together to eliminate specific pathogenic strains in PSC, while limiting the ability of resistance mutants to emerge.

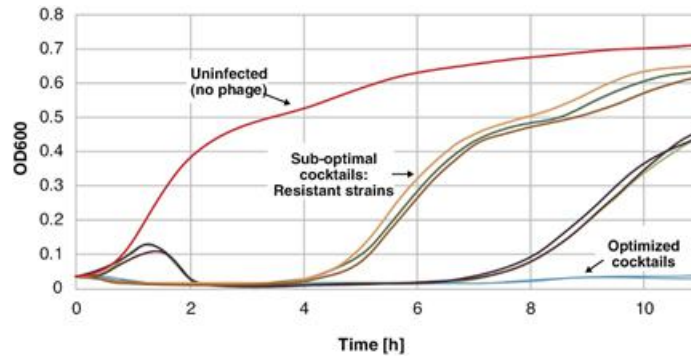


Figure 14. Different phage cocktails tested in the development of BX003. The figure shows the growth of *K. pneumoniae* strains isolated from PSC patients, as measured by optical density or OD, in a liquid *in vitro* culture with and without addition of different phage cocktails.

CRC Program

BiomX is developing phage designed to target specific strains of bacteria that are believed to be pathogenic and that are found in the tumors of patients with CRC. BiomX's goal is not only to use these phage to eliminate these bacteria, but also to have these destroyed bacteria serve as immunostimulators, becoming beacons to help activate a tumor-directed immune response. In contrast to other therapeutic product candidates in BiomX's pipeline that primarily consist of naturally occurring phage or evolved variants, BiomX's CRC phage program is highly dependent on its synthetic engineering expertise to engineer phage genomes to both increase the antibacterial potency of naturally occurring bacterial strains as well as to potentially deliver immunostimulatory payloads to tumors.

Turning immunologically cold tumors into hot tumors

Tumors enriched in mutations and immune cells, such as melanoma and non-small cell lung cancer, are considered "hot" tumors, while those with few mutations and little immune infiltration, such as pancreatic, prostate cancer, and the majority of CRC are called "cold" tumors. Hot tumors are considered good candidates for immunology therapies because these tumors are populated with immune cells that have the potential to have anti-tumor activity if it were not for the presence of various immunosuppressive impediments. There are many approaches that have been approved and are under development for addressing these impediments and activating tumor destruction through immunological attack.

Cold tumors have poor responses to most immuno-oncology therapies because these tumors are largely devoid of immune cells. Various methods are being investigated with the intent of turning cold tumors into hot tumors. The underlying premise behind most of these methods is to both induce inflammation in the tumor and expose tumor antigens that can be recognized by the immune system. The most direct ways of accomplishing this is through direct injection of immunostimulatory molecules and oncolytic viruses into tumors. Unfortunately, not all tumors are easily accessible for these direct injection methods.

BiomX believes that it can use phage to convert cold tumors into hot tumors by targeting bacteria that are naturally resident in these tumors and releasing an immunostimulatory payload. BiomX's hypothesis is that, by attacking these bacteria with phage, it can expose bacterial proteins and other components brought by the phage to the human immune system, triggering an influx of immune cells. Two factors encourage BiomX to believe that this will be successful: First, the presence of specific strains of bacteria in the tumors; and second, the high specificity of phage for their target bacterial strains. Together, these factors suggest to BiomX that phage administered intravenously can target the bacteria resident in tumors throughout the body, including those tumors that are invisible to imaging or otherwise inaccessible for direct injection. The antibacterial activity of the phage has the potential to have a direct impact especially on those tumors in which the bacteria is believed to support tumor proliferation or help it to evade the immune system. The lysis or destruction of these bacteria by the phage can serve as an immunostimulatory event, helping to recruit components of the immune system, thus turning these tumors into immunologically hot tumors. In principle, BiomX believes that these phage also have the potential to serve as gene delivery vectors capable of delivering genes encoding various immunostimulatory molecules.

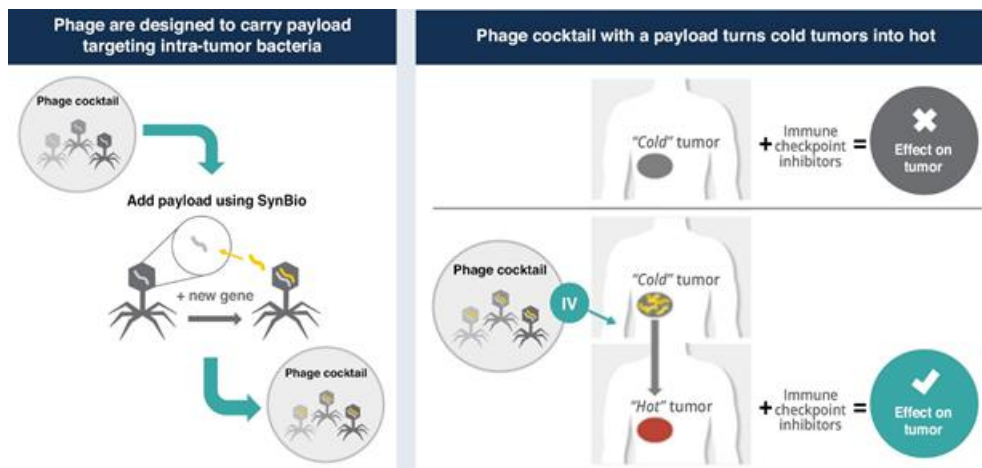


Figure 15. Design of BiomX’s therapeutic product candidates in CRC and potentially in other cancers. We believe that phage can target bacteria in cold tumors and deliver payloads capable of activating an immune response.

BiomX believes that phage can provide many of the potential immuno-oncology benefits of oncolytic viruses via a more convenient and efficient route of administration. Rather than relying on intratumoral injection, phage may be able to efficiently target tumors via systemic intravenous administration. While some oncoviruses also have the possibility to be administered systemically, their ability to specifically target tumors is limited, leading to sequestration in non-tumor tissues such as the liver and spleen, reducing the effective dose and potentially introducing undesired toxicity.

CRC Overview

CRC is the second leading cause of cancer deaths in the United States. The Centers for Disease Control and Prevention (“CDC”) estimates that there were 141,270 new cases of CRC and 52,286 CRC related deaths in the United States in 2016. Over 30 percent of the patients with a new diagnosis of CRC will die within five years. The risk of CRC increases with age; 90 percent of cases are diagnosed in individuals 50 years of age or older. Despite effective screening, leading to a reduction in the mortality from CRC, the number of cases remains high and is expected to increase worldwide to 2.2 million by the year 2030.

Treatment of CRC typically involves the use of cytotoxic chemotherapy and radiation with or without surgery. Treatment with anti-epidermal growth factor receptor or EGFR antibodies as monotherapy or in combination with chemotherapy has been shown to be effective in a subset of CRC patients, however over 40 percent of patients do not respond to anti-EGFR antibody therapies and of those that do, resistance often develops. To date immuno-oncology therapy has had a limited impact in CRC. The majority of colorectal tumors are not associated with high numbers of mutations and thus have a limited number of immunologically active tumor antigens. Only 15 percent of colorectal tumors have mutations in mismatch repair genes and microsatellite instability, capable of generating neoantigens and attracting immune cells. These tumors have been shown to be responsive to treatment with PD-1 checkpoint inhibitors.

Targeting the tumor microbiome in CRC

Although cancer is generally considered to be a disease caused by genetic mutations or by environmental factors, such as exposure to ionizing radiation, environmental carcinogens and so forth, microorganisms are implicated in approximately twenty percent of cases, with one of the most well-known cases being the direct association of *Helicobacter pylori* and gastric cancer. In some cases, these microorganisms can become integral parts of the tumor, aiding its propagation. In other cases, they serve an indirect role by causing inflammation that drives proliferation of cells leading to the development of cancer.

Colorectal tumors have been found to be enriched in the levels of a bacteria species known as *Fusobacterium nucleatum* or *F. nucleatum*. The levels of this bacterium can be hundreds of times higher in tumors than in adjacent non-tumor tissues.

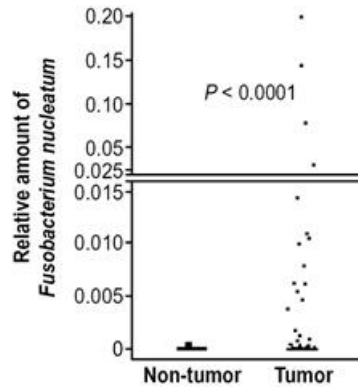


Figure 16. Levels of *F. nucleatum* are elevated in tumors compared to normal tissue.

Direct observation of *F. nucleatum* in CRC tumor samples show that these bacteria appear to be integrally associated with tumor cells and not simply passively attached to the tumor surface. Published studies have shown that *F. nucleatum* bind to tumors via specific interactions between molecules on tumor cells and bacterial proteins.

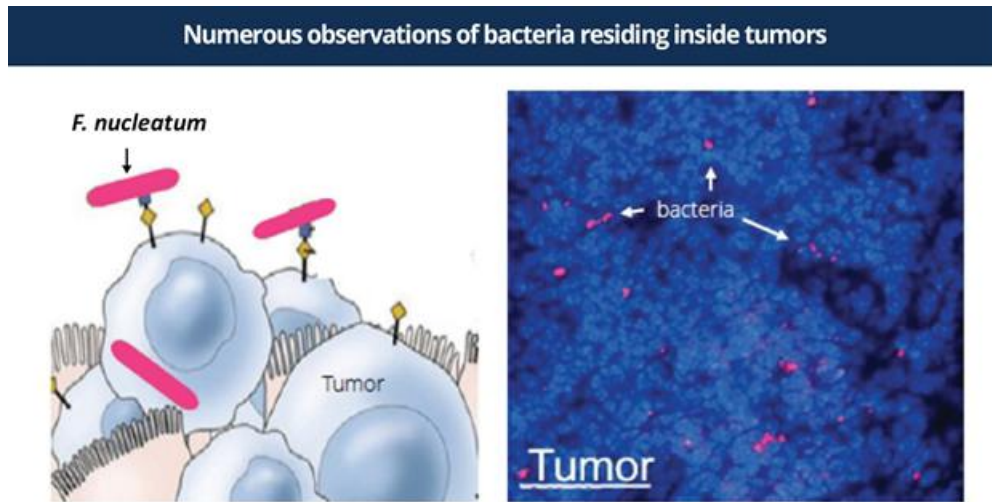


Figure 17. *F. nucleatum* are a bacteria species that reside within colon cancer tumors.

Comparisons of survival rates for CRC patients show that patients with high levels of *F. nucleatum* have a poor prognosis with less than half surviving more than 20 months. In contrast, more than 60 percent of patients with low *F. nucleatum* levels survive beyond 60 months.

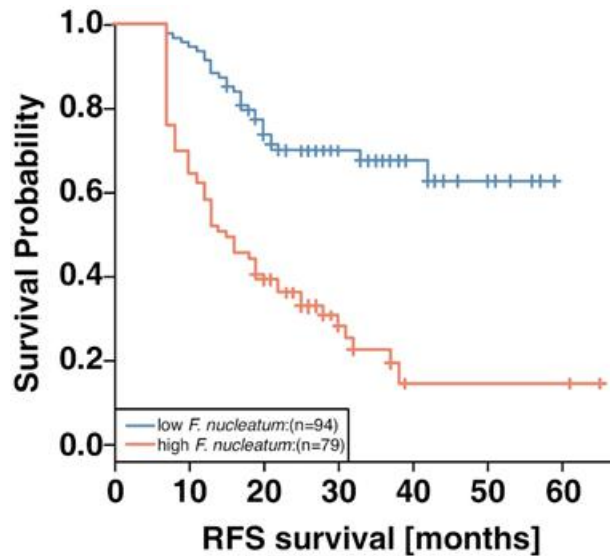


Figure 18. High levels of *F. nucleatum* have been associated with a poor prognosis in patients with CRC tumors.

These findings suggest that *F. nucleatum* is not only associated with colorectal tumors, but that it may also have a pathologic role. Other studies have implicated *F. nucleatum* in stimulating CRC initiation and proliferation, protection from immune attack by binding checkpoint inhibitors, and promoting resistance to chemotherapy. Combined, these results provide justification for the development of therapies designed to eradicate *F. nucleatum* in CRC.

BiomX believes that targeting *F. nucleatum* may provide clinical benefit in CRC through three mechanisms:

- Reductions in the levels of the pathogenic bacteria, thereby lowering its contribution to the propagation of CRC;
- Induction of an inflammatory response due to lysis of the bacteria, which may lead to infiltration of the tumor with immune cells; and
- Ability to deliver gene payloads encoding immunostimulatory genes designed to specifically activate the immune response to the tumor.

Preclinical proof of concept

A panel of phage against *F. nucleatum* were obtained from clinically isolated samples. BiomX sequenced and characterized these phage, some of which were lytic phage and others which were temperate phage, or phage that are capable of infecting bacteria without causing immediate cell lysis or rupturing.

BiomX tested the ability of the phage BiomX isolated to target *F. nucleatum* resident in colorectal tumors by first inducing the formation of tumors in mice by implanting them with CT26 tumor cells. After twelve days of tumor formation, *F. nucleatum* bacteria were added and shown to be present in the tumors. After another twenty-four hours, phage were administered by intravenous infusion. BiomX showed by quantitative PCR that these phage were capable of infecting tumor-associated *F. nucleatum*.

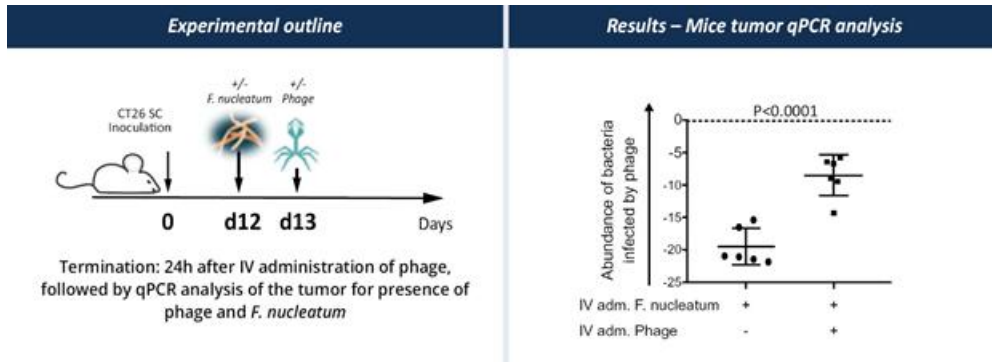


Figure 19. Intravenous administration of phage able to target bacteria in tumors.

BiomX believes that these results support its therapeutic hypothesis that phage can be used to target bacteria resident in tumors. BiomX is currently using synthetic engineering to add genes encoding immunostimulatory payloads which BiomX believes will enhance the ability of these phage to serve as immuno-oncology stimulatory agents capable of turning cold tumors into hot tumors.

Technology platform

Target and biomarker discovery and validation

BiomX accesses microbiome sample collections from both patients and healthy people collected globally. BiomX uses its proprietary computational platform to identify or corroborate potential bacterial targets associated with disease. Candidate targets undergo a robust process of target validation that includes analysis of patient cohorts as well as *in vitro*, *ex vivo* and animal validation models. BiomX then advances valid targets to phage discovery, where BiomX seeks a phage cocktail that can target and destroy these disease-causing bacteria.

The ongoing reduction in sequencing costs is enabling an exponential growth in sequence data that can be generated from the collection of microorganisms in a microbiome, or metagenomic sequences. The microbiome is extremely varied between individuals and even between samples from the same individual taken at multiple sites or at different times. BiomX's target and biomarker discovery technologies have been designed to specifically handle the vast amount of complex data that arises from analyses of patient microbiomes in order to derive specific information. Analyses of the composition of the microbiome and discovering bacterial targets is a problem of high dimensionality difficult to solve with traditional methods.

BiomX has developed the ability to effectively mine metagenomic data from patient and healthy cohorts that BiomX collects itself, accesses from public sources or licenses from third parties. BiomX is constantly improving its computational methods to address this vast quantity of complex data, thereby increasing the amount of data that BiomX can process. BiomX has developed high-scale bioinformatic analysis tools that can process data at the scale of petabytes at what BiomX believes to be a reasonable cost and in a reasonable amount of time.

Classical approaches to metagenomics analyses are based on using sequence data of bacterial strains that have been isolated and sequenced to determine the abundance of individual strains and species of bacteria in a given sample. This approach has inherent limitations: it requires that there is a reference sequence available for many strains of each bacterial species and does not refer to the contributions of individual genes to the pathology. Sequences for novel or less abundant strains of bacteria are not available in reference databases and thus these strains become invisible to the analysis.

BiomX's methods are able to perform higher resolution analyses that use all the available sequence data to produce disease-specific sequence signatures. These signatures can then be used to map the importance of individual genes or pathways in the pathology.

BiomX's target and biomarker discovery platforms focus on two classes of data: microbiome composition and microbiome dynamics. Microbiome composition refers to the characterization of the microbiome to determine the prevalence and relative abundance of strains and genes between groups. Dynamics refers to the changes in microbiome composition, such as bacteria growth rate, and gene expression that are induced upon various potential treatments. BiomX believes that identification of therapeutically relevant targets and signatures requires both an understanding of the microbiome composition and changes that a given therapeutic is likely to induce.

To date BiomX has focused on diseases for which strong associations with specific microbiome changes were available from pioneering work of leading academic laboratories. For each of BiomX's programs, however, BiomX has made significant investments in acquiring clinical samples from diverse demographics and geographies to validate that the published findings are applicable to a broad set of patients. To this end, BiomX has assembled collections of hundreds of samples from patients with IBD and PSC.

Microbiome based biomarkers — BiomX's XMarker platform

In addition to using BiomX's computational platform to discover and validate targets, BiomX has applied its signature identifying technology towards identifying microbiome-derived biomarkers for disease diagnoses and as a means of developing diagnostic tests to identify responders to non-responders to drugs. BiomX has established a collaboration with Janssen Research & Development, LLC ("Janssen") to use BiomX's diagnostic platform, which BiomX calls XMarker, to identify a biomarker signature to stratify responders and non-responders to a key Johnson & Johnson IBD therapeutic. BiomX is using BiomX's computational tools to analyze sequences in the stool microbiome of patients being treated by Janssen with the intent of identifying sequence variations between responders and non-responders. BiomX believes that sequence variations identified through its XMarker platform can be used to develop PCR-based or other molecular tests for screening patients and identifying those most likely to benefit from treatment.

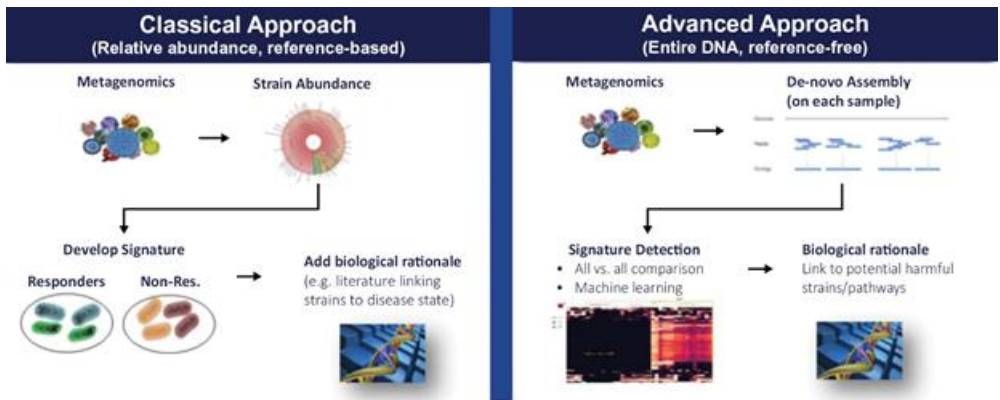


Figure 20. A reference free approach for biomarker discovery versus a classical reference based approach. *Phage discovery and optimization*

BiomX has chosen to develop therapies based on phage because of their high specificity for specific bacterial strains; their strong intrinsic safety profile in certain non-therapeutic applications, including in food or food contact surface categories; and the potential to use genetic engineering to bring synthetic biology approaches to the development of novel therapies. Phage are self-replicating which means that broad antibacterial activity can be obtained using low doses. This replication is also self-limiting — once the target bacteria has been eliminated, the phage are unable to replicate and are thought to be eliminated from the body.

Phage hunting

BiomX's phage discovery process begins with a process BiomX calls phage hunting in which BiomX extracts phage from a broad array of clinical and environmental samples. BiomX isolates both lytic phage and temperate phage, which are capable of both lytic and lysogenic replication, to increase the spectrum of potential phage. Although BiomX's current topical and therapeutic product candidate cocktails are all lytic phage BiomX has developed synthetic biology engineering tools that allow conversion of temperate phage into a strictly lytic form.

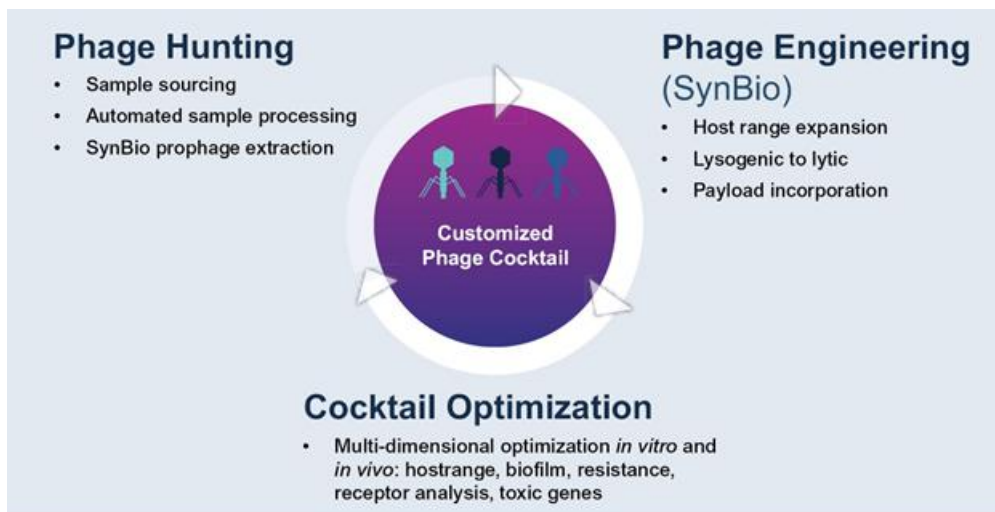


Figure 21. Overview of BiomX’s phage platform.

BiomX then screens phage for the ability to selectively and potently infect the target bacterial strains of interest. Phage that pass BiomX’s initial screens undergo extensive *in silico* and laboratory characterization. BiomX sequences the genomes of all phage candidates and rank them based on sequence diversity and lack of undesirable features, such as antibiotic resistance genes or toxins. BiomX then analyzes the phage for bacterial strain specificity and their ability to cause bacterial cell lysis rather than entering a lysogenic phase in which the phage become resident within the bacteria. Phage candidates are prioritized for various characteristics that will be important during manufacturing such as ease of production and stability. BiomX carries out whole genome analyses of bacteria that have developed resistance to specific phage in order to identify the bacterial receptors used by each phage to infect their target bacteria.

Phage engineering

BiomX’s phage selection process usually begins with screening for naturally occurring phage, but it is not always possible to find phage that exactly match the desired profile. If needed, BiomX modifies the genomes of its phage to create synthetic phage with properties which are not found in nature, but that BiomX believes will be beneficial to BiomX’s use as therapeutic agents. Examples of the types of genetic changes BiomX has introduced into phage include:

- Alteration of their target specificity by modifying genes encoding phage tail fibers, which are typically responsible for recognition of bacterial receptor proteins. This allows BiomX to develop phage with expanded bacterial host range.
- Conversion of temperate phage to lytic phage by disabling genes required for lysogeny.
- Addition of payload genes that are intended to be delivered by the phage and lead to expression of proteins with therapeutic or diagnostic potential.

Changing the target specificity of phage

BiomX has applied two methods to change the target-recognition specificity of phage. One method is to introduce selective mutations directly into the genes encoding the phage tail fibers, the portions of the phage typically responsible for binding to bacterial cell receptors. The second method involves swapping the genes encoding tail fibers that specifically bind to one target receptor with those of a phage that binds to another receptor. BiomX can also create phage with parts of two different types of tail fibers, thus expanding the strains of bacteria that they can target.

Expanding phage host range against multiple targets

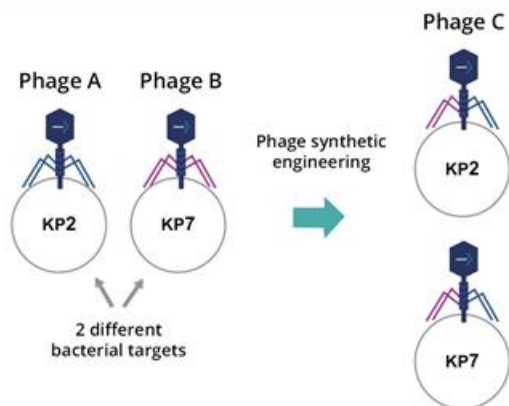


Figure 22. A schematic example of a phage created to have multiple tail fibers.

A published example from one of BiomX's founders demonstrates the ability of tail fiber gene swapping to alter phage specificity. In this experiment T7 phage that were not able to inhibit the growth of *Klebsiella* were engineered to contain the genes for the tail fibers of K11 phage, a potent inhibitor of *Klebsiella*. After swapping the tail fiber genes, the synthetic T7 phage assumed the species specificity of the K11 phage and became potent inhibitors of *Klebsiella*.

