UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended January 31, 2020

or

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

For the transition period from to

Commission File No. 001-37411

BioPharmX Corporation

(Exact name of registrant as specified in its charter)

Delaware	**59-3843182**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
900 E. Hamilton Ave., Suite 100, Campbell, California	**95008**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **650-889-5020**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**BPMX**	**The NYSE American, LLC**

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

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

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

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

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

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☐

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

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

As of July 31, 2019, the last day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the shares of the Registrant's common stock held by non-affiliates was $5.9 million, based upon the closing price of the Registrant's common stock as reported on the NYSE American on July 31, 2019. Shares of the Registrant's common stock held by each executive officer and director and by each person who owns 10 percent or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 29, 2020, there were outstanding 18,278,219 shares of the registrant's common stock, $0.001 par value.

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This Annual Report on Form 10-K, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Words such as "expect," "anticipate," "target," "goal," "project," "hope," "intend," "plan," "believe," "seek," "estimate," "continue," "may," "could," "should," "might," variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements other than statements of historical fact are forward-looking statements, including statements regarding overall trends, operating cost and revenue trends, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions. We have based these forward-looking statements on our current expectations about future events. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons. Given these risks, uncertainties and assumptions you are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. Except as required under federal securities laws and the rules and regulations of the Securities and Exchange Commission ("SEC"), we do not undertake, and specifically decline, any obligation to update any of these statements or to publicly announce the results of any revisions to any forward- looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Unless the context otherwise requires, we use the terms "BioPharmX," "Company," "we," "us" and "our" in this Annual Report on Form 10- K to refer to BioPharmX Corporation and its subsidiary.

BioPharmX, HyantX, Smarter Drug Delivery and the BioPharmX logo are our trademarks. We also refer to trademarks of other corporations or organizations in this report that are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

PART I

ITEM 1. BUSINESS

Overview

We are a specialty pharmaceutical company focused on the dermatology market. Our focus is to develop products that treat dermatologic conditions that are not being adequately addressed or those where current therapies and approaches are suboptimal. Our strategy is to bring new products to market by improving delivery mechanisms and/or identifying alternative applications for U.S. Food and Drug Administration, or FDA, approved or well characterized active pharmaceutical ingredients, or APIs. Our goal is to reduce the time, cost and risks typically associated with new product development by utilizing APIs with demonstrated safety profiles and, when applicable, taking advantage of the regulatory approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDC Act. Section 505(b)(2) permits an applicant for a new product, such as a new or improved formulation or a new use of an approved product, to rely in part, on literature and/or on the FDA's findings of safety and/or effectiveness for a similar previously-approved product. Our approach is to identify the limitations of current treatment options and work to develop novel products using our proprietary HyantX topical drug delivery system.

On January 28, 2020, we entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Timber Pharmaceuticals LLC, a Delaware limited liability company, or Timber, and BITI Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of BioPharmX, or Merger Sub. Subject to the terms and conditions contained in the Merger Agreement, including approval of the transactions contemplated therein by our stockholders and by Timber's members, Merger Sub will be merged with and into Timber, or the Merger, with Timber surviving the Merger as a wholly-owned subsidiary of BioPharmX. As a condition to the closing of the Merger, Timber has agreed to secure $20 million of financing for the combined company. The Merger is currently expected to be completed in the first quarter of fiscal year 2021.

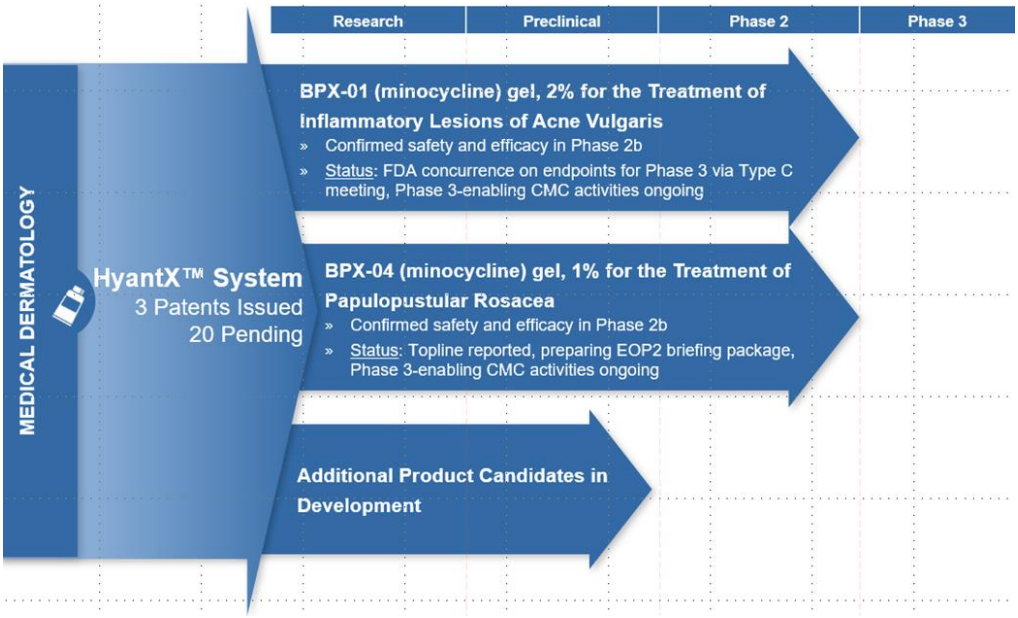
Under the Merger Agreement, following the Merger, the Timber members, including the investors funding the $20 million investment, will own approximately 88.5% of the outstanding common stock of BioPharmX and the BioPharmX stockholders will own approximately 11.5% of the outstanding common stock, subject to certain adjustments as more particularly set forth in the Merger Agreement. The holder of a preferred membership interest in Timber of approximately $1.7 million will receive shares of newly designated preferred stock of BioPharmX which, other than conversion rights, shall have economic terms which are substantially the same as the economic terms of the preferred units of Timber currently outstanding. In addition, as part of the financing transaction, post-closing we will become obligated to issue warrants to purchase additional shares of common stock to the financing source, which may further dilute the holders of interests in the combined company. Upon completion of the Merger, we will change our name to Timber Pharmaceuticals, Inc. and the officers and directors of Timber will become the officers and directors of BioPharmX.

In connection with the Merger Agreement, we entered into a Credit Agreement with Timber, pursuant to which Timber has agreed to make a bridge loan to us, or the Bridge Loan, in an aggregate amount of $2.25 million with $250,000 originial issue discount. The Bridge Loan bears interest at a rate of 12% per annum and is repayable upon the earlier of maturity thereof, the termination (without completion) of the Merger or upon a liquidity event. The Bridge Loan is collateralized by a lien on all of our assets. As of the date of this report, we have received $1,250,000 under the Bridge Loan and the remaining $1,000,000 is expected upon closing of the Merger. As of our fiscal year end, we received $625,000 with $75,000 original issue discount.

Product Candidates

Our current portfolio includes two clinical-stage product candidates: BPX-01 is a 2% minocycline gel for the treatment of inflammatory lesions of acne vulgaris and BPX-04 is a 1% minocycline gel for the treatment of papulopustular rosacea. We have presented a comprehensive overview of the positive clinical results from our Phase 2b trial of BPX-01 for the treatment of moderate-to-severe inflammatory lesions of acne vulgaris and received positive feedback from the FDA regarding our Phase 3 clinical trial plans. We also announced positive topline results from our Phase 2b trial of BPX-04 for the treatment of moderate-to-severe papulopustular rosacea. BPX-04 successfully met both the primary and secondary endpoints of the trial in demonstrating a statistically significant mean change in the number of facial inflammatory lesions and a two-grade improvement to clear or almost clear on the Investigator's Global

Assessment, or IGA, scale from baseline to week 12. We have developed our product portfolio using our HyantX topical drug delivery system. The following chart presents a summary of our product candidates:



HyantX Topical Drug Delivery System

We have developed our product portfolio using our HyantX topical drug delivery system, which is an anhydrous, hydrophilic, non-oily, non-occlusive gel vehicle that allows for the stabilization and solubilization of APIs with the aim to improve bioavailability and therefore lower the required dose of the drug. The system is designed for rapid absorption of API into the skin rather than remaining on the surface as this may cause irritation, a common problem with oil-based ointments and suspensions. The delivery system is particularly suitable for APIs, or a combination of APIs, that undergo degradation by hydrolysis or oxidation. Our lead product candidates are minocycline formulations delivered topically using the HyantX system.

BPX01 (minocycline) gel, 2% — Acne

BPX-01 is a topical antibiotic gel for the treatment of inflammatory lesions of acne, which combines the most widely used oral antibiotic drug (minocycline) for the treatment of inflammatory lesions of acne vulgaris with a proprietary anhydrous hydrophilic topical delivery system, the HyantX delivery system, specifically designed to localize the delivery of the drug while minimizing systemic exposure and the resultant side effects. Our proprietary HyantX topical delivery system allows for a lower dosage of drug by improving the bioavailability with targeted delivery of fully solubilized minocycline. In addition to its bacteriostatic properties, the API, minocycline, also has anti-inflammatory properties, which may help to reduce the inflammation and redness commonly associated with acne.

We completed a Phase 2b randomized, double-blind, three-arm, vehicle-controlled, dose-finding study to assess the efficacy and safety of BPX-01 for the treatment of acne. The multi-center study evaluated two concentrations of BPX-01 (1% and 2% minocycline) and vehicle in 226 subjects, aged 9 to 40, with moderate-to-severe inflammatory, non-nodular acne. The study showed the 2% concentration was statistically superior in reducing the number of inflammatory lesions in patients with moderate-to-severe acne, compared to vehicle (58.5% reduction vs. 43.8%, respectively, at week 12, p=0.03).

Study Arm	Subjects	Mean Change in Inflammatory Lesions	Percent Reduction in Inflammatory Lesions
BPX-01 2%	n=72	-15.4 (p=0.0352)	58.5% (p=0.0256)
BPX-01 1%	n=73	-15.5 (p=0.0543)	54.4% (p=0.0765)
Vehicle	n=74	-11.2	43.8%

This Phase 2b study also measured, as a secondary endpoint, improvement on a five-point investigator's global assessment, or IGA, scale. The observed difference between BPX-01 2% versus vehicle in achieving a two-grade improvement and an IGA score of 0 or 1 at week 12 using the Last-Observation-Carried-Forward method for study participants with missing data was 25.0% (18/72) vs. 17.6% (13/74) producing a chi-square p-value of 0.27 (without Bonferroni correction for pairwise comparison). As a Phase 2b clinical trial, the trial was not powered to measure statistical significance for the secondary endpoint, however, a clear numerical trend was observed in the BPX-01 2% arm compared to vehicle. IGA was included as a secondary endpoint in our Phase 2b study as this information is necessary to calculate sample size estimates to adequately power the Phase 3 studies for success. Since FDA guidance for the approval of topical prescription acne products recommends IGA as a co-primary endpoint along with a reduction in absolute lesion counts for Phase 3 trials to support a New Drug Application, or NDA, the planned Phase 3 studies will be powered to demonstrate statistical significance of IGA improvement with at least a two-grade improvement and a score of clear (0) or almost clear (1) for drug compared to vehicle as well as being powered to show a reduction in inflammatory lesion counts.