Conversion of temperate to lytic phage

Naturally occurring phage can exist either as lytic phage which replicate, creating many copies of themselves and quickly leading to bacterial lysis, or as temperate phage which have the ability to enter into a lysogenic phase and become resident in the bacterial host by integrating into the bacterial chromosome. BiomX can engineer phage that BiomX discovers to disable their ability to enter the lysogenic state by inactivating key lysogenic genes such as regulatory genes or enzymes required for chromosomal integration. For example, the deletion of a repressor required for lysogeny results in the creation of phage that, in contrast to their naturally occurring precursors, are able to induce complete lysis of their target bacteria and suppress bacterial regrowth.

Switching phage mode of action from lysogenic to lytic

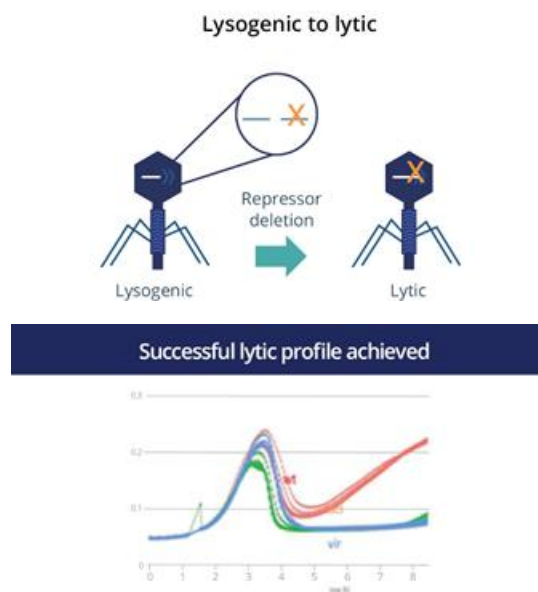


Figure 23. Deletion of a repressor converted a temperate phage (red) into a lytic phage (green) having similar ability to inhibit bacterial growth as a naturally occurring lytic phage (blue).

Addition of payloads to phage

BiomX has extensive experience modifying phage to carry and express gene payloads for a variety of proteins. BiomX has developed a luciferase-based rapid test for *K. pneumoniae* in IBD based on phage used to create BX002. BiomX is now evaluating the introduction of various immunostimulatory genes into phage in BiomX's CRC product candidate. Through this process BiomX has gained proprietary insights enabling BiomX to insert genes in specific areas of the phage genome to maximize expression and limit disruption of phage function.

Cocktail optimization

BiomX's topical and therapeutic product candidates are cocktails of phage which are chosen based on various characteristics including target host range, ability to avoid resistance, stability, ease of manufacturing and biofilm penetration. BiomX employs various techniques to prioritize and enrich for the selection of phage that target different receptors. BiomX conducts extensive computational and laboratory tests to optimize the selection of phage components of BiomX's cocktails to maximize their antibacterial activity and the durability of their antibacterial effect.

BiomX's primary strategy to prevent or minimize the emergence of viable bacteria with mutations that allow them to overcome infection by the candidate therapeutic is to always use a cocktail of multiple phage, including those which infect by different receptors, in BiomX's topical and therapeutic product candidates. BiomX hypothesizes that the ability of a bacterium to escape infection by all members of the set of distinct phage in BiomX's cocktail would require simultaneous mutations in multiple genes — a very unlikely event. In practice, this is what BiomX has observed in its preclinical studies. Resistance can emerge when bacteria are treated with single phage or suboptimal cocktails, but it is less likely when a cocktail of diverse phage are used.

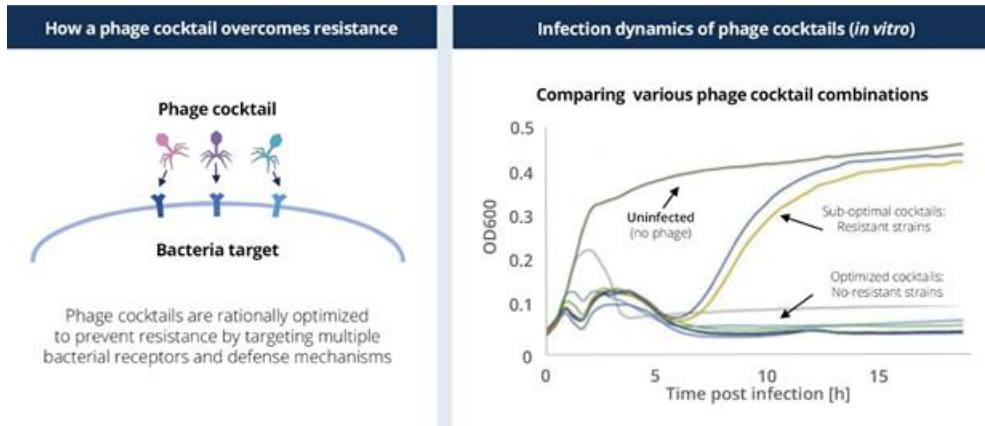


Figure 24. Cocktails of diverse phage prevent emergence of resistant bacteria.

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). 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 co-owns one U.S. provisional patent application with Keio, one U.S. provisional and one PCT application with 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 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 Keio and Yeda one U.S. provisional application and one PCT application 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 one U.S. provisional application, one PCT application and five foreign patent applications (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. non-provisional 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 one U.S. issued patent, five U.S. non-provisional applications, one PCT application, and seven foreign patent applications (Canada, China, Europe, and Israel). These licensed patent families include one issued U.S. Patent 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 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:

- *P. 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"). Upon the 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.

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 September 30, 2019, BiomX had 66 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.

Facilities

The Company maintains its 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 12,492 square feet of laboratory and office space. The lease at 7 Pinhas Sapir Street expires in 2022, subject to an option to extend for an additional five years starting on July 14, 2022. The lease in 2 Ilan Ramon Street expires in 2024, subject to an option to extend for an additional ten years ending on July 14, 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.

Legal Proceedings

As of the date of this prospectus, the Company is not subject to any material legal proceedings.

MANAGEMENT

After completion of the Business Combination, our Board of Directors was reconstituted and is now comprised of eight members, classified into three classes, each comprising as nearly as possible one-third of the directors to serve three-year terms. As Class I directors, each of Mr. Yaron Breski, Mr. Erez Chimovits and Dr. Robbie Woodman will serve until the 2020 annual meeting; as Class II directors, each of Dr. Gbola Amusa and Mr. Jonas Grossman will serve until the 2021 annual meeting; and as Class III directors, each of Dr. Russell Greig, Mr. Jonathan Solomon and Ms. Lynne Sullivan will serve until the 2022 annual meeting, or in each case until their respective successors are duly elected and qualified, or until their earlier resignation, removal or death.

The Company's directors and executive officers are:

| Name | Age | Position |
|------------------------|-----|--|
| Dr. Russell Greig | 67 | Director and Chairman of the Board |
| Jonathan Solomon | 42 | Chief Executive Officer and Director |
| Assaf Oron | 44 | Chief Business Officer |
| Dr. Sailaja Puttagunta | 51 | Chief Medical Officer |
| Dr. Merav Bassan | 54 | Chief Development Officer |
| Uri Ben-Or | 49 | Interim Chief Financial Officer |
| Marina Wolfson | 35 | Vice President of Finance and Operations |
| Dr. Gbola Amusa | 45 | Director |
| Yaron Breski | 41 | Director |
| Erez Chimovits | 55 | Director |
| Jonas Grossman | 45 | Director |
| Lynne Sullivan | 53 | Director |
| Dr. Robbie Woodman | 41 | Director |

Dr. Russell Greig has served as a director and chairman of the Board of Directors of the Company since October 2019. Dr. Greig has more than 35 years' experience in the pharmaceutical industry, with knowledge and expertise in research and development, business development and commercial operations. He spent the majority of his career at GlaxoSmithKline ("GSK"), where he held a number of positions including GSK's President of Pharmaceuticals International from 2003 to 2008 and Senior Vice President Worldwide Business Development. From 2008 to 2010, Dr. Greig was also President of SR One, GSK's Corporate Venture Group. He is currently Chairman of AM Pharma and Mint Solutions in The Netherlands, and Bionor in Norway. In addition, Dr. Greig serves as a board member of Onxeo S.A. in France, and previously served on the boards of Tigenix N.V. (acquired by Takeda Pharmaceutical Company Limited), and Ablynx N.V. (acquired by Sanofi, France). He is also a Venture Partner at Kurma Life Sciences (France). He was previously Chairman of Syntaxin Ltd (UK) (sold to Ipsen), Novagali Pharma S.A. (France) (acquired by Santen Pharmaceutical Co., Ltd.), and Isonova AB (Sweden) (acquired by Novavax, Inc. (Nasdaq:NVAX)). He served as acting Chief Executive Officer at Genoea Biosciences (Nasdaq: GNCA) and Isonova AB for an interim period. He was also a member of the Scottish Scientific Advisory Committee, reporting to the First Minister of Scotland.

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 a 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 M.B.A. 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.

Uri Ben-Or has served as the Interim Chief Financial Officer since October 2019. In January 2007, Mr. Ben-Or founded CFO Direct Ltd., in which he has served as the Chief Executive Officer and through which he provides his services to our company. Mr. Ben-Or is currently the Chief Financial Officer of BiondVax Pharmaceuticals Ltd. (Nasdaq: BVXV), Together Pharma Ltd. (TASE), Cannabics Pharmaceuticals Inc. (OTC: CNBX), Opectra Ltd. (TASE), Geffen Biomed Investments Ltd. (TASE), and Medic Therapeutic Ltd., and is the Chief Executive Officer and Chief Financial Officer of Maayan Ventures Ltd. (TASE). Mr. Ben-Or was also the Chief Financial Officer of My Size Inc. (Nasdaq: MYSZ; TASE) from September 2010 to May 2016, Intercure Ltd. (TASE) from February 2011 to January 2016, D. Medical Industries Ltd. (TASE) from February 2013 to April 2015, Therapix Biosciences Ltd. from October 2014 to March 2015 (Nasdaq: TRPX), Procognia Ltd. (TASE) from September 2012 to December 2014, Glycominds Ltd. (TASE) from October 2001 to April 2014, and WideMed Ltd. (TASE) from November 2007 to November 2010. Prior to that, Mr. Ben-Or was an auditor at PriceWaterhouseCoopers from May 1997 to July 1999. Mr. Ben-Or holds a B.A. in Accounting from The College of Management Academic Studies, and an M.B.A. from Bar-Ilan University and is a certified public accountant in Israel.

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 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.

Dr. Ghola Amusa has served as a director of the Company since March 2018, and served as the Executive Chairman of the Company from March 2018 to October 2019. Dr. Amusa has served as Partner, Director of Research, and Head of Healthcare Equity Research at Chardan Capital Markets LLC since December 2014. At Chardan, he has established the healthcare vision by focusing on disruptive healthcare segments, such as gene therapy/genetic medicines, that have the highest potential for significant investment returns. Dr. Amusa was previously Managing Director, Head of European Pharma Research, and Global Pharma & Biotech Coordinator at UBS (from 2007 to 2013), where he oversaw 25 analysts. Prior to UBS, Dr. Amusa was a Senior Research Analyst and Head of European Pharma research at Sanford Bernstein. He started his career in finance at Goldman Sachs as an Associate in the Healthcare Investment Banking Group, where he worked on large transactions including the Amgen/Immunex merger. Additionally, Dr. Amusa was previously a Healthcare Finance & Strategy Consultant working with governments, companies, leading foundations and think tanks. He holds an M.D. from Washington University Medical School, an M.B.A. with High Honors from the University of Chicago Booth School of Business, and a B.S.E. with Honors from Duke University.

Yaron Breski has served as a director of the Company since October 2019, and served as a director of BiomX from November 2018 to October 2019. Mr. Breski is a Partner at RMGP Bio-Pharma Investment Fund, L.P., which he co-founded in May 2017, and has served as Managing Director at RM Global Partners LLC since October 2014. Previously, Mr. Breski served as Executive Director of Business Development at biotechnology company Rosetta Genomics. Mr. Breski holds a B.Sc. in Biology, Magna Cum Laude, research track for honors students from the Tel Aviv University; and an M.B.A. from The Wharton School, University of Pennsylvania.

Erez Chimovits has served as a director of the Company since October 2019, and served as a director of BiomX from January 2016 to October 2019. Mr. Chimovits has served as Senior Managing Director at healthcare investment firm OrbiMed Advisors LLC since 2010. Prior to joining OrbiMed, Mr. Chimovits was the Chief Executive Officer of pharmaceutical company NasVax Ltd. (now Therapix Biosciences Ltd.) and spent more than seven years with predictive drug discovery and development company Compugen Ltd., serving as President of Compugen USA Inc. and as Executive Vice President of Commercial Operations. Mr. Chimovits earned his M.B.A., M.Sc. in Microbiology, and B.Sc. from Tel Aviv University.

Jonas Grossman has served as a director of the Company from its formation in November 2017 to Closing Date and remains to serve as a director of the Company to date. Mr. Grossman has served as Partner and Head of Capital Markets for Chardan Capital Markets LLC, a New York headquartered broker/dealer, since December 2003. Mr. Grossman has served as President of Chardan Capital Markets LLC since September 2015. Since 2003, Mr. Grossman has overseen the firm's deal origination, syndication, secondary market sales and trading and corporate access initiatives. He has extensive transactional experience having led or managed over 400 transactions during his tenure at Chardan. Since December 2006, Mr. Grossman has served as a founding partner for Cornix Advisors, LLC, a New York based hedge fund. From 2001 until 2003, Mr. Grossman worked at Ramius Capital Group, LLC, a global multi-strategy hedge fund where he served as Vice President and Head Trader. Mr. Grossman has served as a director for China Broadband (NASDAQ: SSC) from January 2008 until November 2010. He holds a B.A. in Economics from Cornell University and an M.B.A. from NYU's Stern School of Business.

Lynne Sullivan has served as a director of the Company since November 2019. Ms. Sullivan was most recently the Chief Financial Officer of Compass Therapeutics, LLC, a biotechnology company ("Compass"), where she has worked from December 2018 to August 2019. Prior to Compass, Ms. Sullivan served as Biogen Inc.'s Senior Vice President of Finance from 2016 to December 2018, where she also served as Vice President of Tax and Corporate Finance from February 2015 to March 2016 and Vice President of Tax from April 2008 to February 2015. Prior to that, Ms. Sullivan was the Vice President Tax at EMD Serono and the Vice President of Tax North America at Merck KGaA. Ms. Sullivan is currently a member of the board of directors of resTORbio, Inc., a public biopharmaceutical company (Nasdaq: TORC), Solid Biosciences Inc., a public life sciences company (Nasdaq: SLDB), and Inheris Pharma. Ms. Sullivan was a Certified Public Account for over 20 years and was also a Tax Partner at Arthur Anderson, where she led the North East Region's Tax Consulting Practice for the firm. She received an M.S. in Taxation from Bentley University and a B.S.B.A. from Suffolk University.

Dr. Robbie Woodman has served as a director of the Company since October 2019 and served as a director of BiomX from June 2018 to October 2019. Dr. Woodman joined Takeda Ventures, Inc. ("Takeda Ventures") in March 2018 as Senior Partner. Prior to joining Takeda Ventures, Dr. Woodman served as Director of Healthcare Investments at venture capital and private equity firm Touchstone Innovations Plc (formerly Imperial Innovations) from December 2012 to January 2017 and as Director of Healthcare Ventures from September 2012 through December 2016. Dr. Woodman previously served as Principal in the life science team at venture capital firm Sofinnova Partners. Dr. Woodman holds an M.Sc. in Biochemistry from the University of Oxford and a Ph.D. in Oncology from the University of Cambridge.

Number and Terms of Office of Officers and Directors

Our board of directors is divided into three classes, Class I, Class II and Class III, with only one class of directors being elected in each year.

Our officers are elected by the board of directors and serve at the discretion of the board of directors, rather than for specific terms of office. Our board of directors is authorized to appoint persons to the offices set forth in our bylaws as it deems appropriate. Our bylaws provide that our officers may consist of a Chief Executive Officer, President, Chief Financial Officer, Vice Presidents, Secretary, Assistant Secretaries, Treasurer and such other offices as may be determined by the board of directors.

Director Independence

The NYSE American requires that a majority of our Board of Directors be composed of "independent directors," which is defined generally as a person other than an officer or employee of the company or its subsidiaries or any other individual having a relationship, which, in the opinion of the company's Board of Directors would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director.

Dr. Gbola Amusa, Mr. Yaron Breski, Mr. Erez Chimovits, Dr. Russell Greig, Mr. Jonas Grossman, Ms. Lynne Sullivan and Dr. Robbie Woodman are our independent directors. Our independent directors have regularly scheduled meetings at which only independent directors are present.

Committees of the Board of Directors

Audit Committee

The Audit Committee, which is established in accordance with Section 3(a)(58)(A) of the Exchange Act, engages the Company's independent accountants, reviewing their independence and performance; reviews the Company's accounting and financial reporting processes and the integrity of its financial statements; the audits of the Company's financial statements and the appointment, compensation, qualifications, independence and performance of the Company's independent auditors; the Company's compliance with legal and regulatory requirements; and the performance of the Company's internal audit function and internal control over financial reporting. The Audit Committee has held four meetings during 2019.

The members of the Audit Committee are Ms. Lynne Sullivan, Dr. Gbola Amusa and Dr. Russell Greig, each of whom is an independent director under NYSE American's listing standards and satisfies the additional independence requirements of Rule 10A-3 of the Exchange Act. Lynne Sullivan is the Chairperson of the Audit Committee. The Board of Directors has determined that Lynne Sullivan qualifies as an "audit committee financial expert," as defined under the rules and regulations of the SEC.

Compensation Committee

The Compensation Committee reviews annually the Company's corporate goals and objectives relevant to the officers' compensation, evaluates the officers' performance in light of such goals and objectives, determines and approves the officers' compensation level based on this evaluation; makes recommendations to the Board of Directors regarding approval, disapproval, modification, or termination of existing or proposed employee benefit plans, makes recommendations to the Board of Directors with respect to the compensation of our executive officers, other than the Chief Executive Officer, and administers the Company's incentive-compensation plans and equity-based plans. The Compensation Committee has the authority to delegate any of its responsibilities to subcommittees as it may deem appropriate in its sole discretion. The Chief Executive Officer of the Company may not be present during voting or deliberations of the Compensation Committee with respect to his compensation. The Company's executive officers do not play a role in suggesting their own salaries. Neither the Company nor the Compensation Committee has engaged any compensation consultant who has a role in determining or recommending the amount or form of executive or director compensation. The Compensation Committee has held one meeting during 2019.

The members of the Compensation Committee are Mr. Erez Chimovits, Mr. Jonas Grossman and Dr. Russell Greig, each of whom is an independent director under NYSE American's listing standards. Erez Chimovits is the Chairperson of the Compensation Committee.

Nominating Committee

The Nominating Committee is responsible for overseeing the selection of persons to be nominated to serve on our Board of Directors. Specifically, the Nominating Committee makes recommendations to the Board of Directors regarding the size and composition of the Board of Directors, establishes procedures for the director nomination process and screens and recommends candidates for election to the Board of Directors. On an annual basis, the Nominating Committee recommends for approval by the Board of Directors certain desired qualifications and characteristics for Board of Directors membership. Additionally, the Nominating Committee establishes and oversees the annual assessment of the performance of the Board of Directors as a whole and its individual members. The Nominating Committee will consider a number of qualifications relating to management and leadership experience, background and integrity and professionalism in evaluating a person's candidacy for membership on the Board of Directors. The Nominating Committee may require certain skills or attributes, such as financial or accounting experience, to meet specific needs of the Board of Directors that arise from time to time and will also consider the overall experience and makeup of its members to obtain a broad and diverse mix of Board of Directors members. The Nominating Committee does not distinguish among nominees recommended by stockholders and other persons. The Nominating Committee has held one meeting during 2019.

The members of the Nominating Committee are Dr. Russell Greig, Mr. Jonas Grossman and Dr. Robbie Woodman, each of whom is an independent director under NYSE American's listing standards. Dr. Russell Greig is the Chairperson of the Nominating Committee.

Voting Agreement

In October 2019, we entered into a voting agreement (the “Voting Agreement”) with certain founders of Chardan Healthcare Acquisition Corp. and BiomX security holders, which provides that for a period of two years following the Closing Date of the Business Combination, the parties agree to vote:

- in favor of two members of the Board of Directors to be selected by our Sponsor;
- in favor of five members of the Board of Directors to be selected by SRS; and
- in favor of maintaining the size of the Board of Directors at seven.

In November 2019, pursuant to Section 10 of the Voting Agreement, we signed a waiver letter (the “Waiver Letter to the Voting Agreement”) with SRS and the majority of the holders of the Company’s voting securities, waiving Section 2.3 of the Voting Agreement requiring that the size of the Board of Directors be maintained at seven persons. The waiver expires on the earlier of (i) the six-month anniversary of the date of the Waiver Letter to the Voting Agreement and (ii) the date of the Company’s annual meeting of stockholders in 2020.

DIRECTOR COMPENSATION

During fiscal year 2018, BiomX did not pay cash compensation to any non-employee director for service as a director. BiomX reimburses its non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings.

In November 2019, the Board of Directors approved and began implementing a compensation program that consists of annual retainer fees and long-term equity awards for our non-employee directors. Dr. Robbie Woodman has waived any right to receive any form of compensation, including stock options being granted to each non-employee director of the Company, but will continue to be reimbursed for reasonable travel, lodging and other out-of-pocket expenses incurred by him in connection with attending board of director and committee meetings.

EXECUTIVE COMPENSATION

Compensation of Directors and Executive Officers of BiomX

Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by, and paid to the named executive officers of BiomX for services rendered to BiomX in all capacities for the years indicated.

| Name and Principal Position⁽¹⁾ | Year | Salary (\$) | Bonus⁽²⁾ (\$) | Option Awards (\$) | All Other Compensation (\$) | Total (\$) |
|--|-------------|------------------------|-------------------------------------|-----------------------------------|--|-----------------------|
| Jonathan Solomon | 2018 | 275,744 | 77,332 | 175,908 | 75,569 | 604,553 |
| Chief Executive Officer | 2017 | 266,022 | 54,403 | 174,173 | 71,519 | 566,117 |
| Assaf Oron | 2018 | 144,269 | 38,726 | 105,964 | 33,841 | 322,799 |
| Chief Business Officer | 2017 | 140,044 | 28,654 | 79,525 | 33,820 | 282,043 |
| Myriam Golembo | 2018 | 131,031 | 15,502 | 18,301 | 31,733 | 196,568 |
| Vice President of Development | 2017 | 66,805 | 9,601 | 13,398 | 16,637 | 106,440 |

(1) All payments were originally made in Israeli shekels.

(2) Amounts in this column represent the grant date fair value of the option awards computed in accordance with FASB ASC Topic 718. See “Note 10 — C. Share-based compensation” to the BiomX consolidated financial statements included in this prospectus for a discussion of the assumptions made by BiomX in the valuation of these option awards.

Employment Agreements

Jonathan Solomon

Pursuant to an employment agreement dated February 1, 2016, by and between BiomX and Mr. Solomon, as the Chief Executive Officer of BiomX, Mr. Solomon is entitled to a base salary of NIS 64,000, or approximately \$18,020, per month, and an additional gross payment of NIS 16,000, or approximately \$4,500, per month for up to 40 hours per month worked outside of normal business hours and normal business days (together with the base salary, "Mr. Solomon's Salary"). Mr. Solomon's Salary was increased 3.00% for the 2019 fiscal year, to a base salary of NIS 65,920, or approximately \$18,540, per month, and an overtime payment of NIS 16,480, or approximately \$4,635, per month.

The employment agreement provides that Mr. Solomon received an initial award of options to purchase 69,257 ordinary shares of BiomX, the terms and conditions of which are governed by an award agreement between Mr. Solomon and BiomX. In addition, Mr. Solomon was also entitled to receive a second award of options to purchase additional common shares of BiomX equal to 5% of BiomX's share capital on a fully diluted basis after the closing of a funding of up to \$10 million at a pre-money valuation of at least \$12 million which award was received on March 26, 2017.

BiomX also makes customary contributions on Mr. Solomon's behalf to a pension fund or a managers insurance company, at Mr. Solomon's election, in an amount equal to 8.33% of his Salary, allocated to a fund for severance pay, and an additional amount equal to 5.00% of the Salary in case Mr. Solomon is insured through a managers insurance policy, or 6.50% of Mr. Solomon's Salary in case Mr. Solomon is insured through a pension fund, which shall be allocated to a provident fund or pension plan. In case Mr. Solomon chooses to allocate his pension payments to a managers insurance policy (and not a pension fund), the Company shall also insure him under a work disability insurance policy at the rate required to insure 100% of Mr. Solomon's Salary and for this purpose will contribute an amount of up to 2.50% of Mr. Solomon's Salary insured in such insurance policy for disability insurance in a policy and/or insurance company. These payments are intended to be in lieu of any severance pay that Mr. Solomon would otherwise be entitled to receive from BiomX in accordance with Severance Pay Law 5723-1963 (the "Severance Pay Law"). BiomX also contributes 7.50% of Mr. Solomon's monthly Salary to a recognized educational fund. The company reimburses Mr. Solomon for automobile maintenance and transportation expenses of NIS 2,000, or \$560, per month.