The safety results of the study showed that no subjects experienced serious treatment-related adverse side effects. As cutaneous tolerability of a topical therapy is a significant driver in patient compliance, we are encouraged that 97% of cutaneous tolerability signs or symptoms were "none" or "mild" at week 12.

Blood draws in this study showed that plasma minocycline levels following topical use were undetectable in all but a single subject, whose level – 42 ng/mL – was less than one-tenth of that measured after a single standard adult dosage of oral minocycline.

BPX04 (minocycline) gel, 1% — Rosacea

BPX-04 is a novel topical gel formulation of fully solubilized minocycline for the treatment of papulopustular rosacea. The product candidate leverages the HyantX™ topical delivery system, an anhydrous hydrophilic gel formulation, designed for rapid absorption of active pharmaceutical ingredients into the skin rather than remaining on the surface, a common problem with oil-based ointments and suspensions.

We completed a randomized, double-blind, vehicle-controlled Phase 2b trial, which enrolled 206 subjects aged 18 years and above with moderate-to-severe papulopustular rosacea across 11 sites in the United States. The study evaluated the safety and efficacy of once daily application of BPX-04, a 1% minocycline gel, versus a vehicle control over a 12-week treatment period.

The study was designed to demonstrate a statistically significant mean change in the number of facial inflammatory lesions from baseline to week 12. The secondary endpoint, the proportion of subjects with a two-grade improvement to clear or almost clear on the IGA scale from baseline to week 12, was included to collect sufficient data to design a Phase 3 program with co-primary efficacy endpoints, however, as is standard in a Phase 2 trial, the study was not designed to demonstrate statistical significance on the secondary endpoint.

Baseline Severity

The mean inflammatory lesion count at baseline was 23.9 and 24.0 for the BPX-04 and vehicle treatment groups, respectively.

The proportion of subjects with an IGA score of 3 ("moderate") and 4 ("severe") at baseline was 92.7% and 7.3% for the BPX-04 treatment group, respectively, and 91.1% and 8.9% for the vehicle treatment group, respectively.

Safety and Tolerability

BPX-04 appeared to be generally well-tolerated. The most commonly reported adverse events across both treatment groups were upper respiratory tract infection (5.3%), gastroenteritis (2.4%) and headache (2.4%) with the majority of these adverse events determined to be not treatment-related. There were no serious treatment-related adverse events.

Efficacy Assessments

The below table details the primary and secondary efficacy results from the trial whereby BPX-04 demonstrated a statistically significant improvement from baseline. In addition to meeting the primary and secondary endpoints of the trial, BPX-04 demonstrated a statistically significant reduction in the number of facial inflammatory lesions at all time points (weeks 4, 8 and 12).

	BPX-04 Gel (N=96)	**Vehicle (N=101)**
Primary endpoint*: **Mean change in the number of facial inflammatory lesions from baseline to week 12**	-13.6	-10.3
Secondary endpoint:*** **Proportion of subjects with a two-grade improvement in IGA to 0 ("clear") or 1 ("almost clear") from baseline to week 12**	52.3%	32.3%

*MMRM (mixed-effects model for repeated measures), ITT, MI; **GLMM (generalized linear mixed model), ITT, MI

Note: The ITT population was prospectively defined as all study patients randomized who received at least one dose of the study product and with at least one evaluation of primary and secondary endpoint measures post-baseline visit. There were 9 subjects randomized that did not meet the ITT criteria as there were no evaluation visits post-baseline.

Other Products

On November 27, 2018, we entered into an agreement to divest the rights to our molecular iodine technology, or BPX-03, and our dietary supplement product, VI_2OLET. Each of our prior collaboration, license, colocation and supply agreements related to VI_2OLET were terminated or assigned to the purchaser. We do not expect to receive any royalty revenue in the near future.

Target Markets

The Acne Market

Acne is a common inflammatory skin condition considered a chronic disease with accompanying negative aesthetic and social impact on patients. Propionibacterium acnes (P. acnes) are normal inhabitants on human skin and have been implicated in the pathogenesis of inflammatory lesions of acne vulgaris.

In the United States alone, acne affects between 40 million and 50 million people each year according to the American Academy of Dermatology. According to SSR Health, a provider of health care focused investment research, branded acne prescription medication accounted for $4.2 billion in sales in the rolling twelve month period ending September 2017 ($2.0 billion topical and $2.2 billion oral). The leading manufacturers are Galderma S.A., Almirall S.A.,

Bausch Health Companies Inc., Teva Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Ltd., and Mayne Pharma Group Limited.

The Rosacea Market

Rosacea is a chronic dermatologic condition characterized by redness, stinging and inflammatory lesions primarily on the face. It has four subtypes including erythematotelangiectatic rosacea, papulopustular rosacea, phymatous rosacea, and ocular rosacea. Symptoms include dilated blood vessels, redness, swelling, and acne-like papules and pustules on the face. Although the biology of rosacea remains unclear, it is thought to be an inflammatory disorder that involves immune responses and microorganisms.

Rosacea is estimated to affect more than 16 million people in the United States alone, according to the National Rosacea Society. The rosacea market is estimated to be greater than $1.0 billion in the United States according to Symphony Health Services. Branded prescription product revenue was $590.0 million in 2017 according to SSR Health, with more than 90% of this revenue being generated by three brands. The leading manufacturers are Galderma S.A. and LEO Pharma A/S.