Assaf Oron

Pursuant to an employment agreement dated January 1, 2017, by and between BiomX and Mr. Oron, as the Chief Business Officer of BiomX, Mr. Oron is entitled to a base salary of NIS 31,500, or approximately \$8,870, per month, and an additional gross payment of NIS 8,500, or approximately \$2,390, per month for up to 40 hours per month worked outside of normal business hours and normal business days (together with the base salary, "Mr. Oron's Salary"). Mr. Oron's Salary was increased 3.00% for the 2019 fiscal year, to a base salary of NIS 32,445, or approximately \$9,125, per month, and an additional gross payment of NIS 8,755, or approximately \$2,460, per month.

BiomX also makes customary contributions on Mr. Oron's behalf to a pension fund or a managers insurance company, at Mr. Oron's election, in an amount equal to 8.33% of Mr. Oron's Salary, allocated to a fund for severance pay, and an additional amount equal to 5.00% of Mr. Oron's Salary in case Mr. Oron is insured through a managers insurance policy, or 6.50% of Mr. Oron's Salary in case Mr. Oron is insured through a pension fund, which shall be allocated to a provident fund or pension plan. In case Mr. Oron chooses to allocate his pension payments to a managers insurance policy (and not a pension fund), the company shall also insure him under a work disability insurance policy at the rate required to insure 75% of Mr. Oron's Salary and for this purpose will contribute an amount of up to 2.50% of the Salary insured in such insurance policy for disability insurance in a policy and/or insurance company. These payments are in lieu of any severance pay that Mr. Oron would otherwise be entitled to receive from BiomX in accordance with the Severance Law. BiomX also contributes 7.50% of Mr. Oron's monthly Salary (not to exceed NIS 15,712, or approximately \$4,419) to a recognized educational fund. The company reimburses Mr. Oron for automobile maintenance and transportation expenses of NIS 2,500, or approximately \$700, per month.

Myriam Golembo

Pursuant to an employment agreement dated April 18, 2017, by and between BiomX and Dr. Golembo, as the Vice President of Development of BiomX, Dr. Golembo is entitled to a base salary of NIS 29,000, or approximately \$8,165, per month, and an additional gross payment of NIS 7,000, or approximately \$1,970, per month for up to 40 hours per month worked outside of normal business hours and normal business days (together with the base salary, "Dr. Golembo's Salary"). Dr. Golembo's Salary was increased 3.00% for the 2019 fiscal year, to a base salary of NIS 29,870, or approximately \$8,400, per month, and an additional gross payment of NIS 7,210, or approximately \$2,025, per month.

BiomX also makes customary contributions on Dr. Golembo's behalf to a pension fund or a managers insurance company, at Dr. Golembo's election, in an amount equal to 8.33% of Dr. Golembo's Salary, allocated to a fund for severance pay, and an additional amount equal to 5.00% of Dr. Golembo's Salary in case Dr. Golembo is insured through a managers insurance policy, or 6.50% of Dr. Golembo's Salary in case Dr. Golembo is insured through a pension fund, which shall be allocated to a provident fund or pension plan. In case Dr. Golembo chooses to allocate her pension payments to a managers insurance policy (and not a pension fund), the company shall also insure her under a work disability insurance policy at the rate required to insure 75% of Dr. Golembo's Salary and for this purpose will contribute an amount of up to 2.50% of Dr. Golembo's Salary insured in such insurance policy for disability insurance in a policy and/or insurance company. These payments are in lieu of any severance pay that Dr. Golembo would otherwise be entitled to receive from BiomX in accordance with the Severance Law. BiomX also contributes 7.50% of Dr. Golembo's monthly Salary to a recognized educational fund (not to exceed NIS 15,712, or approximately \$4,419). The company reimburses Dr. Golembo for automobile maintenance and transportation expenses of NIS 2,500, or approximately \$700, per month.

Outstanding Equity Awards at 2018 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by the named executive officers of BiomX as of December 31, 2018.

| <u>Name</u> | <u>Grant Date</u> | <u>Number of Securities Underlying Unexercised Options (#) Exercisable⁽¹⁾</u> | <u>Number of Securities Underlying Unexercised Options (#) Unexercisable⁽¹⁾</u> | <u>Option Exercise Price (\$)</u> | <u>Option Expiration Date</u> |
|---|--|--|--|-----------------------------------|--|
| Jonathan Solomon Chief Executive Officer | 11/13/2016 03/26/2017 05/21/2018 | 115,110 ⁽²⁾ 79,681 — | 52,324 ⁽²⁾ 102,452 201,718 | 0.5377 1.6914 1.9735 | 01/07/2027 03/26/2027 05/21/2028 |
| Assaf Oron Chief Business Officer | 03/26/2017 05/21/2018 | 67,970 — | 87,393 82,667 | 1.6914 1.9735 | 03/26/2027 05/21/2028 |
| Myriam Golembo Vice President of Development | 03/26/2017 06/27/2018 | 14,563 — | 24,278 7,480 | 1.6914 1.9735 | 03/26/2027 06/27/2028 |

(1) Unless otherwise indicated, options vest and become exercisable as follows: 25% of the options on the first anniversary of the "vesting commencement date" (as defined in the applicable notice of option grant) and, thereafter, in 12 equal quarterly installments of 6.25% each.

(2) 13,851 options vested and became exercisable upon Mr. Solomon's appointment as Chief Executive Officer of BiomX. The remainder of the options vest and become exercisable as follows: 25% of the options on February 1, 2017 and, thereafter, in 12 equal quarterly installments of 6.25% each.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics applicable to our directors, officers and employees.

The Board's Role in Risk Oversight

Although our management is primarily responsible for managing our risk exposure on a daily basis, our board of directors oversees the risk management processes. Our board, as a whole, determines the appropriate level of risk for our Company, assesses the specific risks that we face, and reviews management's strategies for adequately mitigating and managing the identified risks. Although our board administers this risk management oversight function, our audit committee supports our board in discharging its oversight duties and addresses risks inherent in its area.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our Common Stock as of October 28, 2019 based on information obtained from the persons named below, with respect to the beneficial ownership of our Common Stock, by:

- each person known by us to be the beneficial owner of more than 5% of our outstanding Common Stock;
- each of our executive officers and directors that beneficially owns our Common Stock; and
- all our executive officers and directors as a group.

Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all Common Stock beneficially owned by them.

| Name and Address of Beneficial Owner⁽¹⁾ | Amount and Nature of Beneficial Ownership | Percent of Class |
|---|--|-------------------------|
| Chardan Investments, LLC ⁽²⁾ | 4,607,500 | 17.9% |
| Takeda Pharmaceutical Company Limited | | |
| Takeda Ventures, Inc. ⁽³⁾ | 2,470,935 | 10.8% |
| OrbiMed Advisors Israel Limited | | |
| OrbiMed Israel GP Ltd. | | |
| OrbiMed Israel Partners, Limited Partnership ⁽⁴⁾ | 2,290,490 | 10.0% |
| Johnson & Johnson Innovation – JJDC, Inc. ⁽⁵⁾ | 2,133,402 | 9.3% |
| Jonathan Solomon ⁽⁶⁾ | 326,440 | 1.4% |
| Assaf Oron ⁽⁷⁾ | 137,809 | * |
| Dr. Sailaja Puttagunta ⁽⁸⁾ | 45,985 | * |
| Dr. Merav Bassan | 0 | 0 |
| Myriam Golebo ⁽⁹⁾ | 26,610 | * |
| Uri Ben-Or | 0 | 0 |
| Marina Wolfson | 0 | 0 |
| Dr. Russell Greig | 0 | 0 |
| Dr. Gbola Amusa ⁽¹⁰⁾ | 0 | 0 |
| Yaron Breski | 0 | 0 |
| Erez Chimovits | 0 | 0 |
| Jonas Grossman ⁽¹¹⁾ | 4,607,500 | 17.9% |
| Lynne Sullivan | 0 | 0 |
| Dr. Robbie Woodman | 0 | 0 |
| All directors and officers as a group (Post-Business Combination) (14 persons) | 5,144,344 | 19.4% |

* Less than 1%.

- (1) Unless otherwise indicated, the business address of each of the individuals is c/o BiomX Ltd., 7 Pinhas Sapir St., Floor 2, Ness Ziona 7414002, Israel.
- (2) Represents 1,707,500 shares of Common Stock held by our Sponsor and warrants to purchase 2,900,000 shares of Common Stock held by Mountain Wood, LLC, which owns approximately 67.96% of our Sponsor. Jonas Grossman, a member of our Board of Directors is the managing member of each of our Sponsor and Mountain Wood, LLC, and thereby has sole voting and dispositive power over such shares. The business address of each of the foregoing is c/o Chardan Healthcare Acquisition Corp., 17 State Street, 21st Floor, New York, NY 10004.
- (3) The business address of Takeda Ventures is 435 Tasso Street, Suite 300, Palo Alto, CA 94301 USA. Takeda Ventures is a wholly-owned direct subsidiary of Takeda Pharmaceuticals U.S.A., Inc. (“Takeda USA”). Takeda Pharmaceuticals International AG and Takeda Pharmaceutical Company Limited together own 100% of Takeda USA. Takeda Pharmaceuticals International AG is a wholly-owned direct subsidiary of Takeda Pharmaceutical Company Limited. As a result, Takeda Pharmaceutical Company Limited may be deemed to have voting and investment power over all of the shares of Common Stock held by Takeda Ventures, and Takeda Pharmaceutical Company Limited may be deemed to be the indirect beneficial owner of the shares held by Takeda Ventures.
- (4) Represents 1,649,151 shares of Common Stock held directly by OrbiMed Israel Partners, Limited Partnership (“OIP LP”) and 641,339 shares of Common Stock held directly by OrbiMed Israel Incubator L.P. (“OII LP”), 89 Medinat Hayehudim St., Building E, Herzliya 4614001 Israel. OrbiMed Israel BioFund GP Limited Partnership (“BioFund GP LP”) is the general partner of each of OIP LP and OII LP, and OrbiMed Israel GP Ltd. (“Israel GP”) is the general partner of BioFund GP LP. OrbiMed Advisors Israel Limited (“Advisors Israel Ltd”) is the majority shareholder of Israel GP. As a result, Advisors Israel Ltd and Israel GP may be deemed to have shared voting and investment power over all of the shares of Common Stock held by each of OIP LP and OII LP, and both Advisors Israel Ltd and Israel GP may be deemed to directly or indirectly, including by reason of their mutual affiliation, to be the beneficial owners of the shares held by each of OIP LP and OII LP. Advisors Israel Ltd exercises this investment power through an investment committee comprised of Carl L. Gordon, Jonathan T. Silverstein, Nissim Darvish, Anat Naschitz, and Erez Chimovits, each of whom disclaims beneficial ownership of the shares held by OIP LP and OII LP.
- (5) The address for Johnson & Johnson Innovation-JJDC, Inc. (“JJDC”) is 410 George Street, New Brunswick, New Jersey 08901. JJDC has voting and dispositive power over 2,133,402 shares of common stock.
- (6) Amount represents 326,440 options that will be exercisable within 60 days from October 28, 2019.
- (7) Amount represents 137,809 options that will be exercisable within 60 days from October 28, 2019.
- (8) Amount represents 45,985 options that will be exercisable within 60 days from October 28, 2019.
- (9) Amount represents 26,610 options that will be exercisable within 60 days from October 28, 2019.
- (10) Mr. Amusa’s business address is c/o Chardan Healthcare Acquisition Corp., 17 State Street, 21st Floor, New York, NY 10004.
- (11) See note (2) above regarding shares beneficially owned by Jonas Grossman.

Restrictions on transfers of certain shares of Common Stock

In connection with this prospectus, certain Selling Securityholders have agreed not to offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any of these shares, enter into a transaction which would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of these shares, whether any such aforementioned transaction is to be settled by delivery of these shares, in cash or otherwise, or publicly disclose the intention to make any such offer, sale, pledge or disposition for a period of six months after the consummation of the Business Combination or until April 28, 2020 (the “Lock-up Agreement”). See “Selling Securityholders” beginning on page 102.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Certain Transactions of the Company

Related-Person Transactions Policy

Our Related-Person Transactions Policy requires us to avoid, wherever possible, all related party transactions that could result in actual or potential conflicts of interests, except under guidelines approved by the Board of Directors (or the audit committee). A related-person transactions is defined as a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any Related Person (as defined in the said policy) are, were or will be participants in which the amount involved exceeds \$120,000 and in which any Related Person had, has or will have a direct or indirect material interest. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions. under this policy.

Our audit committee, pursuant to its written charter, is responsible for reviewing and approving related-party transactions to the extent we enter into such transactions. All ongoing and future transactions between us and any of our officers and directors or their respective affiliates will be on terms believed by us to be no less favorable to us than are available from unaffiliated third parties. Such transactions will require prior approval by our audit committee and a majority of our uninterested "independent" directors, or the members of our Board of Directors who do not have an interest in the transaction, in either case who had access, at our expense, to our attorneys or independent legal counsel. We will not enter into any such transaction unless our audit committee and a majority of our disinterested "independent" directors determine that the terms of such transaction are no less favorable to us than those that would be available to us with respect to such a transaction from unaffiliated third parties. Additionally, we require each of our directors and executive officers to complete a directors' and officers' questionnaire that elicits information about related party transactions.

These procedures are intended to determine whether any such related party transaction impairs the independence of a director or presents a conflict of interest on the part of a director, employee or officer.

Insider Shares

In March 2018, our Sponsor purchased an aggregate of 1,437,500 shares for an aggregate purchase price of \$25,000. 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).

Mountain Wood, LLC, an affiliate of our Sponsor, purchased from us an aggregate of 2,900,000 Private Placement Warrants at \$0.40 per Private Placement Warrant (for a total purchase price of \$1,160,000), with each warrant exercisable for one share of Common Stock at an exercise price of \$11.50 per share simultaneously with the closing of our IPO.

The holders of our Public Units as well as the holders of the Private Placement Warrants (and all underlying securities) and any securities our initial stockholders, officers, directors or their affiliates may be issued in payment of working capital loans made to us, will be entitled to registration rights pursuant to an agreement signed by us in connection with our IPO. The holders of a majority of these securities are entitled to make up to two demands that we register such securities. The holders of the majority of the insider shares can elect to exercise these registration rights at any time commencing three months prior to the date on which these shares of Common Stock are to be released from escrow. The holders of a majority of the Public Shares issued to our Sponsor prior to the IPO or securities issued in payment of working capital loans made to us can elect to exercise these registration rights at any time after we consummate the Business Combination. In addition, the holders have certain "piggy-back" registration rights with respect to registration statements filed subsequent to our consummation of the Business Combination. We will bear the expenses incurred in connection with the filing of any such registration statements.

As of December 13, 2018, the Sponsor had loaned CHAC a total of \$105,500 for costs associated with the IPO. The Company repaid the loans and advances from the proceeds of the IPO.

Certain Transactions of BiomX

Janssen Agreement

On October 31, 2018, BiomX entered into a research collaboration agreement (the “Janssen Agreement”) with Janssen, an affiliate of BiomX shareholder Johnson & Johnson Development Corporation, for a collaboration on biomarker discovery for IBD. Under the Janssen Agreement, BiomX is eligible to receive fees totaling \$167,000 in installments \$50,000 within 60 days of signing of the agreement, \$17,000 upon completion of data processing, and two installments of \$50,000 each, upon delivery of Signature Phase I of the Final Study Report (both terms as defined within the Janssen Agreement). Unless terminated earlier, the Janssen Agreement will continue in effect until 30 days after the parties complete the research program and BiomX provides Janssen with a final study report.

Indemnification Agreement

BiomX entered into an indemnification agreement with FutuRx Ltd. on December 13, 2017. According to the agreement, the aggregate amount of the indemnification shall not exceed an aggregate of NIS 2,295,000, or approximately \$646,340. In addition, the indemnification is limited to liability in connection with BiomX’s compliance with the IIA regulations, and such indemnification undertakings shall be in addition to any other indemnification obligations under which BiomX is bound.

Shareholder Loans

BiomX has committed to enter into loan agreements in an aggregate amount of up to \$1.9 million with certain of its shareholders who are subject to taxation in Israel, pursuant to which BiomX will extend to such shareholders loans for the purpose of paying Israeli capital gain taxes payable by them in connection with the issuance to them of Public Shares in exchange for their BiomX shares upon consummation of the Business Combination. The loans are for a period of up to two years, are non-recourse and are secured by Public Shares issued to them that have a value (based on \$10 per share, the attributed price of the Public Shares immediately prior to such issuance) that equals three times the loan amount. If any of such shareholders defaults on such loan, BiomX will have the right to forfeit or sell such number of Public 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 September 30, 2019, no loans had been granted.

The Company has adopted a new related-persons transactions policy that sets forth the policies and procedures for the review and approval or ratification of related-person transactions.

On October 28, 2019, the Company entered into a purchase agreement (the “Cornix Purchase Agreement”) with Cornix LLC (“Cornix”), an affiliate of Chardan Capital Markets LLC, wherein Cornix agreed to purchase \$300,000 shares of Common Stock within three months of the date of the Cornix Purchase Agreement, and until the earlier of six months from the date of the last purchase of such shares and the date that the closing price of the Common Stock has been in excess of \$15.00 per share for three consecutive trading days, Cornix agreed that it will not offer for sale, sell, pledge, grant any option to purchase or otherwise dispose of such shares.

SELLING SECURITYHOLDERS

Up to 15,741,829 shares of Common Stock may be offered for resale, from time to time, by the Selling Securityholders under this prospectus, which consist of (a) 3,500,000 shares of Common Stock that may be issued upon the exercise of 7,000,000 Public Warrants originally sold as part of the units offered in our IPO and which entitle the holder to purchase one-half (1/2) of a share of Common Stock at an exercise price of \$11.50 per whole share of Common Stock, (b) 2,900,000 shares of Common Stock that may be issued upon the exercise of 2,900,000 Private Placement Warrants issued in a private placement that closed simultaneously with the consummation of the IPO, which entitle the holder to purchase Common Stock at an exercise price of \$11.50 per share of Common Stock, (c) 7,604,329 shares of Common Stock issued in a private placement in connection with the consummation of the Business Combination and (d) 1,737,500 shares of Common Stock sold in one or more private placements prior to the IPO.

In addition, certain Selling Securityholders may offer and sell, from time to time, the 2,900,000 Private Placement Warrants covered by this prospectus. The securities being registered by the registration statement of which this prospectus forms a part are being registered pursuant to registration rights granted to the Selling Securityholders in connection with our initial organization, the IPO and/or the Business Combination. See the section entitled "Plan of Distribution" for further information regarding the Selling Securityholders' method of distributing these securities.

The following tables set forth, with respect to each Selling Securityholder, the number of shares of Common Stock and Private Placement Warrants (i) known to us to be beneficially owned as of November 27, 2019, (ii) being offered hereby and (iii) beneficially owned after giving effect to the sale by the Selling Securityholder of all of its Offered Securities. The number of shares of Common Stock set forth in the following table as beneficially owned as of November 27, 2019 and being offered hereby includes shares issuable upon the exercise of our Private Placement Warrants. The immediately following table also sets forth the percentage of Common Stock beneficially owned by a Selling Securityholder after giving effect to the sale by the Selling Securityholder of all Offered Securities, based on 22,041,620 shares of Common Stock outstanding as of December 3, 2019.

The Selling Securityholders are not making any representation that any shares of Common Stock or Private Placement Warrants covered by this prospectus will be offered for sale. Because each Selling Securityholder may dispose of all, none or some portion of their securities, no estimate can be given as to the number of securities that will be beneficially owned by a Selling Securityholder upon termination of this offering. In addition, the Selling Securityholders may have sold, transferred or otherwise disposed of their securities in transactions exempt from the registration requirements of the Securities Act after the date on which the information in the table is presented. Approximately 86% of the shares of Common Stock beneficially owned by the Selling Securityholders are subject to the Lock-up Agreement. See "Restrictions on transfers of certain shares of Common Stock" beginning on page 99. For purposes of the tables below, however, we have assumed upon termination of this offering none of the Offered Securities will be beneficially owned by the Selling Securityholders, and we have further assumed that the Selling Securityholders will not acquire beneficial ownership of any additional securities during the offering.

We may amend or supplement this prospectus from time to time in the future to update or change this Selling Securityholders list and the securities that may be resold.

Common Stock

| Name | Number of Shares of Common Stock Beneficially Owned(1) | Number of Shares of Common Stock Offered Hereby | Shares of Common Stock Beneficially Owned After Completion of the Offering(1) | |
|--|--|---|---|------------|
| | | | Number | Percentage |
| Johnson & Johnson Innovation – JJDC, Inc. (2) | 2,133,402 | 1,831,577 | 301,825 | 1.4% |
| Chardan Investments LLC (3) | 1,707,500 | 1,707,500 | 0 | 0% |
| OrbiMed Israel Partners, LP (4) | 1,649,150 | 1,325,087 | 324,063 | 1.5% |
| 8VC Fund I, L.P. (5) | 1,068,810 | 868,192 | 200,618 | * |
| SBI JI Innovation Fund LP (6) | 807,717 | 693,479 | 114,238 | * |
| Hans W. Schoepflin Trust (7) | 731,848 | 628,325 | 103,523 | * |
| OrbiMed Israel Incubator Limited Partnership (4) | 641,339 | 641,339 | 0 | 0% |
| 8VC Angel Fund I, L.P. (8) | 346,668 | 346,668 | 0 | 0% |
| Yeda Research & Development Co. Ltd. (9) | 792,406 | 792,406 | 0 | 0% |
| 2016 KIF-MiraeAsset ICT Venture Fund | 177,411 | 177,411 | 0 | 0% |
| Mirae Asset Young Start-Up Investment Fund | 177,411 | 177,411 | 0 | 0% |
| Baruch Family Revocable Trust | 47,310 | 47,310 | 0 | 0% |
| Rafi Gidron | 38,118 | 38,118 | 0 | 0% |
| 8VC Entrepreneurs Fund I, L.P. (5) | 17,381 | 14,119 | 3,262 | * |
| Guy Harmelin | 8,740 | 8,740 | 0 | 0% |
| 8VC Angel Fund I Associates, L.P. (8) | 8,159 | 8,159 | 0 | 0% |
| Elliot Gnedy | 7,510 | 7,500 | 10 | * |
| Eric Kusseluk | 7,500 | 7,500 | 0 | 0% |
| Michael Rice | 7,500 | 7,500 | 0 | 0% |
| Richard Giroux | 7,500 | 7,500 | 0 | 0% |
| CFAM 2017 LLC | 4,896 | 4,286 | 610 | * |
| Alon Hirsch | 1,702 | 1,702 | 0 | 0% |

* Less than 1%.

- The amounts and percentages of Common Stock beneficially owned are determined in accordance with the SEC's rules, pursuant to which a person is deemed to be a "beneficial owner" of a security if that person has or shares voting or investment power or has the right to acquire such power within 60 days through exercise of any option, warrant or other right. Securities that can be so acquired are deemed to be outstanding for purposes of computing such person's ownership percentage, but not for purposes of computing any other person's percentage. Under these rules, more than one person may be deemed beneficial owner of the same securities, and a person may be deemed to be a beneficial owner of securities as to which such person has no economic interest. Except as otherwise indicated in these footnotes, each of the beneficial owners has, to our knowledge, sole voting and investment power with respect to the indicated shares of Common Stock.
- The 1,831,577 shares of Common Stock of Johnson & Johnson Innovation – JJDC, Inc. offered in this prospectus are subject to the Lock-up Agreement.
- The 1,707,500 shares of Common Stock of Chardan Investments LLC offered in this prospectus are subject to the Lock-up Agreement.
- The 1,649,150 shares are held directly by OrbiMed Israel Partners Limited Partnership ("OIP LP") and the 641,339 shares are held directly by OrbiMed Israel Incubator Limited Partnership ("OII LP"). OrbiMed Israel GP Ltd. ("OrbiMed Israel") is the general partner of OrbiMed Israel BioFund GP Limited Partnership ("OrbiMed BioFund"), which is the general partner of each of OIP LP and OII LP. By virtue of such relationships, OrbiMed Israel and OrbiMed BioFund may be deemed to have voting and investment power over the securities held by OIP LP and OII LP, as a result may be deemed to have beneficial ownership over such securities. OrbiMed Israel exercises investment and voting power through an investment committee comprised of Carl L. Gordon, Jonathan T. Silverstein, Nissim Darvish, Anat Naschitz and Erez Chimovits. Messrs. Gordon, Silverstein Darvish, Naschitz and Chimovits and OrbiMed Israel disclaim beneficial ownership of the shares held by the OIP LP and OII LP except to the extent of his or its pecuniary interest therein. The 1,325,087 shares of Common Stock of OrbiMed Israel Partners, LP offered in this prospectus are subject to the Lock-up Agreement.
- The shares held directly by 8VC Fund I, L.P. and 8VC Entrepreneurs Fund I, L.P. (both, the "8VC Fund I Entities") are indirectly held by 8VC GP I, LLC ("8VC GP I"), the general partner of the 8VC Fund I Entities, which has voting and dispositive power with respect to the shares held by the 8VC Fund I Entities. The managing member of 8VC GP I is Joe Lonsdale. Mr. Lonsdale and 8VC GP I disclaim beneficial ownership of the shares held by the 8VC Fund I Entities except to the extent of his or its pecuniary interest therein. The 868,192 and 14,119 shares offered by 8VC Fund I, L.P. and 8VC Entrepreneurs Fund I, L.P. respectively are subject to the Lock-up Agreement.
- The 693,479 shares offered by SBI JI Innovation Fund LP are subject to the Lock-up Agreement.
- The 628,325 shares offered by Hans W. Schoepflin Trust are subject to the Lock-up Agreement.
- The shares held directly by 8VC Angel Fund I, L.P. and 8VC Angel Fund I Associates, L.P. (both, the "8VC Angel Fund Entities") are indirectly held by 8VC Angel GP I, LLC ("8VC Angel GP"), the general partner of the 8VC Angel Fund Entities, which has voting and dispositive power with respect to the shares held by the 8VC Angel Fund Entities. The managing members of 8VC Angel GP are Jake Medwell, Drew Oetting and Kimberly Scotti. Messrs. Medwell and Oetting, Ms. Scotti and 8VC Angel GP disclaim beneficial ownership of the shares held by the 8VC Angel Fund Entities except to the extent of his, her or its pecuniary interest therein. The 346,668 and 8,159 shares offered by 8VC Angel Fund I, L.P. and 8VC Angel Fund I Associates, L.P. are subject to the Lock-up Agreement.
- The number of shares of Common Stock beneficially owned by Yeda Research & Development Co. Ltd. includes 598,998 shares of our Common Stock issuable upon exercisable of 598,998 warrants.

Private Placement Warrants

| Name | Number of Private Placement Warrants Beneficially Owned(1) | Number of Private Placement Warrants Offered Hereby | Private Placement Warrants Beneficially Owned After Completion of the Offering | |
|------------------------|--|---|--|------------|
| | | | Number | Percentage |
| Mountain Wood, LLC (1) | 2,900,000 | 2,900,000 | 0 | 0 |

(1) Represents warrants to purchase 2,900,000 shares of Common Stock held by Mountain Wood, LLC, which owns approximately 67.96% of our Sponsor. Jonas Grossman, a member of our Board of Directors is the managing member of each of our Sponsor and Mountain Wood, LLC, and thereby has sole voting and dispositive power over such shares. The business address of each of the foregoing is c/o Chardan Healthcare Acquisition Corp., 17 State Street, 21st Floor, New York, NY 10004.

PLAN OF DISTRIBUTION

We are registering the resale of Common Stock and Private Placement Warrants, offered by this prospectus on behalf of the Selling Securityholders. The Selling Securityholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling Common Stock and Private Placement Warrants received after the date of this prospectus from a Selling Securityholder as a gift, pledge, limited liability company or partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their securities on any stock exchange, market or trading facility on which such securities are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale or at negotiated prices.

The Selling Securityholders may use any one or more of the following methods when disposing of their securities or interests therein:

- in market transactions, including transactions on a national securities exchange or quotations service or OTC market;
- in privately negotiated transactions;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- in a block trade in which a broker-dealer will attempt to sell a block of securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- through the settlement of short sales (including short sales “against the box”), in each case subject to compliance with the Securities Act and other applicable securities laws;
- through one or more underwriters in a public offering on a firm commitment or best-efforts basis;
- an exchange distribution in accordance with the rules of the applicable exchange, if any;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- broker-dealers may agree with the Selling Securityholders to sell a specified number of such securities at a stipulated price per security;
- directly to one or more purchasers;
- in other ways not involving market makers or established trading markets;
- by pledge to secure debts and other obligations;
- through agents; or
- in any combination of the above or by any other legally available means.

The Selling Securityholders may, from time to time, pledge or grant a security interest in some or all of the securities owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell their securities, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of Selling Securityholders to include the pledgee, transferee or other successors in interest as Selling Securityholders under this prospectus. The Selling Securityholders also may transfer their securities in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our securities or interests therein, the Selling Securityholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of our securities in the course of hedging the positions they assume. The Selling Securityholders may also sell their securities short and deliver these securities to close out their short positions, or loan or pledge such securities to broker-dealers that in turn may sell these securities. The Selling Securityholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealers or other financial institutions of securities offered by this prospectus, which securities such broker-dealers or other financial institutions may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the Selling Securityholders from the sale of the securities offered by them will be the purchase price of the security less discounts or commissions, if any. Each of the Selling Securityholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of their securities to be made directly or through agents. We will not receive any of the proceeds from the resale of securities being offered by the Selling Securityholders named herein. However, we will receive proceeds from the exercise of the Warrants if they are exercised by a holder thereof.

The Selling Securityholders also may resell all or a portion of their securities in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

The Selling Securityholders and any broker-dealers that act in connection with the sale of securities might be deemed to be “underwriters” within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by such broker-dealers and any profit on the resale of the securities sold by them while acting as principals might be deemed to be underwriting discounts or commissions under the Securities Act.

To the extent required, the securities to be sold, the names of the Selling Securityholders, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

DESCRIPTION OF SECURITIES

General

Our Amended and Restated Certificate of Incorporation currently authorizes the issuance of 30,000,000 shares of Common Stock, and 1,000,000 shares of preferred stock, par value \$0.0001. As of December 3, 2019, 22,041,620 shares of Common Stock were issued and outstanding. As of October 28, 2019, immediately after the consummation of the Business Combination, 22,835,153 shares of Common Stock were issued and outstanding and no preferred shares were issued or outstanding. The following description summarizes the material terms of our capital stock. Because it is only a summary, it may not contain all the information that is important to you.

Common Stock

Our holders of record of our Common Stock are entitled to one vote for each share held on all matters to be voted on by stockholders. Our stockholders have no conversion, preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to the shares of Common Stock. Our Board of Directors is divided into three classes, each of which will generally serve for a term of three years with only one class of directors being elected in each year. There is no cumulative voting with respect to the election of directors. Our stockholders are entitled to receive ratable dividends when, as and if declared by our Board of Directors out of funds legally available therefor.

We have not paid any cash dividends on our Common Stock to date and do not intend to pay cash dividends. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of our Board of Directors at such time.

Preferred Stock

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

Warrants

As of September 30, 2019, we have 7,000,000 Public Warrants and 2,900,000 Private Placement Warrants outstanding.

Each Public Warrant entitles the registered holder to purchase one-half (1/2) of a share of Common Stock at a price of \$11.50 per whole share, subject to adjustment as discussed below, at any time commencing on December 18, 2019. Pursuant to the warrant agreement, a warrant holder may exercise its warrants only for a whole number of shares. This means that only an even number of Public Warrants may be exercised at any given time by a warrant holder. However, no Public Warrants will be exercisable for cash unless we have an effective and current registration statement covering the shares of Common Stock issuable upon exercise of the Public Warrants and a current prospectus relating to such shares of Common Stock. Notwithstanding the foregoing, if this registration statement is not effective by February 25, 2020, Public Warrant holders may, until such time as the registration statement becomes effective and during any period when we shall have failed to maintain an effective registration statement, exercise warrants on a cashless basis pursuant to an available exemption from registration under the Securities Act. The warrants will expire five years from the closing of the Business Combination at 5:00 p.m., New York City time.

The Private Placement Warrants are identical to the Public Warrants underlying the Public Units issued in our IPO except that (i) each Private Placement Warrant is exercisable for one share of Common Stock at an exercise price of \$11.50 per share, and (ii) such Private Placement Warrants are exercisable for cash (even if this registration statement covering the shares of Common Stock issuable upon exercise of the Public Warrants is not effective) or on a cashless basis, at the holder's option, and will not be redeemable by us, in each case so long as they are still held by the initial purchasers or their affiliates.

We may call the outstanding Public Warrants for redemption (but not the Private Placement Warrants), in whole and not in part, at a price of \$0.01 per warrant:

- at any time while the Public Warrants are exercisable,
- upon not less than 30 days' prior written notice of redemption to each warrant holder,
- if, and only if, the reported last sale price of the shares of Common Stock equals or exceeds \$16.00 per share, for any 20 trading days within a 30-day trading period ending on the third business day prior to the notice of redemption to 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 Public Warrants at the time of redemption and for the entire 30-day trading period referred to above and continuing each day thereafter until the date of redemption.

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

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

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

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

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

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

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

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

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

Contractual Arrangements with respect to the Private Placement Warrants

We have agreed that so long as the Private Placement Warrants are still held by the initial purchasers or their affiliates, we will not redeem such Private Placement Warrants and we will allow the holders to exercise such Private Placement Warrants on a cashless basis. However, once any of the foregoing Private Placement Warrants are transferred from the initial purchasers or their affiliates, these arrangements will no longer apply.

Our Transfer Agent and Warrant Agent

The transfer agent for our shares of Common Stock and warrant agent for our Warrants is Continental Stock Transfer & Trust Company, 17 Battery Place, New York, New York 10004.

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

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

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

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

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

Special meeting of stockholders

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

Advance notice requirements for stockholder proposals and director nominations

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

Rule 144

Pursuant to Rule 144, a person who has beneficially owned restricted shares of our Common Stock or Warrants for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale and have filed all required reports under Section 13 or 15(d) of the Exchange Act during the 12 months (or such shorter period as we were required to file reports) preceding the sale.

Persons who have beneficially owned restricted shares of our Common Stock or Warrants for at least six months but who are our affiliates at the time of, or at any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of:

- 1% of the total number of shares of Common Stock then outstanding; or
- the average weekly reported trading volume of the Common Stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales by our affiliates under Rule 144 are also limited by manner of sale provisions and notice requirements and to the availability of current public information about us.

For purposes of the six-month holding period requirement of Rule 144, a person who beneficially owns restricted shares of our Common Stock issued pursuant to a cashless exercise of a Warrant shall be deemed to have acquired such shares, and the holding period for such shares shall be deemed to have commenced, on the date the Warrant was originally issued.

Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies

Rule 144 is not available for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. However, Rule 144 also includes an important exception to this prohibition if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company.

The Company filed its "Form 10 Information" with SEC on November 1, 2019 by filing a Current Report on Form 8-K to report the closing of the Business Combination and related matters, as amended and supplemented by Current Reports on Form 8-K/A filed by the Company on November 4 and 13, 2019.

Registration Rights Agreement

The holders of our (i) Public Shares issued and outstanding on the date of this prospectus, (ii) Private Placement Warrants (and underlying securities) and any securities issued to our initial stockholders, officers, directors or their affiliates in payment of working capital loans made to us, (iii) Public Warrants, (iv) shares of Common Stock issued in connection with the Business Combination and underlying warrants issued in exchange for BiomX warrants and (v) shares of Common Stock subject to stockholder purchase agreements to the extent not registered, are entitled to registration rights pursuant to an agreement signed as of the effective date of this offering. The holders of a majority of these securities are entitled to make up to two demands that we register such securities. The holders of the majority of the Public Shares and Public Warrants can elect to exercise these registration rights at any time commencing three months prior to the date on which these Public Shares and Public Warrants are released from escrow. The holders of a majority of the Private Placement Warrants (and underlying securities), securities issued in payment of working capital loans (or underlying securities), shares of Common Stock issued in connection with the Business Combination and underlying warrants issued in exchange for BiomX warrants and shares of Common Stock subject to stockholder purchase agreements to the extent not registered, can elect to exercise these registration rights at any time. In addition, the holders have certain “piggy-back” registration rights with respect to this registration statement. We will bear the expenses incurred in connection with the filing of this registration statement.

In connection with the closing of the Business Combination, on October 28, 2019, we entered into a Registration Rights Agreement (the “Registration Rights Agreement”) with certain shareholders of BiomX.

Under the Registration Rights Agreement, the shareholders were granted registration rights that obligate us to register for resale under the Securities Act, all or any portion of the shares of Common Stock issued as consideration in the Business Combination (the “Registrable Securities”) on or after the six-month anniversary of the Closing Date upon the demand of the holders of 25% of the Registrable Securities; provided that we shall not be obligated to effect more than an aggregate of two demands for registration under the Registration Rights Agreement.

In addition, if at any time on or after the Closing Date, we propose to file a registration statement under the Securities Act with respect to an offering of equity securities (or securities or other obligations exercisable or exchangeable for, or convertible into, equity securities), we shall give written notice of such proposed filing to the holders of the Registrable Securities and offer them an opportunity to register the sale of such number of Registrable Securities as such holders may request in writing, subject to the rights of other persons having registration rights with respect to shares of Common Stock pursuant to written contractual “piggy-back” registration rights and customary cut-backs.

In addition, subject to certain exceptions, the holders of the Registrable Securities are entitled under the Registration Rights Agreement to request in writing that we register the resale of any or all of such Registrable Securities on Form S-3 or any similar short-form registration that may be available at such time.

We agreed to use our best efforts to effect the registration and sale of such Registrable Securities as expeditiously as possible.

Under the Registration Rights Agreement, we agreed to indemnify the holders of Registrable Securities and each of their respective officers, employees, affiliates, directors, partners, members, attorneys and agents and control persons from and against any expenses, losses, judgments, claims, damages or liabilities, whether joint or several, arising out of or based upon any untrue statement (or allegedly untrue statement) of a material fact in any registration statement or prospectus pursuant to which the sale of such Registrable Securities is registered under the Securities Act, unless such liability arises from any untrue statement or allegedly untrue statement or omission or alleged omission made in such registration statement or prospectus in reliance upon and in conformity with information furnished to us by such selling holder expressly for use therein. Each selling holder of Registrable Securities, including Registrable Securities in any registration statement or prospectus, agreed to indemnify us and certain persons or entities related to the Company, such as our officers and directors and underwriters, against all losses caused by their misstatements or omissions in those documents.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

The following is a discussion of the material U.S. federal income tax considerations generally applicable to the acquisition, ownership and disposition of our Common Stock and Warrants. This discussion is limited to certain U.S. federal income tax considerations to beneficial owners of our securities who hold the securities as a capital asset within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). This discussion does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including the alternative minimum tax, the Medicare contribution tax on certain investment income and the different consequences that may apply if you are subject to special rules that apply to certain types of investors, such as:

- financial institutions or financial services entities;
- broker-dealers;
- insurance companies;
- governments or agencies or instrumentalities thereof;
- regulated investment companies;
- real estate investment trusts;
- expatriates or former long-term residents of the United States;
- persons that actually or constructively own five percent or more of our voting shares;
- persons that acquired our securities pursuant to an exercise of employee share options, in connection with employee share incentive plans or otherwise as compensation;
- dealers or traders subject to a mark to market method of accounting with respect to the securities;
- persons holding the securities as part of a "straddle," hedge, constructive sale, conversion or other integrated or similar transaction;
- U.S. holders (as defined below) whose functional currency is not the U.S. dollar;
- persons subject to special tax accounting rules under Section 451(b) of the Code; partnerships or other pass through entities for U.S. federal income tax purposes; and
- tax exempt entities.

If you are a partnership for U.S. federal income tax purposes, the U.S. federal income tax treatment of your partners will generally depend on the status of the partners and your activities.

This discussion is based on the Code and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. tax law other than the U.S. federal income tax (such as gift, estate or Medicare contribution taxes) or except as discussed below, any tax reporting obligations of a holder of our securities. This discussion also assumes that any distribution made (or deemed made on our securities and any consideration received (or deemed received) by a holder from the sale or other disposition of our securities will be in U.S. dollars.

We have not sought, and will not seek, a ruling from the Internal Revenue Service (the "IRS") as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion.

THIS DISCUSSION IS ONLY A SUMMARY OF THE U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES. EACH PROSPECTIVE INVESTOR IN OUR SECURITIES IS URGED TO CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY STATE, LOCAL, AND NON-U.S. TAX LAWS, AS WELL AS U.S. FEDERAL TAX LAWS AND ANY APPLICABLE TAX TREATIES.

U.S. Holders

This section applies to you if you are a “U.S. holder.” A U.S. holder is a beneficial owner of our securities that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust, or (ii) it has in effect a valid election to be treated as a U.S. person.

Taxation of Distributions. If we pay cash distributions to U.S. holders of shares of our Common Stock, such distributions generally will be treated as a dividend for U.S. federal income tax purposes to the extent the distribution is paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. holder’s adjusted tax basis in our Common Stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the common stock and will be treated as described under “U.S. holders — Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Our Securities” below.

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder generally will constitute “qualified dividends” that will be subject to tax at the maximum tax rate accorded to long-term capital gains.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Our Securities. Upon a sale or other taxable disposition of our securities which, in general, would include a redemption of common stock or warrants, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder’s adjusted tax basis in such securities. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder’s holding period for the securities so disposed of exceeds one year. Long-term capital gains recognized by non-corporate U.S. holders will be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to various limitations that are not described herein because a discussion of such limitations depends on each U.S. holder’s particular facts and circumstances.

Generally, the amount of gain or loss recognized by a U.S. holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. holder’s adjusted tax basis in its securities so disposed of. A U.S. holder’s adjusted tax basis in its common stock or warrants generally will equal the U.S. holder’s acquisition cost less, in the case of a share of common stock, any prior distributions treated as a return of capital.

Exercise or Lapse of a Warrant. Except as discussed below with respect to the cashless exercise of a warrant, a U.S. holder generally will not recognize taxable gain or loss from the acquisition of common stock upon exercise of a warrant for cash. The U.S. holder’s tax basis in the share of our Common Stock received upon exercise of the warrant generally will be an amount equal to the sum of the U.S. holder’s initial investment in the warrant and the exercise price. If a warrant is allowed to lapse unexercised, a U.S. holder generally will recognize a capital loss equal to such holder’s tax basis in the warrant.

The tax consequences of a cashless exercise of a warrant are not clear under current tax law. A cashless exercise may be tax-free, either because the exercise is not a realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either tax-free situation, a U.S. holder’s basis in the common stock received would equal the holder’s basis in the warrant. If the cashless exercise were treated as not being a realization event, it is unclear whether a U.S. holder’s holding period for the shares of Common Stock would be treated as commencing on the date of exercise of the warrant or the day following the date of exercise of the warrant. If the cashless exercise were treated as a recapitalization, the holding period of the common stock would include the holding period of the warrant.

It is also possible that a cashless exercise could be treated in part as a taxable exchange in which gain or loss would be recognized. In such event, a U.S. holder could be deemed to have surrendered warrants equal to the number of common shares having a value equal to the exercise price for the total number of warrants to be exercised. The U.S. holder would recognize capital gain or loss in an amount equal to the difference between the fair market value the warrants deemed surrendered and the U.S. holder’s tax basis in the warrants deemed surrendered. In this case, a U.S. holder’s tax basis in the common stock received would equal the sum of the fair market value of the warrants deemed surrendered and the U.S. holder’s tax basis in the warrants exercised. It is unclear whether a U.S. holder’s holding period for the shares of Common Stock would commence on the date of exercise of the warrant or the day following the date of exercise of the warrant.

Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance which, if any, of the alternative tax consequences described above would be adopted by the IRS or a court of law. Accordingly, U.S. holders should consult their tax advisors regarding the tax consequences of a cashless exercise.

Possible Constructive Distributions. The terms of each warrant provide for an adjustment to the number of shares of Common Stock for which the warrant may be exercised or to the exercise price of the warrant in certain events, as discussed in the section of this prospectus captioned “Description of Securities — Warrants.” An adjustment which has the effect of preventing dilution generally is not taxable. The U.S. holders of the warrants would, however, be treated as receiving a constructive distribution from us if, for example, the adjustment increases the warrant holders’ proportionate interest in our assets or earnings and profits (e.g., through an increase in the number of shares of Common Stock that would be obtained upon exercise) as a result of a distribution of cash to the holders of shares of our Common Stock which is taxable to the U.S. holders of such shares as described under “U.S. holders — Taxation of Distributions” above. For example, if the exercise price of the warrants is decreased as a result of certain taxable dividends paid to holders of the common stock (as contemplated by the terms of the warrant in certain circumstances), then the amount by which such exercise was decreased could be considered an increase in the warrant holder’s proportionate interest in our assets or earnings and profits, which may result in a constructive distribution to holders of the warrants. Such constructive distribution would be subject to tax as described under that section in the same manner as if the U.S. holders of the warrants received a cash distribution from us equal to the fair market value of such increased interest. For certain information reporting purposes, we are required to determine the date and amount of any such constructive distributions. Recently proposed Treasury regulations, which we may rely on prior to the issuance of final regulations, specify how the date and amount of constructive distributions are determined.

Information Reporting and Backup Withholding. In general, information reporting requirements may apply to dividends paid to a U.S. holder and to the proceeds of the sale or other disposition of our securities, unless the U.S. holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn).

Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against a U.S. holder’s U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Non-U.S. Holders

This section applies to you if you are a “Non-U.S. holder.” A Non-U.S. holder is a beneficial owner of our securities who or that is, for U.S. federal income tax purposes:

- a non-resident alien individual, other than certain former citizens and residents of the United States subject to U.S. tax as expatriates;
- a foreign corporation; or
- an estate or trust that is not a U.S. holder;

but does not include an individual who is present in the United States for 183 days or more in the taxable year of disposition.

If you are such an individual, you should consult your tax advisor regarding the U.S. federal income tax consequences of the sale or other disposition of a security.

Taxation of Distributions. In general, any distributions we make to a Non-U.S. holder of shares of our Common Stock, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the Non-U.S. holder’s conduct of a trade or business within the United States, we will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such Non-U.S. holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E). Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the Non-U.S. holder’s adjusted tax basis in its shares of our Common Stock and, to the extent such distribution exceeds the Non-U.S. holder’s adjusted tax basis, as gain realized from the sale or other disposition of the common stock, which will be treated as described under “Non-U.S. holders — Gain on Sale, Taxable Exchange or Other Taxable Disposition of Our Securities” below. In addition, if we determine that we are classified as a “United States real property holding corporation” (see “Non-U.S. holders — Gain on Sale, Taxable Exchange or Other Taxable Disposition of Our Securities” below), we will withhold 15% of any distribution that exceeds our current and accumulated earnings and profits.

The withholding tax does not apply to dividends paid to a Non-U.S. holder who provides a Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States. Instead, the effectively connected dividends will be subject to regular U.S. federal income tax as if the Non-U.S. holder were a U.S. resident, subject to an applicable income tax treaty providing otherwise. A Non-U.S. corporation receiving effectively connected dividends may also be subject to an additional "branch profits tax" imposed at a rate of 30% (or a lower treaty rate).

Exercise of a Warrant. The U.S. federal income tax treatment of a Non-U.S. holder's exercise of a warrant, or the lapse of a warrant held by a Non-U.S. holder, generally will correspond to the U.S. federal income tax treatment of the exercise or lapse of a warrant by a U.S. holder, as described under "U.S. holders — Exercise or Lapse of a Warrant" above, although to the extent a cashless exercise results in a taxable exchange, the consequences would be similar to those described below in "Non-U.S. holders — Gain on Sale, Taxable Exchange or Other Taxable Disposition of Our Securities."

Possible Constructive Distributions. Under certain circumstances, a Non-U.S. holder may be deemed to have received a constructive dividend (see "— U.S. holders — Possible Constructive Distributions" above). Any such constructive distribution deemed received will be treated, and therefore generally be subject to withholding, in the same manner as an actual dividend received (and may be subject to information reporting), as discussed above under "— Non-U.S. Holders — Taxation of Distributions." Because a constructive dividend received by a Non-U.S. holder would not give rise to any cash from which any applicable withholding tax could be satisfied, if we or the withholding agent pays withholding taxes on the Non-U.S. holder's behalf with respect to amounts which are includible in the Non-U.S. holder's income but which are not paid in cash, we or the withholding agent may withhold any such withholding tax from any other payments owed to the Non-U.S. holder or other assets, including cash payments of interest payable on the notes, shares of common stock or cash payable upon conversion, or proceeds from a sale subsequently paid or credited to the Non-U.S. holder. If we deduct, or such withholding agent deducts, any such amount from interest payments on a Non-U.S. holder's notes under these circumstances, such Non-U.S. holder should consult its own tax advisor as to whether it can obtain a refund for all or a portion of any tax withheld.

Gain on Sale, Taxable Exchange or Other Taxable Disposition of Our Securities. A Non-U.S. holder generally will not be subject to U.S. federal income or withholding tax in respect of gain recognized on a sale, taxable exchange or other taxable disposition of our securities unless:

- the gain is effectively connected with the conduct of a trade or business by the Non-U.S. holder within the United States (and, under certain income tax treaties, is attributable to a United States permanent establishment or fixed base maintained by the Non-U.S. holder); or
- we are or have been a "U.S. real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. holder held our securities, and, in the case where shares of our Common Stock are regularly traded on an established securities market, the Non-U.S. holder has owned, directly or constructively, more than 5% of our Common Stock at any time within the shorter of the five-year period preceding the disposition or such Non-U.S. holder's holding period for the shares of our Common Stock. There can be no assurance that our Common Stock will be treated as regularly traded on an established securities market for this purpose.

Unless an applicable treaty provides otherwise, gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates as if the Non-U.S. holder were a U.S. resident. Any gains described in the first bullet point above of a Non-U.S. holder that is a foreign corporation may also be subject to an additional "branch profits tax" at a 30% rate (or lower treaty rate).

If the second bullet point above applies to a Non-U.S. holder, gain recognized by such holder on the sale, exchange or other disposition of our securities will be subject to tax at generally applicable U.S. federal income tax rates. In addition, a buyer of our securities from such holder may be required to withhold U.S. federal income tax at a rate of 15% of the amount realized upon such disposition. We will be classified as a U.S. real property holding corporation if the fair market value of our "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of our worldwide real property interests plus our other assets used or held for use in a trade or business, as determined for U.S. federal income tax purposes.