Competitive Strengths

We believe that the strengths and differentiating benefits of our HyantX topical delivery system and the expertise of our team in the areas of product development and commercialization for prescription products are the core elements driving our Company. The key elements of our competitive strengths include the following:

- A proprietary topical drug delivery technology with broad applicability across APIs that are more susceptible to degradation by hydrolysis or oxidation;
- Late-stage product candidates with demonstrated clinical efficacy and promising safety profiles;
- A management team experienced in developing and commercializing drug delivery platforms, and
- An experienced medical advisory board providing strategic leadership and clinical guidance within the dermatology community.

Technology and Intellectual Property

Overview

Our success, in large part, depends upon our ability to obtain and protect our proprietary products and platform technologies. Our goal is to develop an intellectual property portfolio that enables us to capitalize on the research and development that we have performed to date, particularly for each of the products in our development pipeline. We rely on a combination of patent, copyright, trademark and trade secret laws in the United States and other countries to protect our intellectual property.

We also rely on a combination of non-disclosure, confidentiality and other contractual restrictions to protect our technologies and intellectual property. We require our employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with us. We also require them to agree to disclose and assign to us all inventions conceived in connection with the relationship.

Patents

Patent protection is an important aspect of our product development process and we are actively developing intellectual property in-house. We have a total of six U.S. provisional and utility patent applications pending related to our topical compositions for dermatological conditions. We have seven issued U.S. patents. Four of these patents relate to a microparticle drug delivery technology. Two of these relate to BPX-01, BPX-04 and the HyantX topical delivery system. We also have one issued international patent and 18 pending international patent applications. Of the 18 pending international applications, 16 relate to BPX-01, BPX-04 and the HyantX topical delivery system and two relate to a microparticle drug delivery technology. These international patent applications resulted from development of our unique

formulations, for example with minocycline, and were filed according to local laws of the Patent Cooperation Treaty. Generally, a patent application filed according to the Patent Cooperation Treaty enables us to apply for patent protection for the invention(s) described in the application in individual countries within a specified period after filing the application. Generally, patents issued in the United States are effective for 20 years from the earliest non-provisional filing date, if the application from which the patent issues was filed on or after June 8, 1995 (otherwise the term is the longer of 17 years from the issue date and 20 years from the earliest non-provisional filing date). The duration of patent terms for non-U.S. patents is typically 20 years from the earliest corresponding national or international filing date.

Trademarks

We have applied for trademark protection for several trademarks in the United States. The U.S. Patent and Trademark Office, or USPTO, has registered several of our trademarks: “BIOPHARMX,” “HYANTX” and “SMARTER DRUG DELIVERY”.

We have also applied for trademark protection in three markets outside the United States. In the European Union and China, we have a registered trademark for “BIOPHARMX”.

Research and Development

A core competency is providing the link between concept and commercialization through focused, practical product development based on innovative research. We employ highly-qualified scientists and utilize consultants specializing in our various product development areas. Research and development expenses for the years ended January 31, 2020 and 2019 were $4.7 million and $9.1 million, respectively.

As a Campbell-based company, we are located in a region with many strong biotechnology and pharmaceutical companies, which have drawn a high caliber of scientists and scientific support staff to the region. While there is intense competition for this type of personnel, we believe our location enables us to expand our product development and consultant resources as our business grows. Our location also provides us with convenient access to local formulation resources and preclinical testing facilities.

Manufacturing, Supply and Production

We utilize contract manufacturers to produce our products for clinical development and commercial distribution. We have no plans to establish in-house manufacturing capabilities for large-scale production at this time.

Marketing, Sales & Distribution

Our team has experience in the commercialization of prescription products across several different therapeutic areas. While BPX-01 and BPX-04 continue through clinical development, we have commenced our go-to-market strategic planning for these products including, but not limited to, organizing a medical advisory board of dermatologists in the United States, educating physicians through publishing our preclinical and clinical results at several industry conferences and developing our market access and pricing strategy. Our commercialization plans will largely depend on whether we enter into a strategic partnership for one or both of the product candidates and the nature of such partnership.

Customers

Potential customers for our product candidates include pharmaceutical companies, physician’s practices, dermatologists and general practitioners.

Competition

Acne

While the acne market has a number of competitive products, BPX-01 is being developed to combine the most successful oral antibiotic drug (minocycline) for the treatment of moderate to severe acne with a targeted topical antibiotic technology specifically designed to localize the delivery of the drug while minimizing systemic side effects. At the present time, there is no FDA-approved topical solution for this drug.

A number of approved prescription acne products currently exist in oral form such as isotretinoins, antibiotics, antimicrobials and oral contraceptives. These treatments are marketed by a number of large pharmaceutical and specialty pharmaceutical companies including, but not limited to: Almirall S.A., Bausch Health Companies Inc., Teva Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Ltd., and Mayne Pharma Group Limited. Additionally, there are several prescription acne products that exist in topical form such as antibiotics, antimicrobials, azelaic acids, retinoids, or some combination of the two. These topical solutions are marketed by companies such as Galderma S.A., Almirall S.A., Bausch Health Companies Inc., and Mayne Pharma Group Limited. In addition to prescription acne therapies discussed above, there are numerous over-the-counter, or OTC, products in the form of benzoyl peroxide and salicylic acid topical solutions available from various cosmetic and cosmeceutical companies such as Aveeno, Clean & Clear, Clearasil, Neutrogena and Proactiv.

Energy-based devices have also been widely used by dermatologists, such as intense pulsed light, or IPL, and a device called elos, by Syneron Medical Ltd. and Candela Corporation, that uses a combination of IPL and radiofrequency technologies. Combination drug-device treatments, such as fractional lasers and photodynamic therapy, or PDT, with blue light, such as BLU-U by Dusa Pharmaceuticals, have been used to treat acne.