Information Reporting and Backup Withholding. Information returns will be filed with the IRS in connection with payments of dividends and the proceeds from a sale or other disposition of our securities. A Non-U.S. holder may have to comply with certification procedures to establish that it is not a United States person in order to avoid information reporting and backup withholding requirements. The certification procedures required to claim a reduced rate of withholding under a treaty will satisfy the certification requirements necessary to avoid the backup withholding as well. The amount of any backup withholding from a payment to a Non-U.S. holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

FATCA Withholding Taxes

Provisions commonly referred to as "FATCA" impose withholding of 30% on payments of dividends (including constructive dividends) on our securities, and, beginning January 1, 2019, sales or other disposition proceeds from our securities to "foreign financial institutions" (which is broadly defined for this purpose and in general includes investment vehicles) and certain other Non-U.S. entities unless various U.S. information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in or accounts with those entities) have been satisfied, or an exemption applies (typically certified as to by the delivery of a properly completed IRS Form W-8BEN-E). If FATCA withholding is imposed, a beneficial owner of the payment that is not a foreign financial institution (or that is a foreign financial institution entitled to a reduced rate of withholding tax with respect to such payment under an income tax treaty) generally may be entitled to a refund or credit of any amounts withheld by filing a U.S. federal income tax return and providing certain other information to the IRS (which may entail significant administrative burden). Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Notwithstanding the foregoing, the IRS has issued proposed regulations, upon which taxpayers may generally rely, that exclude gross proceeds from the sale or other disposition of our securities from the application of the withholding tax imposed under FATCA. Prospective investors should consult their tax advisers regarding the effects of FATCA on their investment in our securities.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Mayer Brown LLP.

EXPERTS

The financial statements of the Company included in this prospectus have been audited by Brightman Almagor Zohar & Co., an independent registered public accounting firm, as stated in their report appearing herein, and are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are subject to the filing requirements of the Exchange Act. Therefore, we file periodic reports, proxy statements and other information with the Commission. The Commission maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act available free of charge through a link on the Investors section of our website located at www.biomx.com as soon as reasonably practicable after they are filed with or furnished to the Commission. The information contained in or accessible through our website or contained on other websites is not a part of, and is not incorporated into, this prospectus.

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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, 2018 and 2017, the related consolidated statements of consolidated loss, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our 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 audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our 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
December 13, 2019

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

BIOMX INC.
(FORMERLY CHARDAN HEALTHCARE ACQUISITION CORP.)
CONSOLIDATED BALANCE SHEETS

| | <u>Note</u> | <u>As of December 31,</u> | |
|--|-------------|---------------------------|---------------|
| | | <u>2018</u> | <u>2017</u> |
| | | <u>USD In thousands</u> | |
| ASSETS | | | |
| Current assets | | | |
| Cash and cash equivalents | | 8,604 | 6,898 |
| Restricted cash | | 89 | 95 |
| Short-term deposits | 2D | 31,055 | 1,154 |
| Other receivables | 3 | 140 | 327 |
| Total current assets | | <u>39,888</u> | <u>8,474</u> |
| Property and equipment, net | 4 | <u>887</u> | <u>960</u> |
| In-process research and development ("R&D") | 5 | <u>4,556</u> | <u>4,556</u> |
| | | <u>45,331</u> | <u>13,990</u> |

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

BIOMX LTD.
CONSOLIDATED BALANCE SHEETS

| | <u>Note</u> | <u>As of December 31,</u> | |
|---|-------------|---------------------------|---------------|
| | | <u>2018</u> | <u>2017</u> |
| | | <u>USD In thousands</u> | |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | | |
| Current liabilities | | | |
| Trade account payables | | 193 | 421 |
| Other account payables | 6 | 1,396 | 1,038 |
| Related parties | 7 | 50 | - |
| Total current liabilities | | <u>1,639</u> | <u>1,459</u> |
| Non-current liabilities | | | |
| Contingent liabilities | 5 | 889 | 1,001 |
| Total non-current liabilities | | <u>889</u> | <u>1,001</u> |
| Commitments and Contingent Liabilities | 8 | | |
| Shareholders' equity | | | |
| Ordinary shares (pre-merger - BiomX Ltd.), \$ 0.0001 par value ("Ordinary Shares"); Authorized 33,954,304 shares as of December 31, 2018 and 26,468,133 shares as of December 31, 2017. Issued and outstanding 2,307,871 shares as of December 31, 2018 and 1,580,159 shares as of December 31, 2017. | | (*) | (*) |
| Ordinary A shares (pre-merger - BiomX Ltd.), \$ 0.0001 par value ("Ordinary A Shares"); Authorized 2,417,575 shares as of December 31, 2018 and December 31, 2017. Issued and outstanding 0 as of December 31, 2018 and 696,774 shares as of December 31, 2017. | | (*) | (*) |
| Preferred A shares (pre-merger - BiomX Ltd.), ("Preferred A Shares"); \$ 0.0001 par value; Authorized 16,430,668 shares as of December 31, 2018 and December 31, 2017. Issued and outstanding 7,543,831 shares as of December 31, 2018 and 4,514,841 shares as of December 31, 2017. | | 1 | (*) |
| Preferred B shares (pre-merger - BiomX Ltd.), ("Preferred B Shares"); \$ 0.0001 par value; Authorized 6,858,371 shares as of December 31, 2018 and 0 shares as of December 31, 2017. Issued and outstanding 5,170,357 shares as of December 31, 2018 and 0 shares as of December 31, 2017. | | 1 | - |
| Additional paid in capital | | 64,410 | 20,419 |
| Accumulated deficit | | (21,609) | (8,889) |
| Total shareholders' equity | | <u>42,803</u> | <u>11,530</u> |
| | | <u>45,331</u> | <u>13,990</u> |

(*) Less than \$1,000.

** 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

| | Note | Year ended December 31, | | |
|---|------|-------------------------|-----------|-----------|
| | | 2018 | 2017 | 2016 |
| | | USD In thousands | | |
| Research and development (“R&D”) expenses, net | 11 | 9,135 | 4,176 | 1,149 |
| General and administrative expenses | 12 | 3,360 | 2,536 | 620 |
| Operating Loss | | 12,495 | 6,712 | 1,769 |
| Revaluation of convertible note | 9 | - | - | 133 |
| Financial expenses, net | | 225 | (279) | (2) |
| Net Loss | | 12,720 | 6,433 | 1,900 |
| Basic and diluted loss per Ordinary Shares and Ordinary A Shares | 14 | 7.62 | 3.76 | 1.01 |
| Weighted average number of Ordinary Shares and Ordinary A Shares outstanding, basic and diluted | | 2,002,464 | 1,967,669 | 1,963,071 |

** 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.
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
 USD in thousands except share data

| | Ordinary Shares (pre-merger - BiomX Ltd.) | | Ordinary A Shares (pre-merger - BiomX Ltd.) | | Preferred A Shares (pre-merger - BiomX Ltd.) | | Preferred B Shares (pre-merger - BiomX Ltd.) | | Additional paid in capital | Accumulated deficit | Total shareholders' equity (deficit) |
|--|---|--------|---|--------|--|--------|--|--------|----------------------------|---------------------|--------------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| Balance as of January 1, 2016 | 2,265,899 | (*) | - | - | 566,068 | (*) | - | - | 1,198 | (556) | 642 |
| Share-based payment | - | - | - | - | - | - | - | - | 247 | - | 247 |
| Net loss | - | - | - | - | - | - | - | - | - | (1,900) | (1,900) |
| Balance as of December 31, 2016 | 2,265,899 | (*) | - | - | 566,068 | (*) | - | - | 1,445 | (2,456) | (1,011) |
| Issuance of shares (**) | - | - | - | - | 3,028,990 | (*) | - | - | 13,002 | - | 13,002 |
| Conversion of Ordinary to Ordinary A Shares | (696,774) | - | 696,774 | (*) | - | - | - | - | - | - | - |
| Shares issued in connection with convertible note conversion | - | - | - | - | 315,334 | (*) | - | - | 1,333 | - | 1,333 |
| Shares issued in connection with acquisition of subsidiary | - | - | - | - | 604,449 | (*) | - | - | 3,329 | - | 3,329 |
| Share-based payment | - | - | - | - | - | - | - | - | 1,310 | - | 1,310 |
| Exercise of options | 11,034 | (*) | - | - | - | - | - | - | - | - | - |
| Net loss | - | - | - | - | - | - | - | - | - | (6,433) | (6,433) |
| Balance as of December 31, 2017 | 1,580,159 | (*) | 696,774 | (*) | 4,514,841 | (*) | - | - | 20,419 | (8,889) | 11,530 |
| Issuance of shares (***) | - | - | - | - | 3,028,990 | 1 | 5,170,357 | 1 | 43,040 | - | 43,042 |
| Conversion of 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 |

(*) Less than \$1,000.

(**) Net of issuance expenses in amount of \$73,000.

(***) Net of issuance expenses in amount of \$114,000.

** 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

| | For year ended December 31, | | |
|---|--------------------------------|----------------|----------------|
| | 2018 | 2017 | 2016 |
| | USD In thousands | | |
| CASH FLOWS – OPERATING ACTIVITIES | | | |
| Net loss | (12,720) | (6,433) | (1,900) |
| Adjustments required to reconcile cash flows used in operating activities | | | |
| Depreciation | 210 | 95 | 23 |
| Share-based compensation | 951 | 1,310 | 247 |
| Accrued interest | - | - | 2 |
| Revaluation of convertible security and contingent liabilities | (112) | - | 133 |
| Changes in operating assets and liabilities: | | | |
| Other receivables | 187 | (225) | 63 |
| Trade account payables | (228) | 407 | (15) |
| Other account payables | 358 | 783 | 92 |
| Related parties | 50 | (37) | 19 |
| Net cash used in operating activities | (11,304) | (4,100) | (1,336) |
| CASH FLOWS – INVESTING ACTIVITIES | | | |
| Increase in short-term deposit | (29,901) | (1,154) | - |
| Acquisition of a subsidiary, net of cash acquired | - | (112) | - |
| Purchase of property and equipment | (137) | (850) | (98) |
| Net cash used in investing activities | (30,038) | (2,116) | (98) |
| CASH FLOWS – FINANCING ACTIVITIES | | | |
| Issuance of preferred shares, net of issuance costs | 43,042 | 12,953 | - |
| Proceeds from issuance of convertible notes | - | - | 1,200 |
| Exercise of stock options | (*) | (*) | - |
| Net cash provided by financing activities | 43,042 | 12,953 | 1,200 |
| Increase in cash and cash equivalents and restricted cash | 1,700 | 6,737 | (234) |
| Cash and cash equivalents and restricted cash at the beginning of the year | 6,993 | 256 | 490 |
| Cash and cash equivalents and restricted cash at the end of the year | 8,693 | 6,993 | 256 |

(*) Less than \$1,000.

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

BIOMX INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

| For the year ended December 31, | | |
|------------------------------------|------|------|
| 2018 | 2017 | 2016 |
| USD In thousands | | |

SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:

| | | | |
|---|---|-------|---|
| Conversion of convertible notes into Preferred A Shares | - | 1,333 | - |
|---|---|-------|---|

Appendix A: Acquisitions of subsidiary consolidated for the first time

| | | | |
|---|---|-------|---|
| Working capital (excluding cash and cash equivalents) | - | (78) | - |
| Property and equipment, net | - | 14 | - |
| In-process R&D | - | 4,556 | - |
| Acquisition of a subsidiary, net of cash acquired | - | 4,492 | - |

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 (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, Chardan Healthcare Acquisition Corp. 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 Israel.

On October 28, 2019, the Company acquired (the “Recapitalization Transaction”) 100% of the outstanding shares of BiomX Israel. 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. In addition, the company reserved 1,555,942 shares for the warrants and Options of BiomX Israel. 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 financial statements of the Company were replaced with the financial statements of BiomX Israel for all periods presented.

Following the Recapitalization Transaction, the Company retained the \$60.1 Million balance held in the trust account.

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 securities of the combined company began trading on the NYSE American stock exchange on October 28 and the combined company was renamed BiomX Inc.

Commencing October 29, 2019 the combined company shares of common stock, units, and warrants are traded under the symbols PHGE, PHGE.U, and PHGE.WS, respectively.

The Company and its subsidiaries, BiomX Ltd. and RondinX Ltd. are collectively referred to as the “Company”.

B. Risk factors:

To date, the Company has not generated revenue from its operations. As of November 29, 2019, the Company had unrestricted cash and cash equivalent balance and short-term deposits of approximately \$85million, 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.

Due to 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 either 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 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.

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

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

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

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 BiomX and its wholly owned subsidiary, RondinX since its acquisition in November 2017. 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 Translation.”

All transaction gains and losses from remeasurement of monetary balance sheet items denominated in non-dollar 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.

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 interest income in the consolidated statement of comprehensive loss during the years for which the Company held short-term deposits.

The Company has deposits denominated in USD held with Bank Hapoalim US and Bank Leumi Israel that bear fixed annual interest of 2.9% to 3.6%.

E. Property and equipment:

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

| | % |
|-------------------------|--------------------------------------|
| Laboratory equipment | 15 |
| Computers and software | 33 |
| Equipment and furniture | 15 |
| Leasehold improvements | Shorter of lease term or useful life |

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

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (Cont.)

E. Property and equipment (Cont.):

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, 2018, 2017, and 2016, no impairment expenses were recorded.

F. 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.

G. 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, 2018 and 2017, the Company had a full valuation allowance against deferred tax assets.

The Company is subject to the provisions of ASC 740-10-25, Income Taxes (ASC 740). ASC 740 prescribes a more likely-than-not threshold for the financial statement recognition of uncertain tax positions. ASC 740 clarifies the accounting for income taxes by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. On a yearly basis, the Company undergoes a process to evaluate whether income tax accruals are in accordance with ASC 740 guidance on uncertain tax positions. The Company has not recorded any liability for uncertain tax positions for the years ended December 31, 2018, 2017, or 2016.

H. 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.

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

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (Cont.)

H. Fair value of financial instruments (Cont.)

There were no changes in the fair value hierarchy leveling during the years ended December 31, 2018, 2017, and 2016.

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, as of December 31, 2018 and 2017:

| | December 31, 2018 | | | Fair Value |
|--------------------------|-------------------|---------|---------|------------|
| | Level 1 | Level 2 | Level 3 | |
| Liabilities | | | | |
| Contingent consideration | - | - | 889 | 889 |

| | December 31, 2017 | | | Fair Value |
|--------------------------|-------------------|---------|---------|------------|
| | Level 1 | Level 2 | Level 3 | |
| Liabilities | | | | |
| Contingent consideration | - | - | 1,001 | 1,001 |

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.

I. R&D costs:

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

J. Basic and diluted loss per share:

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

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

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (Cont.)

K. 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 to 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 statement of comprehensive loss as and when the services are received from the Company’s employees. Total expenses with respect to these contributions were \$283 thousand, \$145 thousand, and \$42 thousand for the years ended December 31, 2018, 2017, and 2016, respectively.

L. 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.

The Company accounts for share-based compensation awards to non-employees in accordance with FASB ASC 505-50, “Equity-Based Payments to Non-Employees” (“FASB ASC 505-50”). Under FASB ASC 505-50, the Company determines the fair value of the warrants or share-based compensation awards granted as either the fair value of the consideration received, or the fair value of the equity instruments issued, whichever is more reliably measurable.

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. Non-employee share-based payments are recorded as an expense over the service period, as if the Company had paid cash for the services. At the end of each financial reporting period, prior to vesting or prior to the completion of the services, the fair value of the share-based payments will be remeasured and the non-cash expense recognized during the period will be adjusted accordingly. Since the fair value of share-based payments granted to non-employees is subject to change in the future, the amount of the future expense will include fair value remeasurements until the share-based payments are fully vested or the service completed.

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

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (Cont.)

L. Stock compensation plans: (Cont.)

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

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.

M. Recent Accounting Standards:

In February 2016, the FASB issued ASU 2016-02 “Leases” to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. For operating leases, the ASU requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, on its balance sheet. The ASU retains the current accounting for lessors and does not make significant changes to the recognition, measurement, and presentation of expenses and cash flows by a lessee.

In July 2018, the FASB issued ASU No. 2018-11, “Targeted Improvements - Leases (Topic 842).” This update provides an optional transition method that allows entities to elect to apply the standard prospectively at its effective date versus recasting the prior periods presented. If elected, an entity would recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company plans to adopt this ASU in the first quarter of 2019.

While the Company continues to assess all of the effects of adoption, it currently believes the most significant effects from implementing this standard relate to the recognition of new right-of-use (“ROU”) assets and lease liabilities on its balance sheet for office space operating lease. Upon adoption, the Company currently expects to recognize additional ROU assets and lease liabilities of approximately \$377K, based on the present value of the remaining minimum rental payments under current leasing standards for its existing operating lease.

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 June 2018, the FASB issued ASU No. 2018-07 “Compensation– Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.” These amendments expand the scope of Topic 718, Compensation – Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, Equity – Equity-Based Payments to Non-Employees. The Company plans to adopt this standard in the first quarter of 2019. ASU 2018-07 is not expected to have a material impact on Company’s consolidated financial statements.

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

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (Cont.)

M. Recent Accounting Standards: (Cont.)

In August 2018, the FASB issued ASU 2018-13, "Changes to Disclosure Requirements for Fair Value Measurements," which will improve the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements and 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 expects to adopt this standard in the first quarter of fiscal year 2020. This standard is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

NOTE 3 – OTHER RECEIVABLES

| | As of December 31, | |
|-----------------------------|---------------------------|-------------|
| | 2018 | 2017 |
| | USD In thousands | |
| Government institutions | 129 | 199 |
| Grant income receivable | - | 128 |
| Prepaid expenses and others | 11 | - |
| | <u>140</u> | <u>327</u> |

NOTE 4 – PROPERTY AND EQUIPMENT, NET

| | As of December 31, | |
|-------------------------|---------------------------|--------------|
| | 2018 | 2017 |
| | USD In thousands | |
| Cost: | | |
| Computers and software | 272 | 236 |
| Laboratory equipment | 608 | 558 |
| Equipment and furniture | 132 | 120 |
| Leasehold improvements | 214 | 175 |
| | <u>1,226</u> | <u>1,089</u> |
| Depreciation: | | |
| Computers and software | 125 | 60 |
| Laboratory equipment | 165 | 59 |
| Equipment and furniture | 4 | 3 |
| Leasehold improvements | 45 | 7 |
| | <u>339</u> | <u>129</u> |
| | <u>887</u> | <u>960</u> |

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

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 for consideration valued at US\$ 4.5 million. The consideration included the issuance of 640,449 Preferred A Shares, the issuance of warrants to purchase an aggregate of 10,589 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 567,763 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 acquisition on November 27, 2017.

The fair value of the consideration transferred for the business combination was as follows as of November 27, 2017:

| | USD In thousands |
|---|-------------------------|
| Cash | 124 |
| Preferred shares | 2,938 |
| Warrants | 51 |
| Contingent consideration in ordinary shares | 392 |
| Contingent consideration in cash | 999 |
| | 4,504 |

Net cash flow of the acquisition:

| | USD In thousands |
|--|-------------------------|
| Consideration paid in cash | 124 |
| Net of cash and cash equivalents purchased | (12) |
| | 112 |

The fair value of assets acquired and liabilities assumed as of November 27, 2017:

| | USD In thousands |
|-----------------------------|-------------------------|
| Cash | 12 |
| Other receivables | 26 |
| Property and equipment, net | 14 |
| In-process R&D | 4,556 |
| Other account payables | (96) |
| Trade account payables | (8) |
| | 4,504 |

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

NOTE 5 – ACQUISITION OF SUBSIDIARY (Cont.)

Intangible assets acquired in the acquisition 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, 2018, 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, 2018 and 2017.

NOTE 6 – OTHER ACCOUNT PAYABLES

| | As of December 31, | |
|------------------------------------|--------------------|-------|
| | 2018 | 2017 |
| | USD In thousands | |
| Employees and related institutions | 807 | 621 |
| Accrued expenses | 411 | 260 |
| Government institutions | 120 | 126 |
| Deferred income | 58 | - |
| Other account payables | - | 31 |
| | 1,396 | 1,038 |

NOTE 7 – BALANCES AND TRANSACTION WITH RELATED PARTIES

A. Balances with related parties

| | As of December 31, | |
|-----------------------|--------------------|------|
| | 2018 | 2017 |
| | USD In thousands | |
| Janssen (See 1 below) | 50 | - |
| | 50 | - |

B. Transactions with related parties

| | As of December 31, | | |
|---|--------------------|------|------|
| | 2018 | 2017 | 2016 |
| | USD In thousands | | |
| R&D expenses (See Note 8D) | - | - | 163 |
| General and administration expenses (See 2 below) | 28 | 251 | 134 |

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

NOTE 7 – BALANCES AND TRANSACTION WITH RELATED PARTIES

B. Transactions with related parties (Cont.)

1. 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 \$167,000 in installments of \$50,000 within 60 days of signing of the agreement, \$17,000 upon completion of data processing, and two installments of \$50,000 each, upon delivery of Signature Phase I of the Final Study Report (both terms defined within the agreement). Unless terminated earlier, this agreement will continue in effect, until 30 days after the parties complete the research program and BiomX provide Janssen with a final study report. BiomX Israel received the first \$50,000 installment during 2018. This amount was deferred as of December 31, 2018, as the Company has not yet completed its performance obligation with respect to the agreement.
2. In June 2015, an incubator company formation and financing agreement (the “Incubator Agreement”) was signed between BiomX Israel and other investors. According to the agreement, role of the Incubator (as defined within the agreement) is to provide BiomX Israel 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, \$251 thousand, and \$134 thousand for the years ended December 31, 2018, 2017, and 2016, respectively, with respect to this agreement.
3. BiomX Israel entered into a credit line agreement with the Incubator in May 2015 (the “Credit Line Agreement”), according to which, during the Incubator Period (as defined within the Credit Line Agreement) of BiomX Israel, the Incubator may provide loans to BiomX Israel, upon BiomX Israel’s request and subject to the Incubator’s discretion. The loans bear annual interest equivalent to the minimal interest amount recognized and attributed by the Israel Tax Authority, and shall be repaid on a date that is the earlier of (i) the occurrence of an acceleration event, liquidation of the Company, initial public offering or realization event, (ii) within 14 days from a written notice sent by the Company, or (iii) within seven months. The Credit Line Agreement ended on May 31, 2018.

BiomX Israel received a loan in the amount of \$209 thousand during 2015 that was repaid as of December 31, 2015. BiomX Israel received an additional loan during 2016 in the amount of \$107 thousand that was repaid in full by December 31, 2016. The loans bore interest of 2.56% and 3.05% during 2016 and 2015, respectively. Total interest expenses recorded during for the year ended December 31, 2016 was approximately \$1 thousand and \$2 thousand for the years ended December 31, 2016 and 2015, respectively.

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 2,295,000. 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.

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

NOTE 8 – 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 2,700,000 (approximately \$726 thousand) per request. According to the IIA directives, the IIA transferred to the Company 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 the Company. 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 Company's R&D programs and generating sales. The Company 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, 2018; therefore, no liability was recorded in these consolidated financial statements.

Total research and development income recorded in the consolidated statement of comprehensive loss was \$646 thousand, \$660 thousand, and \$302 thousand for the years ended December 31, 2018, 2017, and 2016. As of December 31, 2018 the Company had a contingent obligation to the IIA in the amount of approximately \$1.9 million including annual interest of LIBOR linked to the Dollar.

- B. In June 2015, BiomX Israel entered into a Research and License Agreement (the "2015 License Agreement") as amended with Yeda Research and Development Company Limited ("Yeda"), according to which Yeda undertakes to procure the performance of the 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 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, 2018, 2017 and 2016.
- C. 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 \$16,000. As part of the agreement, the Company has a bank guarantee to the property owner in the amount of approximately \$91 thousand representing four monthly lease payments. Lease expenses recorded in the consolidated statements of comprehensive loss were \$198 thousand and \$192 thousand for the years ended December 31, 2018, and 2017, respectively.

BIOMX INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)

- D.** 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 will pay \$10,000 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 10 below for the terms of the warrants granted. In the event of certain mergers and acquisitions by the BiomX Israel, Yeda will be entitled to an amount equivalent to 1% of the consideration received under such transaction, as adjusted per the terms of the agreement. See also Note 15 – Subsequent Events 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, 2018 and 2017.
- E.** 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 of \$25,000 during the year ended 2017 and is required to pay certain license maintenance fees of up to \$250,000 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 do not include liabilities with respect to this agreement as the Company has not yet generated revenue and the achievement of certain milestones is not probable.
- F.** As successor in interest to RondinX, 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 \$10,000 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 included in the financial statements as of December 31, 2018 with respect to the agreement.
- 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.

The consolidated financial statements do not include liabilities with respect to this agreement as the BiomX Israel has not yet generated revenue and the achievement of certain milestones does not meet the probable threshold.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 9 – CONVERTIBLE NOTES

On August 9, 2016, BiomX Israel and several of its shareholders entered into a Bridge Financing Agreement (the “BFA”). According to the BFA, BiomX Israel issued convertible notes and received an aggregate principal amount of \$1,200 thousands. The convertible notes did not bear interest and were convertible into Preferred A-2 Shares of BiomX Israel, according to the conditions set in the BFA. The fair value of the convertible notes was calculated according to the discount on BiomX Israel’s Preferred A shares as described in the BFA. The difference between the fair value of the convertible note and principal amount received was recorded as a finance expense in the consolidated statement of comprehensive loss in the amount of \$133 thousand upon issuance of the note. There was no change in the fair value of the note as of December 31, 2016. During 2017, the convertible notes were converted into 315,334 Preferred A-2 Shares. Refer to Note 10.