While there historically has been no FDA-approved topical minocycline solution for acne or otherwise, on October 18, 2019, Foamix Pharmaceuticals Ltd. announced FDA approval of AMZEEQ™, a 4% topical minocycline foam.

Rosacea

Unlike the acne market, the rosacea market has a relatively limited number of available therapies. The challenge with current topical treatments is that skin with rosacea is easily aggravated by too much drug or an irritating vehicle. BPX-04 is designed to deliver the active, minocycline, into the skin without further irritating the skin. While the cause of rosacea is unclear, there are various oral and topical medications to treat the condition, such as antibiotics, anti-parasitics, azelaic acid and alpha-A agonists. Current treatments are marketed by companies such as Aclaris Therapeutics, Inc., LEO Pharma A/S, and Galderma S.A. In addition to prescription rosacea therapies, devices such as IPL and the pulsed dye laser can be helpful in treating other rosacea symptoms, such as telangiectasia and vascular erythema.

While there is no FDA-approved topical minocycline solution for rosacea or otherwise, we are aware of two competitive products which have completed Phase 2 and Phase 3 clinical trials, respectively, with the competitive product having completed Phase 3 clinical trials having submitted an NDA for the treatment of papulopustular rosacea.

Government Regulation

In the United States, foods, drugs, medical devices, cosmetics, tobacco products and radiation-emitting products are subject to extensive regulation by the FDA. The FDC Act and other federal and state statutes and regulations govern, among other things, the manufacture, distribution and sale of these products. These laws and regulations prescribe criminal and civil penalties that can be assessed, and violation of these laws and regulations can result in enforcement action by the FDA and other regulatory agencies.

FDA Regulation of Drugs

New Drug Approval Process

Pharmaceutical products are subject to extensive regulation by the FDA. The FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new

drug, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the IND to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, after the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in instances where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently approximately $2,943,000 for fiscal year 2020. Under an approved NDA, the applicant is subject to an annual program fee, currently approximately $325,000 per prescription product for fiscal year 2020. These fees typically increase annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. If the NDA submission is filed, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee – typically a panel that includes clinicians and other experts – for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMPs is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs, or supplements to NDAs, must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted, except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to an NDA submitted on or after August 18, 2020.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity – patent or non-patent – for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and

reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The Hatch-Waxman Amendments

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant's product or method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been received by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Exclusivity provisions under the FDC Act also can delay the submission or the approval of certain applications. The FDC Act provides a five-year period of non-patent exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity, or NCE. A drug is entitled to NCE exclusivity if it contains a drug substance no active moiety of which has been previously approved by the FDA. During the exclusivity period, the FDA may not accept for review an ANDA or file a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. The FDC Act also provides three years of market exclusivity for an NDA, including a 505(b)(2) NDA, or supplement to an existing NDA if new

clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions for use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs for the original conditions of use, such as the originally approved indication. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

After NDA approval, the owner of relevant drug patent may apply for up to a five year patent term extension. Only one patent may be extended for each regulatory review period, which is composed of two parts: a testing phase and an approval phase. The allowable patent term extension is calculated as half of the drug's testing phase – the time between the day the IND becomes effective and NDA submission – and all of the review phase – the time between NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years and only one patent may be extended.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2), or 505(b)(2), NDA, which enables the applicant to rely, in part, on studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference or use, such as the FDA's findings of safety and/or effectiveness for a similar previously approved product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and

promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered. In addition, prescription drug manufacturers in the United States must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities, and have procedures in place to identify and properly handle suspect and illegitimate products.

Regulation Outside the United States

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, BioPharmX would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulation and Marketing Authorization in the European Union

The process governing approval of medicinal products in the European Union, or E.U., follows essentially the same lines as in the United States and, likewise, generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable E.U. Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application, or CTA, which must be approved before human clinical trials may begin;
- performance of adequate and well controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a marketing authorization application, or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMP;
- potential audits of the nonclinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant E.U. regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical Trial Approval

Requirements for the conduct of clinical trials in the European Union including GCP are implemented in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, approval must be obtained from the competent national authority of an E.U. member state in which a study is planned to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the E.U. legislators passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the E.U., the new E.U. clinical trials legislation was passed as a regulation that is directly applicable in all E.U. member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of the EMA, the new Clinical Trials Regulation became applicable in 2019. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for old system.

The new Regulation (EU) No 536/2014 aims to simplify and streamline the approval of clinical trial in the E.U. The main characteristics of the regulation include:

- a streamlined application procedure via a single entry point, the E.U. portal;
- a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states;
- a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed jointly by all member states concerned. Part II is assessed separately by each member state concerned;
- strictly defined deadlines for the assessment of clinical trial application; and
- the involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Regulation (EU) No 536/2014.

Marketing Authorization

Authorization to market a product in the member states of the European Union proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

Centralized Authorization Procedure

The centralized procedure enables applicants to obtain a marketing authorization that is valid in all E.U. member states based on a single application. Certain medicinal products, including products developed by means of biotechnological processes, must undergo the centralized authorization procedure for marketing authorization, which, if granted by the European Commission, is automatically valid in all 28 E.U. member states. The EMA and the European Commission administer this centralized authorization procedure pursuant to Regulation (EC) No 726/2004.

Pursuant to Regulation (EC) No 726/2004, this procedure is mandatory for:

- medicinal products developed by means of one of the following biotechnological processes:
    - recombinant DNA technology;
    - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
    - hybridoma and monoclonal antibody methods;
- advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No. 1394/2007 on advanced therapy medicinal products;
- medicinal products for human use containing a new active substance that, on the date of effectiveness of this regulation, was not authorized in the E.U., and for which the therapeutic indication is the treatment of any of the following diseases:

    cancer;

    neurodegenerative disorder;

    diabetes;

    auto-immune diseases and other immune dysfunctions; and

    viral diseases;

- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance or if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization is in the interest of patients in the European Union.