The Company concluded that the value of the convertible notes was predominantly based on a fixed monetary amount represented by the 10% discount on the Company’s Preferred A shares. Accordingly, the convertible notes were classified as debt and was measured at its fair value, pursuant to the provisions of ASC 480-10, “Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity.” The fair value of the convertible note was measured based on observable inputs as the fixed monetary value of the variable number of Preferred A-2 Shares to be issued upon conversion (Level 2 measurement).

NOTE 10 – SHAREHOLDERS EQUITY

A. Share Capital:

Preferred Stock:

The Company is authorized to issue 1,000,000 shares of preferred stock with a par value of \$0.0001 per share with such designation, rights and preferences as may be determined from time to time by the Company’s Board of Directors.

Common Stock:

The Company is authorized to issue 30,000,000 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, 2018, the Company had 2,473,414 issued and outstanding common shares.

Ordinary Shares (pre-merger- BiomX Ltd.):

The Ordinary Shares entitle their holders the right to receive notice of, and to participate and vote in, all general meetings, to receive dividends and, subject to the Articles to participate in the distribution of the surplus assets and funds of the Company in a Liquidation Event (as defined in the Articles). The holder of an Ordinary Share has no other right and such holder may waive, in writing, any of the rights set forth above, including the rights to receive notices of, and to participate and vote in, all general meetings; provided, however, that such holder will be entitled to any other mandatory right of a shareholder in a private Company pursuant to the Companies Law which cannot be waived.

Ordinary A Shares (pre-merger- BiomX Ltd.):

The Ordinary A Shares are convertible into Ordinary Shares upon the closing of each and every investment round (as defined in the Articles), by providing a notice to this effect to the Company. The holders of the Ordinary A Shares are entitled to the rights, preferences, privileges and restrictions granted to and imposed upon the Ordinary Shares. However, the holders of the Ordinary A Shares do not have voting rights.

Preferred A Shares (pre-merger- BiomX Ltd.):

The Preferred A Shares are convertible into 566,068 Ordinary Shares, representing a conversion price of \$1.70 per share, and entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Ordinary Shares and Ordinary A Shares, as well as the right to participate in a distribution of surplus of assets upon liquidation of the Company, merger and acquisition event and distribution of dividend by the Company, at an amount equal to their original issue price plus 8% annual interest accumulated as of the Liquidation Event Date (as defined in the Articles), before any distribution is made to a holder of any Ordinary Shares.

The Preferred A Share conversion price is subject to broad weighted average anti-dilution protection in the event of future funding at an effective share price which is lower than the Preferred A Share conversion price.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – SHAREHOLDERS EQUITY (Cont.)

A. Share Capital (Cont.):

Preferred A-1 Shares (pre-merger- BiomX Ltd.):

The Preferred A-1 Shares are convertible into 6,045,173 Ordinary Shares, representing a conversion price of \$4.23 per share, and entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Preferred A Shares.

Preferred A-2 Shares (pre-merger- BiomX Ltd.):

The Preferred A-2 Shares are convertible into 315,333 Ordinary Shares, representing a conversion price of \$3.81 per share, and entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Preferred A Shares.

Preferred A-3 Shares (pre-merger- BiomX Ltd.):

The Preferred A-3 Shares are convertible into Preferred A-1 Shares upon the closing of each and every investment round (as defined in the Articles), by providing a notice to this effect to the Company. The Preferred A-3 Shares entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Preferred A Shares. However, the Preferred A-3 Shares holders are not entitled to voting rights.

Preferred A-4 Shares (pre-merger- BiomX Ltd.):

Preferred A-4 Shares are convertible into 617,255 Ordinary Shares, representing a conversion price of \$4.86 per share, and entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Preferred A Shares.

Preferred B Shares (pre-merger- BiomX Ltd.):

Preferred B Shares are convertible into 5,478,984 Ordinary Shares, representing a conversion price of \$5.83 per share, and entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Preferred A Shares.

Preferred B Shares entitle their holder to participate in a distribution of surplus of assets upon liquidation of the Company, at an amount equal to their original issue price plus 8% annual interest accumulated as of the Liquidation Event (as defined in the Articles) date, before any distribution is made to holder of any Preferred A Shares (i.e., Preferred A Shares, Preferred A-1 Shares, Preferred A-2 Shares, Preferred A-3 Shares and Preferred A-4 Shares), and any Ordinary Shares.

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 65% of the issued and outstanding ordinary shares and all the preferred shares of BiomX Israel. The number of shares prior to the Reverse Capitalization have been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the Recapitalization Transaction.

BIOMX INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – SHAREHOLDERS EQUITY (Cont.)

B. Issuance of Share Capital:

In June 2015, the Company entered into the Incubator Agreement with the Incubator and other investors (the “June 2015 Investors”). In accordance with the Incubator Agreement, the Company issued 1,963,071 Ordinary Shares at \$0.0001 nominal value to the June 2015 Investors and an additional 302,828 Ordinary Shares at BiomX Israel nominal value to a trustee to be held in trust for the sole purpose of allocation of the Ordinary Shares to employees and consultants of the Company.

In addition, the Company issued 566,068 Preferred A Shares at \$0.0001 nominal value to the investors in consideration for \$960 thousands

In 2016, the Company issued convertible notes, bearing an annual interest at a rate of 0%, for an aggregate consideration of \$1,200 thousands. The notes were converted during 2017 to 315,334 Preferred A-2 Shares at \$0.0001.

On February 2017, the Company entered into a share purchase agreement (the “February 2017 SPA”) with new and existing investors (the “February 2017 Investors”). In accordance with the February 2017 SPA, the Company issued the February 2017 Investors 4,021,404 Preferred A-1 Shares at \$0.0001 nominal value (“Preferred A-1 Shares”), and 315,334 Preferred A-2 Shares at \$0.0001 nominal value in two tranches as follows:

- On February 15, 2017, the Company issued 2,010,702 Preferred A-1 Shares for a total consideration of \$8,500 thousands. In addition, the convertible notes in an amount of \$1,200 thousands granted in August 2016 were converted into 315,334 Preferred A-2 Shares at \$0.0001.
- On February 7, 2018, the Company issued 2,010,702 Preferred A-1 Shares for a total consideration of \$8,500 thousands.

On March 26, 2017 the Company entered into share purchase agreement (the “March 2017 SPA”) with new investors (the “March 2017 Investors”). In accordance with the March SPA, the Company issued to the March 2017 Investors 1,419,320 Preferred A-1 Shares in two tranches as follows:

- On March 30, 2017, the Company issued 709,660 Preferred A-1 Shares for a total consideration of \$3,000 thousands.
- On February 7, 2018, the Company issued 709,660 Preferred A-1 Shares for a total consideration of \$3,000 thousands.

On November 30, 2017, the Company entered into a share purchase agreement (the “November 2017 SPA”) with additional investors (the “November 2017 Investors”). In accordance with the November 2017 SPA, the Company issued the November 2017 Investors 617,256 Preferred A-4 Shares at \$0.0001 nominal value in two tranches as follows:

On December 7, 2017, the Company issued 308,628 Preferred A-4 Shares for a total consideration of \$1,500 thousands.

BIOMX INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – SHAREHOLDERS EQUITY (Cont.)

B. Issuance of Share Capital: (Cont.)

On February 7, 2018, the Company issued 308,628 Preferred A-4 Shares for a total consideration of \$1,500 thousands.

On November 19, 2017, the Company signed an agreement to purchase 100% of RondinX shares (see also Note 5). The initial consideration included an issuance of 604,449 Preferred A-1 Shares and 10,589 warrants to purchase Preferred A-1 shares for no additional consideration.

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 has committed to issue to the November 2018 Investors a total of 5,478,985 Preferred B Shares at \$0.0001 nominal value (the “Preferred B Shares”) for a total consideration of \$31,955 thousands.

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 a total consideration of \$30,155 thousands 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 a total consideration of \$1,800 thousands in accordance with the November 2018 SPA.

C. Share-based compensation:

The BiomX Israel has a plan where it grants option which represents a right to purchase 1 Ordinary Share of the Company 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 IRS Code.

In 2015, the BiomX Israel’s board of directors (the “Board”) approved a plan for allocation of options to employees, service providers and officers. As at December 31, 2018, the number of options available for grant under the approved plan was 712,230 options.

This plan was adopted in 2019 following the reverse recapitalization transaction on October 28, 2019. The options and warrants were assumed by BiomX Inc.

According to the original plan, employees and service providers were entitled to receive options to purchase ordinary shares of BiomX Israel. This plan was adopted in a manner that options granted will entitle their holder to purchase common shares of the Company. As a result, the number of options and exercise price per share were adopted based on the conversion ratio such that there was no change in the fair value of the options under the adjusted plan. All number of options, warrants, and exercise prices in this Note have been restated to reflect the adopted option plan.

On November 2015, the Board approved the grant of 435,500 non-tradable options without consideration to one employee, four consultants and six employees of the Incubator. Based on the considerations in ASC 718-10, the employees of the Incubator were defined as employees based on their relationship with the Company.

The options to two of the consultants were granted at an exercise price of \$0.001 per share. 22% of the options vest and become exercisable on the first and second anniversaries of the vesting commencement date of June 2015. Thereafter, the options vest and become exercisable in three equal annual installments of 18.67% each.

BIOMX INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – SHAREHOLDERS EQUITY (Cont.)

C. Share-based compensation: (Cont.)

The options to the employees of the Incubator and to two consultants were granted at an exercise price of \$0.001 per share. 33% of the options vest and become exercisable on the first anniversary of the vesting commencement date of June 2015. Thereafter, the options vest and become exercisable in 8 equal quarterly installments of 8.375% each.

The options to the Company employee were granted at an exercise price of \$0.001 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 installments of 6.25% each.

During 2016, the Board approved to grant an additional 310,078 non-tradable options without consideration to four employees and five consultants.

The options to three employees were granted at an exercise price of \$0.001 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 installments of 6.25% each.

The options to one additional employee were granted at an exercise price of \$0.54 per share. 33,486 options vest and become exercisable upon appointment as chief executive officer of the Company. The remainder of the options shall vest as follows: 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 installments of 6.25% each.

The options to two consultants were granted at an exercise price of \$0.001 per share. 22% of the options vest and become exercisable on the first and second anniversaries of the vesting commencement date (June 2015). Thereafter, the options vest and become exercisable in three equal annual installments of 18.67% each.

The options to two additional consultants were granted at an exercise price of \$0.54 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 installments of 6.25% each.

The options to one additional consultant were granted at an exercise price of \$1.7 per share. 33% of the options vest and become exercisable on the first anniversary of the vesting commencement date. Thereafter, the options vest and become exercisable in 8 equal quarterly installments of 8.375% each.

The options to additional two consultants were granted at an exercise price of \$0.54 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 installments of 6.25% each.

The options to one additional consultant were granted at an exercise price of \$1.7 per share. 33% of the options vest and become exercisable on the first anniversary of the vesting commencement date (June 2015). Thereafter, the options vest and become exercisable in eight quarterly installments of 8.375% each.

During 2017, the Board approved to grant an additional 1,084,947 non-tradable options without consideration to 29 employees and 5 consultants.

The options to 29 employees and 3 consultants were granted at an exercise price of \$1.69 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 installments of 6.25% each.

BIOMX INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – SHAREHOLDERS EQUITY (Cont.)

The options to 2 additional consultants were granted at an exercise price of \$0.001 per share. 22% of the options vest and become exercisable on the first and second anniversaries of the vesting commencement date (June 2015). Thereafter, the options vest and become exercisable in three equal annual installments of 18.67% each.

During October 2017, 11,034 options were exercised to purchase ordinary shares at an exercise price of \$0.001 per share.

During 2018, the Board approved to grant additional 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 \$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 installments 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.

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

C. Share-based compensation: (Cont.)

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>2018</u> | <u>2017</u> | <u>2016</u> |
|---|-------------|-------------|-------------|
| Underlying value of ordinary share (\$) | 1.7-2 | 0.5-1.7 | 0.5 |
| Exercise price (\$) | 1.7-2 | 0.5-1.7 | 0.001-1.7 |
| Expected volatility (%) | 93.1 | 93.1 | 93.1 |
| Term of the option (years) | 6.25 | 6.25 | 6.9 |
| Risk-free interest rate (%) | 2.25-3.05 | 1.35-2.25 | 1.35-2.25 |

The cost of the benefit embodied in the options granted in 2018, 2017, and 2016 based on their fair value as at the grant date, is estimated to be \$1,451 thousand, \$2,503 thousand, and \$215 thousand, respectively. These amounts will be recognized in statements of comprehensive loss over the vesting period.

Warrants:

- In May 2017, in accordance with the 2017 License Agreement (see also Note 8D), the Company issued to Yeda, for no consideration, 591,382 warrants to purchase Ordinary Shares at \$0.0001. The expense recognized for the years ended December 31, 2017 and 2018 were \$584 thousand and \$704 thousand, respectively which were included in research and development expenses.

BIOMX INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – SHAREHOLDERS EQUITY (Cont.)

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,
- 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.

The fair value of the unvested portion of the warrants granted was remeasured each reporting period as the performance commitment date had not yet been achieved.

2. In November 2017, in accordance with the RondinX share purchase agreement (see also Note 5), the Company issued to Yeda and 2 consultants, for no consideration, 10,589 warrants to purchase Preferred A-1 Shares at \$0.0001 nominal value.

The warrants were fully vested and exercisable on the date of their issuance.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – SHAREHOLDERS EQUITY (Cont.)

C. 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, | | | | | |
|--|--|--------------------------------------|------------------------------|--|--------------------------------------|------------|
| | 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 | <u>1,868,749</u> | <u>1.58</u> | <u>849</u> | <u>702,388</u> | <u>0.69</u> | <u>944</u> |
| Vested at year end | <u>653,201</u> | | | <u>323,111</u> | | |
| Weighted average remaining contractual life – years as of December 31, 2018 | <u>8.65</u> | | | <u>8.1</u> | | |
| | | | | | | |
| | For year ended December 31, | | | | | |
| | 2017 | | | | | |
| | 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 | 353,529 | 0.26 | 105 | 375,457 | 0.15 | 152 |
| Granted | 941,962 | 1.69 | | 142,985 | 0.37 | |
| Forfeited | (5,558) | (*) | | - | | |
| Exercised | (11,034) | (*) | | - | | |
| Outstanding at the end of year | <u>1,278,900</u> | <u>1.29</u> | <u>840</u> | <u>518,442</u> | <u>0.21</u> | <u>915</u> |
| Vested at year end | <u>252,947</u> | | | <u>213,003</u> | | |
| Weighted average remaining contractual life – years as of December 31, 2018 | <u>9.08</u> | | | <u>8.45</u> | | |

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – SHAREHOLDERS EQUITY (Cont.)

C. Share-based compensation: (Cont.)

| | For year ended December 31, | | | | | |
|---|---------------------------------|---------------------------|-------------------|---------------------------------|---------------------------------|---------------------------|
| | 2016 | | | | | |
| | 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 period | 155,544 | (*) | 86 | 279,955 | (*) | 150 |
| Granted | 214,577 | 0.47 | | 95,501 | 0.47 | |
| Forfeited | (16,592) | (*) | | - | | |
| Exercised | - | | | - | | |
| Outstanding at the end of year | 353,529 | 0.26 | 105 | 375,457 | 0.15 | 152 |
| Vested at year end | 70,730 | | | 105,103 | | |
| Weighted average remaining contractual life – years as of December 31, 2016 | 9.43 | | | 9.132 | | |
| | | | | Warrants issued to Yeda | | |
| | | | | Number of Options | Weighted average exercise price | Aggregate intrinsic value |
| Outstanding at January 1, 2017 | | | | - | - | |
| Granted | | | | 591,382 | 0.001 | |
| Outstanding at the December 31, 2017 and December 31, 2018 | | | | 591,382 | 0.001 | 1,200 |
| Vested at the December 31, 2017 and December 31, 2018 | | | | 236,552 | | |
| Weighted average remaining contractual life – years as of December 31, 2017 | | | | 7.36 | | |
| Weighted average remaining contractual life – years as of December 31, 2018 | | | | 6.36 | | |

(*) Less than \$0.01.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – SHAREHOLDERS EQUITY (Cont.)

C. 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, | | |
|----------------------------|-------------------------|--------------|------------|
| | 2018 | 2017 | 2016 |
| | USD In thousands | | |
| R&D | 623 | 952 | 195 |
| General and administrative | 328 | 358 | 52 |
| | <u>951</u> | <u>1,310</u> | <u>247</u> |

The Company recognized share-based compensation expenses in connection with options granted to executive officers of the Company in the amount of \$405 thousand, \$333 thousand, and \$107 thousand for the years ended December 31, 2018, 2017, and 2016, respectively.

The total unrecognized compensation expense was \$3,026, \$1,446 and \$248 thousand as of December 31, 2018, 2017, and 2016, respectively. These expenses will be recognized over a period of approximately 4 years.

NOTE 11 – R&D EXPENSES, NET

| | Year ended December 31, | | |
|---|-------------------------|--------------|--------------|
| | 2018 | 2017 | 2016 |
| | USD In thousands | | |
| Professional service and subcontractors | 4,365 | 1,415 | 676 |
| Salaries and related expenses | 3,972 | 1,865 | 480 |
| Share based payments | 623 | 952 | 195 |
| Depreciation | 210 | 95 | 23 |
| Materials and supplies | 611 | 509 | 77 |
| | <u>9,781</u> | <u>4,836</u> | <u>1,451</u> |
| Less - Grants from the IIA | <u>(646)</u> | <u>(660)</u> | <u>(302)</u> |
| | <u>9,135</u> | <u>4,176</u> | <u>1,149</u> |

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

NOTE 12 – GENERAL AND ADMINISTRATIVE EXPENSES

| | Year ended December 31, | | |
|--------------------------------|-------------------------|--------------|------------|
| | 2018 | 2017 | 2016 |
| | USD In thousands | | |
| Salaries and related expenses | 1,369 | 847 | 223 |
| Incubator overhead | 28 | 251 | 134 |
| Share based payments | 328 | 358 | 52 |
| Professional services | 284 | 341 | 53 |
| Travel expenses | 258 | 186 | 96 |
| Office expenses | 189 | 117 | 16 |
| Recruitment expenses | 209 | 47 | - |
| Rent and rent related expenses | 333 | 194 | - |
| Other | 362 | 195 | 46 |
| | <u>3,360</u> | <u>2,536</u> | <u>620</u> |

NOTE 13 – INCOME TAXES

- A. The Company files income tax returns in the U.S. federal jurisdiction in various state and local jurisdictions and is subject to examination by the various taxing authorities. The Company’s tax returns since inception remain open and subject to examination. The Company considers New York to be a significant state tax jurisdiction. Statutory federal income tax rate is 21%.
- B. As of December 31, 2018, 2017, and 2016, BiomX Israel. had total net operating losses in Israel of approximately \$10,556 thousands, \$5,689 thousands, and \$1,206 thousands, respectively which may be carried forward and offset against taxable income in the future for an indefinite period. BiomX Israel did not have any U.S. federal and state net operating loss carryovers (“NOLs”).
- C. The Company 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.

| | As of December 31, | |
|----------------------------------|--------------------|-------------|
| | 2018 | 2017 |
| | USD In thousands | |
| Net operating loss carry-forward | 10,556 | 5,689 |
| Total deferred tax assets | 2,430 | 1,308 |
| Valuation allowance | (2,430) | (1,308) |
| Net deferred tax assets | <u>\$ -</u> | <u>\$ -</u> |

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

NOTE 13 – INCOME TAXES (Cont.)

D. Reconciliation of Income Taxes:

The following is a reconciliation of the taxes on income assuming that all income is taxed at the ordinary statutory corporate tax rate in Israel and the effective income tax rate:

| | Years ended December 31, | | |
|--|--------------------------|---------|-------|
| | 2018 | 2017 | 2016 |
| | (in thousands) | | |
| Net loss as reported in the statements of comprehensive loss | 12,720 | 6,433 | 1,900 |
| Statutory tax rate | 23% | 24% | 25% |
| Income tax under statutory tax rate | 2,926 | 1,544 | 475 |
| Change in valuation allowance | (2,926) | (1,544) | (475) |
| Actual income tax | \$ - | \$ - | \$ - |

NOTE 14 – BASIC AND DILUTED NET LOSS PER SHARE

The basic and diluted net loss per share and weighted average number of shares of ordinary shares and ordinary A shares stock used in the calculation of basic and diluted net loss per share are as follows (in thousands, except share and per share data)

| | Years ended December 31, | | |
|--|--------------------------|-----------|-----------|
| | 2018 | 2017 | 2016 |
| | (in thousands) | | |
| Net loss for the year | 12,720 | 6,433 | 1,900 |
| Net loss attributable to holders of preferred shares | 2,533 | 961 | 77 |
| Net loss used in the calculation of basic net loss per share | 15,253 | 7,394 | 1,977 |
| Net loss per share | 7.62 | 3.76 | 1.01 |
| Weighted average number of ordinary shares and ordinary A shares | 2,002,464 | 1,967,669 | 1,963,071 |

** 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).

As the inclusion of ordinary share or ordinary A 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.

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

NOTE 15 – SUBSEQUENT EVENTS

In accordance with FASB ASC 855-10-50-1, the Company has analyzed its operations subsequent to December 31, 2018 and up until July 15, 2019, the date these consolidated financial statements were issued, and has determined that it does not have any material subsequent events to disclose except as follows:

On January 8, 2019, the Company issued 308,628 Preferred B Shares for a total consideration of \$1,800 thousands in accordance with the November 2018 SPA.

In April 2019, BiomX Israel signed additional patent license agreement with Keio University and JSR Corporation in Japan. According to the agreement, BiomX Israel the Company received an exclusive sublicense by JSR to certain patent license to certain patent rights related to the Company's Primary Sclerosing Cholangitis program. In return, the Company is required (i) to pay a license issue fee of \$20,000 and annual license fees ranging from \$15,000 to \$25,000 and (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.

In July 2019, the Company, Yeda and BiomX Israel amended the 2015 License Agreement and to the 2017 License Agreement with Yeda (the "Amendment"). Pursuant to the Amendment, following the closing of the Recapitalization Transaction, the provisions of the Yeda license agreements related to the exit fee were amended so that, instead of the exit fee, 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.

Additionally, refer to Note 1 regarding the consummation of the reverse recapitalization transaction on October 28, 2019.

BIOMX INC.
(formerly known as Chardan Healthcare Acquisition Corp.)
INTERIM CONSOLIDATED BALANCE SHEETS
USD in thousands except share data

| | <u>Note</u> | <u>As of</u> | |
|---|-------------|-------------------------------------|------------------------------------|
| | | <u>September 30,</u> <u>2019</u> | <u>December 31,</u> <u>2018</u> |
| ASSETS | | | |
| Current assets | | | |
| Cash and cash equivalents | | 11,570 | 8,604 |
| Restricted cash | | 94 | 89 |
| Short-term deposits | 3 | 18,437 | 31,055 |
| Related party receivable | 9 | 100 | - |
| Other receivables | | 115 | 140 |
| Total current assets | | <u>30,316</u> | <u>39,888</u> |
| Property and equipment, net | | 1,615 | 887 |
| Lease deposit | | 5 | - |
| In-process research and development ("R&D") | 6 | 4,556 | 4,556 |
| Operating lease right-of-use asset | 4 | 1,130 | - |
| Total non-current assets | | <u>7,306</u> | <u>5,443</u> |
| | | <u>37,622</u> | <u>45,331</u> |

The accompanying notes are an integral part of these interim consolidated financial statements.

BIOMX INC.
(formerly known as Chardan Healthcare Acquisition Corp.)
INTERIM CONSOLIDATED BALANCE SHEETS
USD in thousands except share and per share data

| | Note | As of | |
|--|------|-----------------------|----------------------|
| | | September 30, 2019 | December 31, 2018 |
| <u>USD In thousands</u> | | | |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | | |
| Current liabilities | | | |
| Short-term lease liabilities | 4 | 334 | - |
| Trade account payables | | 74 | 193 |
| Other account payables | | 1,245 | 1,396 |
| Related party | 9 | - | 50 |
| Total current liabilities | | <u>1,653</u> | <u>1,639</u> |
| Non-current liabilities | | | |
| Long-term lease liabilities | 4 | 797 | - |
| Contingent liabilities | 5 | 909 | 889 |
| Total non-current liabilities | | <u>1,706</u> | <u>889</u> |
| Commitments and Contingent Liabilities | 7 | | |
| Shareholders' equity | 8 | | |
| Ordinary shares (pre-merger - BiomX Ltd.), \$ 0.0001 par value ("Ordinary Shares"); Authorized - 33,954,304 shares as of September 30, 2019 and December 31, 2018. Issued and outstanding - 2,349,071 shares as of September 30, 2019 and 2,307,871 as of December 31, 2018. | | (*) | (*) |
| Ordinary A shares (pre-merger - BiomX Ltd.), \$ 0.0001 par value ("Ordinary A Shares"); Authorized -2,417,575 shares as of September 30, 2019 and December 31, 2018. Issued and outstanding - 0 as of September 30, 2019 and December 31, 2018. | | - | - |
| Preferred A shares (pre-merger - BiomX Ltd.), \$ 0.0001 par value ("Preferred A Shares"); Authorized - 16,430,668 shares as of as of September 30, 2019 and December 31, 2018. Issued and outstanding - 7,543,831 shares as of as of September 30, 2019 and December 31, 2018. | | 1 | 1 |
| Preferred B shares (pre-merger - BiomX Ltd.), \$ 0.0001 par value ("Preferred B Shares"); Authorized - 6,858,371 shares as of September 30, 2019 and December 31, 2018. Issued and outstanding - 5,478,985 shares as of September 30, 2019 and 5,170,357 shares as of December 31, 2018. | | 1 | 1 |
| Additional paid in capital | | 67,133 | 64,410 |
| Accumulated deficit | | (32,872) | (21,609) |
| Total shareholders' equity | | <u>34,263</u> | <u>42,803</u> |
| | | <u>37,622</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 these interim consolidated financial statements.