Administrative Procedure

Under the centralized authorization procedure, the EMA's Committee for Human Medicinal Products, or CHMP, serves as the scientific committee that renders opinions about the safety, efficacy and quality of medicinal products for human use on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national authority for medicinal products, with expert appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP has 210 days to adopt an opinion as to whether a marketing authorization should be granted. The process usually takes longer in case additional information is requested, which triggers clock-stops in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. When an application is submitted for a marketing authorization in respect of a drug that is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may pursuant to Article 14(9) Regulation (EC) No 726/2004 request an accelerated assessment procedure. If the CHMP accepts such request, the time-limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time-limit

for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After the adoption of the CHMP opinion, a decision on the MAA must be adopted by the European Commission, after consulting the E.U. member states, which in total can take more than 60 days.

Conditional Approval

In specific circumstances, E.U. legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Marketing Authorization under Exceptional Circumstances

Under Article 14(8) Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product and will normally not lead to the completion of a full dossier/approval.

Market Authorizations Granted by Authorities of E.U. Member States

In general, if the centralized procedure is not followed, there are three alternative procedures as prescribed in Directive 2001/83/EC:

- the decentralized procedure allows applicants to file identical applications to several E.U. member states and receive simultaneous national approvals based on the recognition by E.U. member states of an assessment by a reference member state;

- the national procedure is only available for products intended to be authorized in a single E.U. member state; and

- a mutual recognition procedure similar to the decentralized procedure is available when a marketing authorization has already been obtained in at least one E.U. member state.

A marketing authorization may be granted only to an applicant established in the European Union.

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a

company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Periods of Authorization and Renewals

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

Regulatory Data Protection

E.U. legislation also provides for a system of regulatory data and market exclusivity. According to Article 14(11) of Regulation (EC) No 726/2004, as amended, and Article 10(1) of Directive 2001/83/EC, as amended, upon receiving marketing authorization, new chemical entities approved on the basis of complete independent data package benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the E.U. from referencing the innovator's data to assess a generic (abbreviated) application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator is able to gain the period of data exclusivity, another company nevertheless could also market another version of the drug if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical test, preclinical tests and clinical trials. However, products designated as orphan medicinal products enjoy, upon receiving marketing authorization, a period of ten years of orphan market exclusivity. Depending upon the timing and duration of the E.U. marketing authorization process, products may be eligible for up to five years' supplementary protection certificates, or SPCs, pursuant to Regulation (EC) No 469/2009. Such SPCs extend the rights under the basic patent for the drug.

Regulatory Requirements After a Marketing Authorization has been Obtained

If we obtain authorization for a medicinal product in the E.U., we will be required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Pharmacovigilance and other requirements

We will, for example, have to comply with the E.U.'s stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. Other requirements relate, for example, to the manufacturing of products and APIs in accordance with good manufacturing practice standards. E.U. regulators may conduct inspections to verify our compliance with applicable requirements, and we will have to continue to expend time, money and effort to remain compliant. Non-compliance with E.U. requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties in the E.U. Similarly, failure to comply with the

E.U.'s requirements regarding the protection of individual personal data can also lead to significant penalties and sanctions. Individual E.U. member states may also impose various sanctions and penalties if we do not comply with locally applicable requirements.

Manufacturing

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in strict compliance with the EMA's Good Manufacturing Practices, or GMP, requirements and comparable requirements of other regulatory bodies in the E.U., which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its current GMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

Marketing and Promotion

The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83/EC. The applicable regulations aim to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the competent authority of the authorizing member state. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Patent Term Extension

In order to compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary certificate, or SPC, may be granted extending the exclusivity period for that specific product by up to five years. Applications for SPCs must be made to the relevant patent office in each E.U. member state and the granted certificates are valid only in the member state of grant. An application has to be made by the patent owner within six months of the first marketing authorization being granted in the European Union (assuming the patent in question has not expired, lapsed or been revoked) or within six months of the grant of the patent (if the marketing authorization is granted first). In the context of SPCs, the term "product" means the active ingredient or combination of active ingredients for a medicinal product and the term "patent" means a patent protecting such a product or a new manufacturing process or application for it. The duration of an SPC is calculated as the difference between the patent's filing date and the date of the first marketing authorization, minus five years, subject to a maximum term of five years.

A six month pediatric extension of an SPC may be obtained where the patentee has carried out an agreed pediatric investigation plan, the authorized product information includes information on the results of the studies and the product is authorized in all member states of the European Union.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom, or U.K. voted in favor of leaving the E.U., which is commonly referred to as "Brexit." Thereafter, on March 29, 2017, the country formally notified the E.U. of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The U.K. left the E.U. effective at 11 p.m. Greenwich Mean Time on January 31, 2020. This began a transition period that is set to end on December 31, 2020, during which the U.K. and the E.U. will negotiate their future relationship. Since the regulatory framework for pharmaceutical products in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from E.U. directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the U.K. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In the E.U., pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our drug candidate to currently available therapies (so called health technology assessment) in order to obtain reimbursement or pricing approval. For example, the E.U. provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. E.U. member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of BioPharmX placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. The downward pressure on health care costs in general has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various E.U. member states, and parallel distribution (arbitrage between low-priced and high-priced member states), can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal False Statements Statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report annually to Centers for Medicare & Medicaid Services or the Children's Health Insurance Program (with certain exceptions) information related to certain payments and other transfers of value to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members, with such information published on a searchable website on an annual basis; failure to submit required information may result in civil monetary penalties; effective January 1, 2022, transfers of value to physician assistants, nurse practitioners, or clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives must also be reported; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers.

An increasing number of states have enacted legislation requiring pharmaceutical and biotechnology companies to file periodic reports of expenses relating to the marketing and promotion of drug products and gifts and payments to individual healthcare practitioners in these states; to make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities; to report information pertaining to and justifying price increases; or to register their sales representatives. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; price gouging; or pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, further complicating compliance efforts.

Environmental, Health and Safety Matters

The manufacturing facilities of the third-parties that develop our product candidates are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, governing, among other things: the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; chemicals, air, water and ground contamination; and air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage.

These laws, regulations and permits could potentially require the expenditure by us of significant amounts for compliance or remediation. If the third-party manufacturers fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third-party claims, including those relating to personal injury (including exposure to hazardous substances we use, store, handle, transport, manufacture or dispose of), property damage or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations.

In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities that were previously permitted.

Employees

As of January 31, 2020, we had 3 employees, all of whom were full time located in the United States. We also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages and we consider our relations with our employees to be good.

Other Information

We file periodic reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information may be obtained, free of charge, by visiting the SEC's website at www.sec.gov that contains all of the reports, proxy and information statements, and other information that we electronically file or furnish to the SEC.

ITEM 1A. RISK FACTORS

1 Risks Related to Our Financial Position and Need for Additional Capital and Risks Related to the Merger

There is no assurance that the Merger will be completed in a timely manner or at all. If the Merger is not consummated, our business could suffer materially and our stock price could decline.

The closing of the Merger is subject to the satisfaction or waiver of a number of closing conditions, as described in the Merger Agreement, including the required approvals by our stockholders and Timber's stockholders and other customary closing conditions. If the conditions are not satisfied or waived, the Merger may be materially delayed or abandoned. If the Merger is not consummated, our ongoing business may be adversely affected and, without realizing any of the benefits of having consummated the Merger, we will be subject to a number of risks, including the following:

- we have incurred and expected to continue to incur significant expenses related to the Merger even if the Merger is not consummated. We may not have adequate funding to pay for these expenses, which may force it into dissolution, liquidation or bankruptcy;
- we could be obligated to pay Timber a termination fee of up to $1,250,000 under certain circumstances set forth in the Merger Agreement;
- we could default on the Bridge Note and the ownership of the secured assets held as collateral for the Bridge Note could be transferred;
- the price of our stock may decline;
- we may not be able to meet the NYSE American continued listing standards, which may lead to delisting procedures by the NYSE American; and
- we also could be subject to litigation related to any failure to consummate the Merger or to perform our obligations under the Merger Agreement.

If the Merger is not consummated, these risks may materialize and may adversely affect our business, financial condition and the market price of our common stock.

If the Merger is not completed, we may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the Merger with Timber, or at all, and we may otherwise be unable to continue to operate our business. Our Board may decide to pursue a dissolution and liquidation of the company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

While we have entered into the Merger Agreement with Timber, the closing of the Merger may be delayed or may not occur at all and there can be no assurance that the Merger will deliver the anticipated benefits we expect or

enhance stockholder value. If we are unable to consummate the Merger, our Board may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the Merger. Attempting to complete an alternative transaction like the Merger will be costly and time consuming, and we can make no assurances that such an alternative transaction would occur at all. Alternatively, our Board may elect to continue our operations by starting a Phase 3 clinical trial for BPX-01 or BPX-04, which would require that we obtain additional funding, which we do not currently believe could be completed on a timely basis, or our Board could instead decide to pursue a dissolution and liquidation of the company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of the company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include severance obligations, regulatory, clinical and preclinical obligations, lease obligations and fees and expenses related to the Merger, dissolution or liquidation. As a result of this requirement, a portion of our assets would need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation or dissolution of the company.

The issuance of shares of our common stock to Timber stockholders in the Merger will significantly dilute the voting power of our current stockholders.

If the Merger is completed, each outstanding share of Timber common stock will be converted into the right to receive a number of shares of our common stock equal to the exchange ratio. Immediately following the Merger, the former Timber securityholders (including holders of VARs and any investors providing the Timber Funding) immediately before the Merger are expected to own (or have the right to receive) approximately 88.5% of the our common stock, and our securityholders immediately before the Merger are expected to own, or hold rights to acquire, approximately 11.5% of our common stock. The issuance of shares of our common stock to Timber stockholders in the Merger will significantly reduce the relative voting power of each share of our common stock held by our current stockholders. Consequently, our stockholders as a group will have significantly less influence over the management and policies of the combined company after the Merger than prior to the Merger.

If we are unable to repay the Bridge Loan, the ownership of the secured assets held as collateral for the Bridge Loan could be transferred to Timber.

In connection with the Merger Agreement, we entered into a Credit Agreement with Timber, dated as of January 28, 2020 (the “Credit Agreement”), pursuant to which Timber has agreed to make a bridge loan (the “Bridge Loan”) to us in an aggregate amount of $2.5 million, of which $700,000 is currently outstanding. The Bridge Loan is secured by a lien on all of our assets, and if we are unable repay the Bridge Loan, the ownership of the secured assets held as collateral could be transferred to Timber.

We have experienced losses since inception and anticipate that we will continue to incur losses, which makes it difficult to assess our future prospects and financial results.

We are a specialty pharmaceutical company with a limited operating history. Pharmaceutical product development is a highly speculative and costly undertaking and involves a substantial degree of uncertainty. We have never been profitable and, as of January 31, 2020, it had an accumulated deficit of $88.2 million and incurred net losses of $9.7 million and $17.3 million for the years ended January 31, 2020 and 2019, respectively.