BIOMX INC.
(formerly known as Chardan Healthcare Acquisition Corp.)
INTERIM CONSOLIDATED STATEMENTS OF OPERATIONS
USD in thousands except share and per share data

| | Three months ended | | Nine months ended | |
|---|---------------------------|--------------|--------------------------|--------------|
| | September 30, | | September 30, | |
| | 2019 | 2018 | 2019 | 2018 |
| Research and development (“R&D”) expenses, net | 2,858 | 2,474 | 8,458 | 6,117 |
| General and administrative expenses | 1,797 | 777 | 3,987 | 2,212 |
| Operating Loss | 4,655 | 3,251 | 12,445 | 8,329 |
| Financial expenses (income), net | (395) | (46) | (1,182) | 254 |
| Net Loss | 4,260 | 3,205 | 11,263 | 8,583 |
| Basic and diluted loss per Ordinary Shares and Ordinary A Shares | 2.69 | 1.88 | 7.37 | 5.08 |
| Weighted average number of Ordinary Shares and Ordinary A Shares outstanding, basic and diluted | 2,035,625 | 2,005,043 | 2,015,349 | 2,001,605 |

** Number of shares has been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the reverse recapitalization transaction consummated on October 28, 2019 (refer to Note 1).

The accompanying notes are an integral part of these interim consolidated financial statements.

BIOMX INC.
(formerly known as Chardan Healthcare Acquisition Corp.)
INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
USD in thousands except share data

| | Ordinary Shares (pre-merger- BiomX Ltd.) | | Preferred A Shares (pre-merger- BiomX Ltd.) | | Preferred B Shares (pre-merger- BiomX Ltd.) | | Additional paid in capital | Accumulated deficit | Total shareholders' equity |
|---|--|------------|---|----------|---|----------|----------------------------------|------------------------|----------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| Balance as of December 31, 2018 | 2,307,870 | (*) | 7,543,831 | 1 | 5,170,357 | 1 | 64,410 | (21,609) | 42,803 |
| Issuance of shares | - | - | - | - | 308,628 | (*) | 1,800 | - | 1,800 |
| Share-based payment | - | - | - | - | - | - | 304 | - | 304 |
| Net loss | - | - | - | - | - | - | - | (3,225) | (3,225) |
| Balance as of March 31, 2019 | 2,307,870 | (*) | 7,543,831 | 1 | 5,478,985 | 1 | 66,514 | (24,834) | 41,682 |
| Share-based payment | - | - | - | - | - | - | 327 | - | 327 |
| Net loss | - | - | - | - | - | - | - | (3,778) | (3,778) |
| Balance as of June 30, 2019 | 2,307,870 | (*) | 7,543,831 | 1 | 5,478,985 | 1 | 66,841 | (28,612) | 38,231 |
| Share-based payment | - | - | - | - | - | - | 249 | - | 249 |
| Exercise of options | 41,200 | (*) | - | - | - | - | 43 | - | 43 |
| Net loss | - | - | - | - | - | - | - | (4,260) | (4,260) |
| Balance as of September 30, 2019 | <u>2,349,070</u> | <u>(*)</u> | <u>7,543,831</u> | <u>1</u> | <u>5,478,985</u> | <u>1</u> | <u>67,133</u> | <u>(32,872)</u> | <u>34,263</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 consummated on October 28, 2019 (refer to Note 1).

The accompanying notes are an integral part of these interim consolidated financial statements.

BIOMX INC.
(formerly known as Chardan Healthcare Acquisition Corp.)
INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
USD in thousands except share data

| | Ordinary Shares (pre-merger- BiomX Ltd.) | | Ordinary A Shares (pre-merger- BiomX Ltd.) | | Preferred A Shares (pre-merger- BiomX Ltd.) | | Additional paid in capital | Accumulated deficit | Total shareholders' equity |
|---|--|--------|--|--------|---|--------|----------------------------------|------------------------|----------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| Balance as of December 31, 2017 | 1,580,159 | (*) | 696,774 | (*) | 4,514,841 | (*) | 20,419 | (8,889) | 11,530 |
| Issuance of shares | - | - | - | - | 3,028,990 | (*) | 12,998 | - | 13,000 |
| Conversion of shares | 696,774 | (*) | (696,774) | (*) | - | - | - | - | - |
| Exercise of options | 30,938 | (*) | - | - | - | - | - | - | - |
| Share-based payment | - | - | - | - | - | - | 212 | - | 212 |
| Net loss | - | - | - | - | - | - | - | (2,706) | (2,706) |
| Balance as of March 31, 2018 | 2,307,870 | (*) | - | - | 7,543,831 | 1 | 33,630 | (11,595) | 22,036 |
| Share-based payment | - | - | - | - | - | - | 243 | - | 243 |
| Net loss | - | - | - | - | - | - | - | (2,672) | (2,672) |
| Balance as of June 30, 2018 | 2,307,870 | (*) | - | - | 7,543,831 | 1 | 33,873 | (14,267) | 19,607 |
| Share-based payment | - | - | - | - | - | - | 233 | - | 233 |
| Net loss | - | - | - | - | - | - | - | (3,205) | (3,205) |
| Balance as of September 30, 2018 | 2,307,870 | (*) | - | - | 7,543,831 | 1 | 34,106 | (17,472) | 16,635 |

(*) 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 consummated on October 28, 2019 (refer to Note 1).

The accompanying notes are an integral part of these interim consolidated financial statements.

BIOMX INC.
(formerly known as Chardan Healthcare Acquisition Corp.)
INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS
USD in thousands

| | For the Nine months ended | |
|---|----------------------------------|----------------|
| | September 30, | |
| | 2019 | 2018 |
| <u>CASH FLOWS – OPERATING ACTIVITIES</u> | | |
| Net loss | (11,263) | (8,583) |
| Adjustments required to reconcile cash flows used in operating activities | | |
| Depreciation | 259 | 145 |
| Share-based compensation | 880 | 688 |
| Revaluation of contingent liabilities | 20 | 15 |
| Changes in operating assets and liabilities: | | |
| Other receivables | 21 | 105 |
| Trade account payables | (119) | 188 |
| Other account payables | (151) | (362) |
| Related parties | (150) | - |
| Net cash used in operating activities | (10,503) | (7,804) |
| <u>CASH FLOWS – INVESTING ACTIVITIES</u> | | |
| Decrease in short-term deposit | 12,618 | 1,065 |
| Purchase of property and equipment | (987) | (127) |
| Net cash provided by investing activities | 11,631 | 938 |
| <u>CASH FLOWS – FINANCING ACTIVITIES</u> | | |
| Issuance of preferred shares | 1,800 | 13,000 |
| Exercise of stock options | 43 | * |
| Net cash provided by financing activities | 1,843 | 13,000 |
| Increase in cash and cash equivalents and restricted cash | 2,971 | 6,134 |
| Cash and cash equivalents and restricted cash at the beginning of the period | 8,693 | 6,993 |
| Cash and cash equivalents and restricted cash at the end of the Period | 11,664 | 13,127 |
| <u>Supplemental non-cash transactions:</u> | | |
| Recognition of right-of-use asset and lease liability upon adoption of ASU 2016-02 | 645 | - |
| Assets acquired under operating leases | 599 | - |

(*) Less than \$1 thousand.

The accompanying notes are an integral part of these interim consolidated financial statements.

BIOMX INC.
(formerly known as Chardan Healthcare Acquisition Corp.)
NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - GENERAL

A. Description of business:

BiomX Inc. (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, Chardan Healthcare Acquisition Corp. 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.

On October 28, 2019, the Company acquired (the “Recapitalization Transaction”) 100% of the outstanding shares of BiomX Ltd. 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. In addition, the company reserved 1,555,942 shares for the vested warrants and options of BiomX Israel. As a result of the 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 financial statements of the Company were replaced with the financial statements of BiomX Israel for all periods presented.

Following the Recapitalization Transaction, the Company retained the \$60.1 Million balance held in the trust account.

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 reverse recapitalization transaction.

The securities of the combined company began trading on the NYSE American stock exchange on October 28 and the combined company was renamed BiomX Inc.

Commencing October 29, 2019 the combined company shares of common stock, units, and warrants are traded under the symbols PHGE, PHGE.U, and PHGE.WS, respectively

The Company and its subsidiaries, BiomX Ltd. and RondinX Ltd. are collectively referred to as the “Company”.

B. Risk Factors:

To date, the Company has not generated revenue from its operations. As of November 29, 2019, the Company had unrestricted cash and cash equivalent balance and short-term deposits of approximately \$85 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.

Due to 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 either 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 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 periods. Actual results could differ from those estimates.

BIOMX INC.
(formerly known as Chardan Healthcare Acquisition Corp.)
NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Unaudited Interim Financial Statements

These unaudited interim consolidated financial statements have been prepared as of September 30, 2019, and for the three- and nine-month periods ended September 30, 2019 and 2018. Accordingly, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been omitted. These unaudited interim consolidated financial statements should be read in conjunction with the audited financial statements and the accompanying notes of the Company as of and for the years ended December 31, 2018 and 2017.

Operating results for the nine months period ended September 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019.

Significant Accounting Policies

The significant accounting policies followed in the preparation of these unaudited interim consolidated financial statements are identical to those applied in the preparation of the latest annual audited financial statements with the exception of the following:

A. Leases

In February 2016, the Financial Accounting Standards Board issued ASU 2016-02, Leases (Topic 842). The Company adopted this ASU effective January 1, 2019 using the modified retrospective application, applying the ASU to leases in place as of the adoption date. Prior periods have not been adjusted.

Arrangements that are determined to be leases at inception are recognized as long-term right-of-use assets ("ROU") and lease liabilities in the interim 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 Company's leases do not provide an implicit rate, the Company applies its incremental borrowing rate based on the economic environment at commencement date in determining the present value of future lease payments. Lease terms may include options to extend the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases or payments are recognized on a straight-line basis over the lease term.

In accordance with ASC 360-10, management reviews operating lease ROU 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.

B. Stock compensation plans:

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 interim consolidated financial statements and related disclosures.

BIOMX INC.
(formerly known as Chardan Healthcare Acquisition Corp.)
NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (Cont.)

C. 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 that 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 expects to adopt this standard in the first quarter of fiscal year 2020. This standard is not expected to have a material impact on the Company’s consolidated financial statements and related disclosures.

NOTE 3 – SHORT-TERM DEPOSIT

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 interest income in the interim consolidated statement of operations during the periods for which the Company held short-term deposits. The Company has deposits denominated in USD held with Bank Hapoalim US and Bank Leumi Israel that bear fixed annual interest of 2.4% to 3.6%.

NOTE 4 – LEASES

On January 1, 2019, the Company adopted ASU 2016-02 using the modified retrospective approach for all lease arrangements at the beginning period of adoption. Leases existing for the reporting period beginning January 1, 2019 are presented under ASU 2016-02. The Company leases office space under operating leases. At September 30, 2019, the Company’s ROU assets and lease liabilities for operating leases totaled \$1,130 thousand each. The impact of adopting ASU 2016-02 was not material to the Company’s consolidated statement of operations for the periods presented.

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 \$16 thousand. As part of the agreement, the Company has obtained a bank guarantee in favor of the property owner in the amount of approximately \$94 thousand representing four monthly lease and related payments. Lease expenses recorded in the interim consolidated statements of operations were \$96 thousand for the nine months ended September 30, 2019, and 2018 and \$48 thousand for the three months ended September 30, 2019 and 2018.

In September 2019, BiomX Israel entered into a 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 period until 14th of July 2027. Monthly lease payments under the agreement are approximately \$10 thousand. As part of the agreement, BiomX Israel will obtain a bank guarantee in favor of the property owner in the amount of approximately \$58 thousand representing four monthly lease and related payments. Lease expenses recorded in the interim consolidated statements of operations were \$8 thousand for the period ended on September 30, 2019.

BIOMX INC.
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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 4 – LEASES (Cont.)

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

| | Three months ended September 30, 2019 | Nine months ended September 30, 2019 |
|------------------------------------|--|---|
| Cash payments for operating leases | 58 | 167 |

As of September 30, 2019, the Company's operating leases had a weighted average remaining lease term of 4 years and a weighted average discount rate of 3%. Future lease payments under operating leases as of September 30, 2019 were as follows in thousand USD:

| | <u>Operating Leases</u> |
|-------------------------------|-------------------------|
| Remainder of 2019 | \$ 64 |
| 2020 | \$ 332 |
| 2021 | \$ 332 |
| 2022 | \$ 236 |
| 2023 | \$ 124 |
| 2024 | \$ 85 |
| Total future lease payments | \$ 1,173 |
| Less imputed interest | (43) |
| Total lease liability balance | \$ 1,130 |

NOTE 5 – ACQUISITION OF SUBSIDIARY

On November 19, 2017, BiomX Israel signed a share purchase agreement with the shareholders of RondinX Ltd ("RondinX"). In accordance with the share purchase agreement, BiomX Israel acquired 100% ownership and control of RondinX for consideration valued at US\$ 4.5 million. The consideration included the issuance of 604,449 Preferred A Shares, the issuance of warrants to purchase an aggregate of 10,589 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 ("PSC") 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.

The Company completed the RondinX 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 leveling during the nine months ended September 30, 2019 and the year ended December 31, 2018.

BIOMX INC.
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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 5 – ACQUISITION OF SUBSIDIARY (Cont.)

The change in the fair value of the contingent consideration as of September 30, 2019 and December 31, 2018 was as follows in thousand USD:

| | Contingent consideration |
|---|---------------------------------|
| As of December 31, 2018 | 889 |
| Revaluation of contingent consideration | 20 |
| As of September 30, 2019 | 909 |
| | |
| | Contingent consideration |
| As of December 31, 2017 | 1,001 |
| Revaluation of contingent consideration | 15 |
| As of September 30, 2018 | 1,016 |

NOTE 6 – IN-PROCESS RESEARCH AND DEVELOPMENT

Intangible assets acquired in the RondinX 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 September 30, 2019, the in-process R&D efforts had not yet been completed nor abandoned. Based on management’s analysis, there was no impairment for the nine months ended September 30, 2019 and 2018.

NOTE 7 – COMMITMENTS AND CONTINGENT LIABILITIES

- A. During 2015, 2016 and 2017, BiomX Israel submitted three applications to the IIA for a R&D project for the technological incubators program. The approved budget per year was NIS 2,700,000 (approximately \$726 thousand) per application. According to the IIA directives, the IIA transferred to the Company 85% of the approved budget and the rest of the budget was funded by certain shareholders

During 2018, BiomX Israel submitted additional application to the IIA for the Acne project. The application was approved, at an aggregate budget of s NIS 4,221,370 (approximately \$1,206 thousand) from which the IIA’s participation is up to 30% of the budget. As of September 30 2019, the IIA transferred to the Company the amount of NIS 1,078,981 (approximately \$299 thousand), which was recognized in the interim consolidated statement of operations for the period ended September 30, 2019.

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 the Company. 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 Company’s R&D programs and generating sales. The Company 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 September 30, 2019; therefore, no liability was recorded in these consolidated financial statements.

Total research and development income recorded in the interim consolidated statement of operations was \$299 thousand and \$646 for the nine months ended September 30, 2019 and 2018, respectively and \$0 for the three months ended September 30, 2019 and 2018. As of September 30, 2019, the Company had a contingent obligation to the IIA in the amount of approximately 2.2 million including annual interest of LIBOR linked to the USD.

BIOMX INC.
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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7 – COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)

- B.** In June 2015, BiomX Israel entered into a Research and License Agreement (the “2015 License Agreement”) as amended with Yeda Research and Development Company Limited (“Yeda”), according to which Yeda undertakes to procure the performance of the 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 an in-vivo method for measuring immune induction capability (Th1) of bacteria, followed by testing several candidate IBD inducing bacterial strains. During the research period, as defined in the 2015 License Agreement and subject to the terms and conditions specified in the 2015 License Agreement. BiomX Israel contributed an aggregate of approximately \$1.8 million to the research budget agreed upon in the license agreement. In addition, Yeda granted BiomX Israel 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, BiomX Israel will pay Yeda annual license fees of approximately \$10 thousand and royalties on revenues as defined in the 2015 License Agreement. In addition, in the event of certain mergers and acquisitions by the Company, Yeda will be entitled to an amount equivalent to 1% of the consideration received under such transaction (the “Exit Fee”), as adjusted per the terms of the agreement. Upon the closing of the Recapitalization Transaction, the provisions of the Yeda 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 (see note 7I). 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 September 30, 2019 and December 31, 2018.
- C.** In May 2017, BiomX Israel signed an additional agreement with Yeda (the “2017 License Agreement”) according to which, Yeda provided a license to the Company. As consideration for the license, the Company will pay \$10,000 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 8 below for the terms of the warrants granted. In addition, the 2017 License Agreement includes additional consideration contingent upon future sales or sublicensing revenue. As the Company has not yet generated revenue from operations, no provision was included in the interim consolidated financial statements with respect to the 2017 License Agreement as of September 30, 2019 and in the financial statements of December 31, 2018.
- D.** 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, the Company paid an initial license fee of \$25,000 during the year ended December 31, 2017 and is required to pay certain license maintenance fees of up to \$250,000 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. As the Company has not yet generated revenue from operations, and the achievement of certain milestones is not probable, no provision was included in the financial statements with respect to the 2017 License Agreement as of September 30, 2019 and December 31, 2018.

BIOMX INC.
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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7 – COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)

- E.** As successor in interest to RondinX, BiomX Israel is a party to a license agreement dated March 20, 2016 with Yeda, pursuant to which BiomX Israel 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, BiomX Israel will pay license fees of \$10,000 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 included in the financial statements as of as of September 30, 2019 and December 31, 2018 with respect to the agreement.
- F.** In December 2017, BiomX Israel signed a patent license agreement with Keio University and JSR Corporation in Japan. According to the agreement, BiomX Israel received an exclusive patent license to certain patent rights related to the Company's inflammatory bowel disease program. In return, the Company will pay annual license fees of between \$15,000 to \$25,000 subject to the terms and conditions specified in the agreement. Additionally, the Company is obligated to make additional payments based upon the achievement of clinical and regulatory milestones up to an aggregate of \$3.2 million and royalty payments based on future revenue. As the Company has not yet generated revenue from operations, and the achievement of certain milestones is not probable, no provision was included in the financial statements as of as of September 30, 2019 and December 31, 2018 with respect to the agreement.
- G.** 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, the Company is required (i) to pay a license issue fee of \$20,000 and annual license fees ranging from \$15,000 to \$25,000 and (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. As the Company has not yet generated any revenue, and the achievement of certain milestones is not probable, no provision was included in the interim consolidated financial statements as of as of September 30, 2019 and in the financial statements December 31, 2018 with respect to the agreement.
- H.** In July 2019, the BiomX Israel has committed to enter into loan agreements in the aggregate amount of up to \$1,900 thousand, with certain of its shareholders who are subject to taxation in Israel, pursuant to which the BiomX Israel will extend to such shareholders loans for the purpose of paying Israeli capital gain taxes payable by them in connection with the issuance to them of the Company's shares in exchange for their shares in BiomX Israel upon consummation of the Recapitalization Transaction as described in Note 1 . Such loans are for a period of up to two years, are non-recourse and are secured by BiomX shares issued to those shareholders, based on \$10 per share (the attributed price of the BiomX Shares immediately prior to such issuance) that equals three times the loan amount. To date the amount given is \$19 thousand .
- I.** In July 2019, the Company, Yeda and BiomX Israel amended the 2015 License Agreement and to the 2017 License Agreement with Yeda (the "Amendment"). Pursuant to the Amendment, following the closing of the Recapitalization Transaction, the provisions of the Yeda license agreements related to the exit fee were amended so that, the Company is obligated to pay Yeda a one-time payment as described in the amendment which will not exceed 1% of the consideration received under such transaction instead of the Exit Fee, in the event of any merger or acquisition involving BiomX the Company.

BIOMX INC.
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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – SHAREHOLDERS EQUITY

A. Share Capital:

Preferred Stock:

The Company is authorized to issue 1,000,000 shares of preferred stock with a par value of \$0.0001 per share with such designation, rights and preferences as may be determined from time to time by the Company's Board of Directors.

Common Stock:

The Company is authorized to issue 30,000,000 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 September 30, 2019, the Company had 2,296,223 issued and outstanding common shares.

Ordinary Shares (pre-merger- BiomX Ltd.):

The Ordinary Shares entitle their holders the right to receive notice of, and to participate and vote in, all general meetings, to receive dividends and, subject to the Articles to participate in the distribution of the surplus assets and funds of the Company in a Liquidation Event (as defined in the Articles). The holder of an Ordinary Share has no other right and such holder may waive, in writing, any of the rights set forth above, including the rights to receive notices of, and to participate and vote in, all general meetings; provided, however, that such holder will be entitled to any other mandatory right of a shareholder in a private Company pursuant to the Companies Law which cannot be waived.

Ordinary A Shares (pre-merger- BiomX Ltd.):

The Ordinary A Shares are convertible into Ordinary Shares upon the closing of each and every investment round (as defined in the Articles), by providing a notice to this effect to the Company. The holders of the Ordinary A Shares are entitled to the rights, preferences, privileges and restrictions granted to and imposed upon the Ordinary Shares. However, the holders of the Ordinary A Shares do not have voting rights.

Preferred A Shares (pre-merger- BiomX Ltd.):

The Preferred A Shares are convertible into 566,068 Ordinary Shares, representing a conversion price of \$1.70 per share, and entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Ordinary Shares and Ordinary A Shares, as well as the right to participate in a distribution of surplus of assets upon liquidation of the Company, merger and acquisition event and distribution of dividend by the Company, at an amount equal to their original issue price plus 8% annual interest accumulated as of the Liquidation Event Date (as defined in the Articles), before any distribution is made to a holder of any Ordinary Shares.

The Preferred A Share conversion price is subject to broad weighted average anti-dilution protection in the event of future funding at an effective share price which is lower than the Preferred A Share conversion price.

Preferred A-1 Shares (pre-merger- BiomX Ltd.):

The Preferred A-1 Shares are convertible into 6,045,173 Ordinary Shares, representing a conversion price of \$4.23 per share, and entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Preferred A Shares.

BIOMX INC.
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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – SHAREHOLDERS EQUITY (Cont.)

Preferred A-2 Shares (pre-merger- BiomX Ltd.):

The Preferred A-2 Shares are convertible into 315,333 Ordinary Shares, representing a conversion price of \$3.80 per share, and entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Preferred A Shares.

Preferred A-4 Shares (pre-merger- BiomX Ltd.):

Preferred A-4 Shares are convertible into 617,255 Ordinary Shares, representing a conversion price of \$4.86 per share, and entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Preferred A Shares.

Preferred B Shares are convertible into 5,478,984 Ordinary Shares, representing a conversion price of \$5.83 per share, and entitle their holders to the rights, preferences, privileges and restrictions granted to and imposed upon the Preferred A Shares.

Preferred B Shares (pre-merger- BiomX Ltd.):

Preferred B Shares entitle their holder to participate in a distribution of surplus of assets upon liquidation of the Company, at an amount equal to their original issue price plus 8% annual interest accumulated as of the Liquidation Event (as defined in the Articles) date, before any distribution is made to holder of any Preferred A Shares (i.e., Preferred A Shares, Preferred A-1 Shares, Preferred A-2 Shares, Preferred A-3 Shares and Preferred A-4 Shares), and any Ordinary Shares.

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 65% of the issued and outstanding ordinary shares and all the preferred shares of BiomX Israel. The number of shares prior to the Reverse Capitalization have been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the Recapitalization Transaction.

BIOMX INC.
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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – SHAREHOLDERS EQUITY (Cont.)

B. Issuance of Share Capital:

In June 2015, the Company entered into the Incubator Agreement with the Incubator and other investors (the “June 2015 Investors”). In accordance with the Incubator Agreement, the Company issued 1,963,071 Ordinary Shares at \$0.0001 nominal value to the June 2015 Investors and an additional 302,828 Ordinary Shares at \$0.0001 nominal value to a trustee to be held in trust for the sole purpose of allocation of the Ordinary Shares to employees and consultants of the Company.

In addition, the Company issued 566,068 Preferred A Shares at \$0.0001 nominal value to the investors in consideration for \$960 thousands.

On February 2017, the Company entered into a share purchase agreement (the “February 2017 SPA”) with new and existing investors (the “February 2017 Investors”). In accordance with the February 2017 SPA, On February 15, 2017, the Company issued the February 2017 Investors 4,021,404 Preferred A-1 Shares at \$0.0001 nominal value (“Preferred A-1 Shares”), and 315,334 Preferred A-2 Shares at \$0.0001 nominal value in two tranches as follows:

- On February 15, 2017, the Company issued 2,010,702 Preferred A-1 Shares for total consideration of \$8,500 thousand. In addition, the convertible notes in an amount of \$1,200 thousand granted in August 2016 were converted into 315,334 Preferred A-2 Shares at \$0.0001 nominal value.
- On February 7, 2018, the Company issued 2,010,702 Preferred A-1 Shares for total consideration of \$8,500 thousand.

On March 26, 2017 the Company entered into share purchase agreement (the “March 2017 SPA”) with new investors (the “March 2017 Investors”). In accordance with the March SPA, the Company issued to the March 2017 Investors 1,419,320 Preferred A-1 Shares in two tranches as follows:

- On March 30, 2017, the Company issued 709,660 Preferred A-1 Shares for total consideration of \$3,000 thousand.
- On February 7, 2018, the Company issued 709,660 Preferred A-1 Shares for total consideration of \$3,000 thousand.

On November 30, 2017, the Company entered into a share purchase agreement (the “November 2017 SPA”) with additional investors (the “November 2017 Investors”). In accordance with the November 2017 SPA, the Company issued the November 2017 Investors 617,255 Preferred A-4 Shares at \$0.0001 nominal value in two tranches as follows:

- On December 7, 2017, the Company issued 308,628 Preferred A-4 Shares for total consideration of \$1,500 thousand.
- On February 7, 2018, the Company issued 308,628 Preferred A-4 Shares for total consideration of \$1,500 thousand.

BIOMX INC.
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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – SHAREHOLDERS EQUITY (Cont.)

B. Issuance of Share Capital: (Cont.)

On November 19, 2017, the Company signed an agreement to purchase 100% of RondinX shares (see also Note 6). The consideration transferred included an issuance of 604,449 Preferred A-1 Shares and 10,589 warrants to purchase Preferred A-1 shares for no additional consideration.

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.

C. Share-based compensation:

The Company has a plan whereby it grants options which represent a right to purchase 1 Ordinary Share of the Company in consideration of the payment of an exercise price. The options granted have been 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 IRS Code.

This plan was adjusted in 2019 following the reverse recapitalization transaction on October 28, 2019.

According to the original plan, employees and service providers were entitled to receive options to purchase ordinary shares of BiomX Israel. This plan was adjusted in a manner that options granted will entitle their holder to purchase common shares of the Company. As a result, the number of options and exercise price per share were adjusted based on the conversion ratio such that there was no change in the fair value of the options under the adjusted plan. All number of options, warrants, and exercise prices in this Note have been restated to reflect the adjusted option plan.

In 2015, the Company’s Board of Directors (the “Board”) approved a plan for allocation of options to employees, service providers and officers. As of September 30, 2019, the number of options available for grant under the approved plan was 396,908 options.

In November 2015, the Board approved the grant of 435,500 non-tradable options without consideration to one employee, four consultants and six employees of the Incubator. Based on the considerations in ASC 718-10, the employees of the Incubator were defined as employees based on their relationship with the Company.

The options to two of the consultants were granted at an exercise price of \$0.001 per share. 22% of the options vest and become exercisable on the first and second anniversaries of the vesting commencement date of June 2015. Thereafter, the options vest and become exercisable in three equal annual installments of 18.67% each.

The options to the employees of the Incubator and to two consultants were granted at an exercise price of \$0.001 per share. 33% of the options vest and become exercisable on the first anniversary of the vesting commencement date of June 2015. Thereafter, the options vest and become exercisable in 8 equal quarterly installments of 8.375% each.

The options to the Company employee were granted at an exercise price of \$0.001 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 installments of 6.25% each.

During 2016, the Board approved to grant an additional 310,078 non-tradable options without consideration to four employees and five consultants.

The options to three employees were granted at an exercise price of \$0.001 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 installments of 6.25% each.

BIOMX INC.
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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – SHAREHOLDERS EQUITY (Cont.)

C. Share-based compensation: (Cont.)

The options to one additional employee were granted at an exercise price of \$0.54 per share. 33,486 options vest and become exercisable upon appointment as chief executive officer of the Company. The remainder of the options shall vest as follows: 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 installments of 6.25% each.

The options to two consultants were granted at an exercise price of \$0.001 per share.

22% of the options vest and become exercisable on the first and second anniversaries of the vesting commencement date (June 2015). Thereafter, the options vest and become exercisable in three equal annual installments of 18.67% each.

The options to two additional consultants were granted at an exercise price of \$0.54 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 installments of 6.25% each.

The options to one additional consultant were granted at an exercise price of \$1.69 per share. 33% of the options vest and become exercisable on the first anniversary of the vesting commencement date. Thereafter, the options vest and become exercisable in 8 equal quarterly installments of 8.375% each.

During 2017, the Board approved to grant an additional 1,084,947 non-tradable options without consideration to 29 employees and 5 consultants.

The options to 29 employees and 3 consultants were granted at an exercise price of \$1.69 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 installments of 6.25% each.

The options to 2 additional consultants were granted at an exercise price of \$0.001 per share. 22% of the options vest and become exercisable on the first and second anniversaries of the vesting commencement date (June 2015). Thereafter, the options vest and become exercisable in three equal annual installments of 18.67% each.

During October 2017, 11,034 options were exercised to purchase Ordinary Shares at an exercise price of \$0.001 per share.

During 2018, the Board approved to grant additional 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 \$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 installments of 6.25% each.

108,752 options were granted at an exercise price of \$9.91 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.

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

BIOMX INC.
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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – SHAREHOLDERS EQUITY (Cont.)

C. Share-based compensation: (Cont.)

In March 2019, the Board approved to grant additional 514,702 non-tradable options without consideration to 21 employees and 6,051 non-tradable options without consideration to one consultant, at an exercise prices of \$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 installments of 6.25% each.

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 granted during the period was estimated at the date of grant using the following assumptions:

| | Nine months ended September 30, 2019 |
|---|---|
| Underlying value of ordinary share (\$) | 2.03 |
| Exercise price (\$) | 2.03 |
| Expected volatility (%) | 93.1 |
| Term of the option (years) | 6.25 |
| Risk-free interest rate (%) | 2.23 |

The cost of the benefit embodied in the options granted during the nine months ended September 30, 2019, based on their fair value as at the grant date, is estimated to be \$836 thousand. These amounts will be recognized in statements of operations over the vesting period.

Warrants:

1. In May 2017, in accordance with the 2017 License Agreement (see also Note 7C), the Company issued to Yeda, for no consideration, 591,382 warrants to purchase Ordinary Shares at \$0.0001 nominal value. The Company recognized expenses of \$49 thousand and \$46 thousand for the three months ended September 30, 2019 and 2018, respectively and \$97 thousand and \$135 thousand for the nine months ended September 30, 2019 and 2018, respectively, which were included in research and development expenses.

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,
- 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.

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NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – SHAREHOLDERS EQUITY (Cont.)

C. Share-based compensation: (Cont.)

2. In November 2017, in accordance with the RondinX share purchase agreement (see also Note 5), the Company issued to Yeda and 2 consultants, for no consideration, 10,589 warrants to purchase Preferred A-1 Shares at \$0.0001 nominal value.

The warrants were fully vested and exercisable on the date of their issuance.

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

| | For the nine months ended September 30, 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 | 514,702 | 2.03 | | 6,051 | 2.03 | |
| Forfeited | (123,182) | 1.91 | | - | | |
| Exercised | (41,199) | 1.05 | | - | | |
| Outstanding at the end of period | <u>2,219,070</u> | <u>1.68</u> | <u>18,463</u> | <u>708,439</u> | <u>0.7</u> | <u>6,588</u> |
| Vested at end of period | <u>806,496</u> | | | <u>502,304</u> | | |
| Weighted average remaining contractual life – years as of September 30, 2019 | <u>8.89</u> | | | <u>7.37</u> | | |
| | | | | Warrants issued to Yeda | | |
| | | | | Number of Options | Weighted average exercise price | Aggregate intrinsic value |
| Outstanding as of December 31, 2018 | | | | 591,382 | (*) | 1,200 |
| Outstanding as at September 30, 2019 | | | | 591,382 | (*) | 5,912 |
| Vested as at September 30, 2019 and December 31, 2018 | | | | 236,552 | | |
| Weighted average remaining contractual life – years as of September 30, 2019 | | | | 5.61 | | |
| Weighted average remaining contractual life – years as of December 31, 2018 | | | | 6.36 | | |

(*) Less than \$0.01.

BIOMX INC.
(formerly known as Chardan Healthcare Acquisition Corp.)
NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – SHAREHOLDERS EQUITY (Cont.)

C. 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:

| | Nine months ended September 30, | |
|----------------------------|---|-------------|
| | 2019 | 2018 |
| R&D | 520 | 466 |
| General and administrative | 360 | 222 |
| | 880 | 688 |
| | Three months ended September 30, | |
| | 2019 | 2018 |
| R&D | 153 | 121 |
| General and administrative | 96 | 112 |
| | 249 | 233 |

NOTE 9 - RELATED PARTIES

On October 31, 2018, BiomX 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 is eligible to receive fees totaling \$167 thousand in installments of \$50 thousand within 60 days of signing of the agreement, \$17 thousand upon completion of data processing, and two installments of \$50 thousand each, upon delivery of Signature Phase I of the Final Study Report (both terms defined within the agreement). Unless terminated earlier, this agreement will continue in effect, until 30 days after the parties complete the research program and BiomX provide Janssen with a final study report. The research period started during March 2019 and ended on September 2019. As of September 30, 2019, the Company received \$67 thousand with respect to this agreement. and recorded a reduction from research and development expenses of \$167 thousand during the period of nine months ended September 30, 2019.

NOTE 10 - SUBSEQUENT EVENTS

Refer to Note 1 regarding the consummation of the reverse recapitalization transaction.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the various expenses to be incurred in connection with the registration of the securities being registered hereby, all of which will be borne by us. All amounts shown are estimates except the SEC registration fee.

| | | |
|------------------------------------|----|-----------|
| SEC registration fee | \$ | 23,497.83 |
| Transfer agent's fees and expenses | \$ | * |
| Printing expenses | \$ | * |
| Legal fees and expenses | \$ | * |
| Accounting fees and expenses | \$ | * |
| Miscellaneous | \$ | * |
| Total expenses | \$ | * |

* Estimated expenses not presently known.

Item 14. Indemnification of Directors and Officers.

Our certificate of incorporation provides that all our directors, officers, employees and agents shall be entitled to be indemnified by us to the fullest extent permitted by Section 145 of the Delaware General Corporation Law.

Section 145 of the Delaware General Corporation Law concerning indemnification of officers, directors, employees and agents is set forth below.

“Section 145. Indemnification of officers, directors, employees and agents; insurance.

- (a) A corporation shall have power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.
- (b) A corporation shall have power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

- (c) To the extent that a present or former director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (a) and (b) of this section, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.
- (d) Any indemnification under subsections (a) and (b) of this section (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances because the person has met the applicable standard of conduct set forth in subsections (a) and (b) of this section. Such determination shall be made, with respect to a person who is a director or officer at the time of such determination, (1) by a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, or (2) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (3) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (4) by the stockholders.
- (e) Expenses (including attorneys' fees) incurred by an officer or director in defending any civil, criminal, administrative or investigative action, suit or proceeding may be paid by the corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the corporation as authorized in this section. Such expenses (including attorneys' fees) incurred by former officers and directors or other employees and agents may be so paid upon such terms and conditions, if any, as the corporation deems appropriate.
- (f) The indemnification and advancement of expenses provided by, or granted pursuant to, the other subsections of this section shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. A right to indemnification or to advancement of expenses arising under a provision of the certificate of incorporation or a bylaw shall not be eliminated or impaired by an amendment to such provision after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought, unless the provision in effect at the time of such act or omission explicitly authorizes such elimination or impairment after such action or omission has occurred.
- (g) A corporation shall have power to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under this section.
- (h) For purposes of this section, references to "the corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under this section with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued.
- (i) For purposes of this section, references to "other enterprises" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a person with respect to any employee benefit plan; and references to "serving at the request of the corporation" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the corporation" as referred to in this section.

- (j) The indemnification and advancement of expenses provided by, or granted pursuant to, this section shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.
- (k) The Court of Chancery is hereby vested with exclusive jurisdiction to hear and determine all actions for advancement of expenses or indemnification brought under this section or under any bylaw, agreement, vote of stockholders or disinterested directors, or otherwise. The Court of Chancery may summarily determine a corporation's obligation to advance expenses (including attorneys' fees).

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

In accordance with Section 102(b)(7) of the DGCL, our certificate of incorporation provides that no director shall be personally liable to it or any of its stockholders for monetary damages resulting from breaches of their fiduciary duty as directors, except to the extent such limitation on or exemption from liability is not permitted under the DGCL unless they violated their duty of loyalty to us or our stockholders, acted in bad faith, knowingly or intentionally violated the law, authorized unlawful payments of dividends, unlawful stock purchases or unlawful redemptions, or derived improper personal benefit from their actions as directors. The effect of this provision of our certificate of incorporation is to eliminate our rights and those of our stockholders (through stockholders' derivative suits on its behalf) to recover monetary damages against a director for breach of the fiduciary duty of care as a director, including breaches resulting from negligent or grossly negligent behavior, except, as restricted by Section 102(b)(7) of the DGCL. However, this provision does not limit or eliminate our rights or the rights of any stockholder to seek non-monetary relief, such as an injunction or rescission, in the event of a breach of a director's duty of care.

If the DGCL is amended to authorize corporate action further eliminating or limiting the liability of directors, then, in accordance with our certificate of incorporation, the liability of our directors to us or our stockholders will be eliminated or limited to the fullest extent authorized by the DGCL, as so amended. Any repeal or amendment of provisions of the Registrant's certificate of incorporation limiting or eliminating the liability of directors, whether by our stockholders or by changes in law, or the adoption of any other provisions inconsistent therewith, will (unless otherwise required by law) be prospective only, except to the extent such amendment or change in law permits us to further limit or eliminate the liability of directors on a retroactive basis.

Our certificate of incorporation also provides that we will, to the fullest extent authorized or permitted by applicable law, indemnify our current and former officers and directors, as well as those persons who, while directors or officers of our corporation, are or were serving as directors, officers, employees or agents of another entity, trust or other enterprise, including service with respect to an employee benefit plan, in connection with any threatened, pending or completed proceeding, whether civil, criminal, administrative or investigative, against all expense, liability and loss (including, without limitation, attorney's fees, judgments, fines, ERISA excise taxes and penalties and amounts paid in settlement) reasonably incurred or suffered by any such person in connection with any such proceeding. Notwithstanding the foregoing, a person eligible for indemnification pursuant to our certificate of incorporation will be indemnified by us in connection with a proceeding initiated by such person only if such proceeding was authorized by our board of directors, except for proceedings to enforce rights to indemnification.

The right to indemnification conferred by our certificate of incorporation is a contract right that includes the right to be paid by us the expenses incurred in defending or otherwise participating in any proceeding referenced above in advance of its final disposition, provided, however, that if the DGCL requires, an advancement of expenses incurred by our officer or director (solely in the capacity as our officer or director) will be made only upon delivery to us of an undertaking, by or on behalf of such officer or director, to repay all amounts so advanced if it is ultimately determined that such person is not entitled to be indemnified for such expenses under our certificate of incorporation or otherwise.

The rights to indemnification and advancement of expenses will not be deemed exclusive of any other rights which any person covered by our certificate of incorporation may have or hereafter acquire under law, our certificate of incorporation, our bylaws, an agreement, vote of stockholders or disinterested directors, or otherwise.

Any repeal or amendment of provisions of our certificate of incorporation affecting indemnification rights, whether by our stockholders or by changes in law, or the adoption of any other provisions inconsistent therewith, will (unless otherwise required by law) be prospective only, except to the extent such amendment or change in law permits us to provide broader indemnification rights on a retroactive basis, and will not in any way diminish or adversely affect any right or protection existing at the time of such repeal or amendment or adoption of such inconsistent provision with respect to any act or omission occurring prior to such repeal or amendment or adoption of such inconsistent provision. Our certificate of incorporation will also permit us, to the extent and in the manner authorized or permitted by law, to indemnify and to advance expenses to persons other than those specifically covered by our certificate of incorporation.

Our bylaws include the provisions relating to advancement of expenses and indemnification rights consistent with those set forth in our certificate of incorporation. In addition, our bylaws provide for a right of indemnity to bring a suit in the event a claim for indemnification or advancement of expenses is not paid in full by us within a specified period of time. Our bylaws also permit us to purchase and maintain insurance, at our expense, to protect ourselves and/or any of our director, officer, employee or agent or another entity, trust or other enterprise against any expense, liability or loss, whether or not we would have the power to indemnify such person against such expense, liability or loss under the DGCL.

Any repeal or amendment of provisions of our bylaws affecting indemnification rights, whether by our board of directors, stockholders or by changes in applicable law, or the adoption of any other provisions inconsistent therewith, will (unless otherwise required by law) be prospective only, except to the extent such amendment or change in law permits us to provide broader indemnification rights on a retroactive basis, and will not in any way diminish or adversely affect any right or protection existing thereunder with respect to any act or omission occurring prior to such repeal or amendment or adoption of such inconsistent provision.

In addition, we are party to indemnification agreements with each of our directors and executive officers. These agreements require us to indemnify these individuals to the fullest extent permitted by the DGCL against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. We maintain standard policies of insurance that provide coverage (1) to our directors and officers against loss arising from claims made by reason of breach of duty or other wrongful act and (2) to us with respect to indemnification payments that we may make to such directors and officers.

Item 15. Recent Sales of Unregistered Securities.

The 16,625,000 shares of Common Stock and vested securities issued pursuant to the Merger Agreement were issued in reliance upon an exemption from the registration requirements pursuant to Section 4(a)(2) of the Securities Act. The securityholders of BiomX receiving the shares of Common Stock represented their intention to acquire the shares for investment only and not with a view to or for sale in connection with any distribution, and appropriate restrictive legends were affixed to the certificates representing the shares. The parties also had adequate access, through business or other relationships, to information about the Company and BiomX.

Item 16. Exhibits and Financial Statement Schedules

- (a) *Exhibits.* The list of exhibits preceding the signature page of this registration statement is incorporated herein by reference.
- (b) *Financial Statements.* See page F-1 for an index to the financial statements and schedules included in the registration statement.

Item 17. Undertakings

- (a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.
- (b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.
- (c) The undersigned registrant hereby undertakes that:
 - (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
 - (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
 - (3) For the purpose of determining liability under the Securities Act of 1933 to any purchaser, if the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
 - (4) For the purpose of determining liability of a registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of an undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by an undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Ness Ziona, Israel, on this 13th day of December, 2019.

BIOMX INC.

By /s/ Jonathan Solomon
Jonathan Solomon
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each of the undersigned constitutes and appoints Mr. Jonathan Solomon, Mr. Uri Ben-Or 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 Registration Statement 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 Act, this Registration Statement has been signed below by the following persons in the capacities and on the date indicated.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|---|-------------------|
| <u>/s/ Dr. Russell Greig</u> Dr. Russell Greig | Chairman of the Board of Directors | December 13, 2019 |
| <u>/s/ Jonathan Solomon</u> Jonathan Solomon | Chief Executive Officer (Principal Executive Officer) and Director | December 13, 2019 |
| <u>/s/ Uri Ben-Or</u> Uri Ben-Or | Interim Chief Financial Officer (Principal Financial Officer) | December 13, 2019 |
| <u>/s/ Dr. Gbola Amusa</u> Dr. Gbola Amusa | Director | December 13, 2019 |
| <u>/s/ Yaron Breski</u> Yaron Breski | Director | December 13, 2019 |
| <u>/s/ Erez Chimovits</u> Erez Chimovits | Director | December 13, 2019 |
| <u>/s/ Jonas Grossman</u> Jonas Grossman | Director | December 13, 2019 |
| <u>/s/ Lynne Sullivan</u> Lynne Sullivan | Director | December 13, 2019 |
| <u>/s/ Dr. Robbie Woodman</u> Dr. Robbie Woodman | Director | December 13, 2019 |

AUTHORIZED REPRESENTATIVE IN THE UNITED STATES

Pursuant to the requirements of the Securities Act, the undersigned duly authorized representative in the United States of BiomX Inc. has signed this Registration Statement in the City of Killingworth, in the State of Connecticut, on this 13th day of December, 2019.

BIOMX INC.

By /s/ Dr. Sailaja Puttagunta
Dr. Sailaja Puttagunta
Chief Medical Officer

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) |
| 5.1 | Opinion of Mayer Brown LLP regarding the Offered Securities |
| 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* | <u>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)</u> |
| 10.10** | <u>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)</u> |
| 10.11 | <u>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)</u> |
| 10.12 | <u>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)</u> |
| 10.13 | <u>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)</u> |
| 10.14 | <u>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)</u> |
| 10.15 | <u>Investment Management Trust Agreement, dated December 13, 2018, between Continental Stock Transfer & Trust Company and the registrant (Incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed by the registrant on December 18, 2018)</u> |
| 10.16 | <u>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)</u> |
| 10.17 | <u>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)</u> |
| 10.18 | <u>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)</u> |
| 16.1 | <u>Letter from Marcum LLP (Incorporated by reference to Exhibit 16.1 to the registrant's Current Report on Form 8-K filed by the registrant on November 4, 2019)</u> |
| 21.1 | <u>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)</u> |
| 23.1 | <u>Consent of Brightman Almagor Zohar & Co., independent registered public accounting firm</u> |
| 23.2 | <u>Consent of Mayer Brown LLP (included in Exhibit 5.1)</u> |

* 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.

December 13, 2019

BiomX Inc.
7 Pinhas Sapir St., Floor 2
Ness Ziona, Israel 7414002

Re: Registration Statement on Form S-1
BiomX Inc.

Ladies and Gentlemen:

BiomX Inc., a Delaware corporation (the "Company"), has filed with the Securities and Exchange Commission a Registration Statement on Form S-1 (the "Registration Statement"), under the Securities Act of 1933, as amended (the "Act").

The Registration Statement relates to the resale by the selling securityholders identified in the Registration Statement or their permitted transferees of up to 15,741,829 shares of the Company's common stock, par value \$0.0001 per share ("Common Stock"), which consist of (a) 3,500,000 shares of Common Stock that may be issued upon the exercise of 7,000,000 warrants (the "Public Warrants") originally sold as part of the units offered in the Company's initial public offering (the "IPO") and which entitle the holder to purchase one-half (1/2) of a share of Common Stock at an exercise price of \$11.50 per whole share of Common Stock, (b) 2,900,000 shares of Common Stock that may be issued upon the exercise of 2,900,000 warrants (the "Private Placement Warrants," and together with the Public Warrants, the "Warrants") issued in a private placement that closed simultaneously with the consummation of the IPO, which entitle the holder to purchase Common Stock at an exercise price of \$11.50 per share of Common Stock, (c) 7,604,329 shares of Common Stock issued in a private placement in connection with the consummation of the business combination pursuant to that certain merger agreement dated as of July 16, 2019 and amended as of October 11, 2019 (the "Merger Agreement") by and among the Company, BiomX Ltd., CHAC Merger Sub Ltd., an Israeli company and wholly owned subsidiary of the Company, and Shareholder Representative Services LLC, solely in its capacity as the shareholders' representative thereunder, and (d) 1,737,500 shares of Common Stock sold in one or more private placements prior to the IPO. We have acted as counsel to the Company in connection with the preparation and filing of the Registration Statement.

In rendering the opinions set forth below, we have assumed without investigation the genuineness of all signatures and the authenticity of all documents submitted to us as originals, the conformity to authentic original documents of all documents submitted to us as copies, and the veracity of the documents. As to questions of fact material to the opinions hereinafter expressed, we have relied upon the representations and warranties of the Company made in the documents and upon statements of officers of the Company.

Mayer Brown is a global services provider comprising an association of legal practices that are separate entities including Mayer Brown LLP (Illinois, USA), Mayer Brown International LLP (England), Mayer Brown (a Hong Kong partnership) and Tauli & Chequer Advogados (a Brazilian partnership).

Based upon the foregoing examination, and subject to the qualifications set forth below, we are of the opinion that:

1. the Warrants have been duly authorized by the Company and constitute valid and binding obligations of the Company, enforceable against the Company in accordance with their terms,
2. the shares of Common Stock that may be issued upon the exercise of the Warrants have been duly authorized by the Company and, when the Warrants are exercised against payment therefor in accordance with the terms of the applicable warrant agreements, will be validly issued, fully paid and non-assessable, and
3. the shares of Common Stock that were issued pursuant to the Merger Agreement and in one or more private placements prior to the IPO are validly issued, fully paid and non-assessable.

The opinions expressed above are limited to the General Corporation Law of the State of Delaware which includes the statutory provisions thereof as well as all applicable provisions of the Constitution of the State of Delaware and reported judicial decisions interpreting these laws. Our opinion is rendered only with respect to laws, and the rules, regulations and orders thereunder, which are currently in effect.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the reference to us under the caption "Legal Matters" in the prospectus comprising a part of the Registration Statement. In giving this consent, we do not thereby admit that we are included within the category of persons whose consent is required by Section 7 of the Act and the rules and regulations promulgated thereunder.

Very truly yours,

/s/ Mayer Brown LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation in this Registration Statement on Form S-1 of our report dated December 13, 2019, relating to the financial statements of BiomX Inc. as of December 31, 2018 and 2017 appearing in the Prospectus, which is part of this Registration Statement.

We also consent to the reference to our Firm under the heading “Experts” in such Prospectus.

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

Tel Aviv, Israel
December 13, 2019