If the Merger is not consummated, we will likely be required to wind-down and dissolve and we would be required to pay all our debts and contractual obligations, including the Bridge Loan, and set aside certain reserves for potential future claims. While we will also attempt to consummate a financing to allow it to continue as a going concern, based on our recent strategic process, we do not believe that we would be able to consummate a financing on reasonable terms sufficient to obtain such additional financial resources.

If the Merger is not completed and we are unable to raise sufficient additional funds for the development of our product candidates, whether through potential partnering or other strategic arrangements or otherwise, which we do not believe we would be able to do on reasonable terms, we will likely determine to cease operations, wind-down and dissolve (whether in or out of a bankruptcy or court proceeding to do so).

If we do not successfully complete the Merger, we will need substantial additional funding, and will likely be unable to raise the capital necessary to complete a Phase 3 clinical trial, which would likely cause us to wind down and dissolve.

We incurred a net loss of $9.7 million and $17.3 million for the years ended January 31, 2020 and 2019, respectively. As of January 31, 2020, we had cash and cash equivalents of $0.7 million and significant liabilities and obligations. If the Merger is not completed, based on our current operating plan, we expect to fund operations only for a relatively short period of time.

We presented comprehensive BPX-01 Phase 2b clinical data for the treatment of inflammatory lesions of acne and received positive FDA feedback regarding our BPX-01 Phase 3 clinical trial plans. We have completed a Phase 2b clinical trial for BPX-04 for the treatment of papulopustular rosacea. The development of our business will require substantial additional capital in the future to fund our ongoing operations and satisfy our obligations and liabilities. We have historically relied upon both private and public sales of equity or debt securities to fund our operations. We do not believe we can raise the significant capital required to continue operations, and we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment.

Future discovery and preclinical development collaborations are important to us. If we are unable to enter into or maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected.

For some of the our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for development of products in the future. We may seek to enter into enter into a strategic collaboration to fund the continued development of BPX-01 or BPX-04. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. We may not succeed in our efforts to establish a development collaboration or other alternative arrangements for BPX-01 or BPX-04 because third parties may not view these product candidates as having the requisite potential to demonstrate safety and efficacy or profitability. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay our development program on one or more of our other development programs, delay our potential development schedule or reduce the scope of research activities, or decrease our expenditures and undertake discovery or preclinical development activities at our own expense. If we fail to enter into collaborations and does not have sufficient funds or expertise to undertake the necessary development activities, we may not be able to further develop our product candidates or continue to develop our product candidates and our business may be materially and adversely affected.

Future collaborations we may enter into may involve the following risks:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon discovery and preclinical development for a product candidate, repeat or conduct new discovery and preclinical development for a product candidate;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the discovery, preclinical 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;
- collaborators may not properly maintain or defend its intellectual property rights or intellectual property rights licensed to us or may use its proprietary information in such a way as to invite litigation that could jeopardize or invalidate its intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Additionally, subject to its contractual obligations to us, if a collaborator is involved in a business combination, the collaborator might deemphasize or terminate the development of any of its product candidates. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and its perception in the business and financial communities could be adversely affected.

If we are unable to maintain our collaborations, development of our product candidates could be delayed, and we may need additional resources to develop them. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our collaborators.

We have deemed there to be substantial doubt about our ability to continue as a going concern, and in order to fund our operations and execute our business plan we will require additional financing.

Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. Without additional financing, these conditions raise substantial doubt about our ability to continue as a going concern, meaning that we may be unable to continue operations for the foreseeable future or realize assets and discharge liabilities in the ordinary course of operations. As a result, our independent registered public accounting firm included an explanatory paragraph in their report on our consolidated financial statements for the years ended January 31, 2020 and 2019 with

respect to this uncertainty. Such an opinion may materially and adversely affect the price per share of our common stock and/or otherwise limit our ability to raise additional funds through the issuance of debt or equity securities or otherwise. Further, the perception that we may be unable to continue as a going concern may impede our ability to raise additional funds or operate our business due to concerns regarding our ability to discharge our contractual obligations.

We have prepared our condensed consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our consolidated financial statements for the years ended January 31, 2020 and 2019 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. Without additional funds, however, we may be unable to continue as a viable entity, in which case our stockholders may lose all or some of their investment in the company.

The terms of certain of our prior registered direct offerings may materially and adversely impact our ability to obtain additional financing in the future.

We are subject to certain restrictions and obligations in connection with our registered direct offerings, or RDOs, that were consummated in September 2016, April 2017, July 2017, November 2017 and November 2018, which may materially and adversely affect our ability to obtain additional financing in the future. These restrictions and obligations include:

- certain rescission rights if we do not act in a timely manner with respect to our obligations related to the various documents executed in connection with the registered direct offerings, or the RDO Transaction Documents;

- our obligation to repurchase warrants issued to the RDO investors, based on the warrants' Black-Scholes value, in the event of certain fundamental transactions, including, but not limited to, any sale, license, transfer or other disposition of all or substantially all of our assets, any purchase, tender or exchange offer that has been accepted by the holders of 50% or more of our then outstanding shares of common stock, a reclassification, reorganization or recapitalization, or the consummation of a business combination (including, but not limited to, a reorganization, recapitalization, spin-off or scheme of arrangement) involving the acquisition of more than 50% of our then outstanding shares of common stock;

- certain indemnification obligations; and

- our obligation to pay liquidated damages in connection with certain events, including failure to comply with the public information requirements under Rule 144 of the Securities Act of 1933, as amended, or the Securities Act, or to remove restrictive legends in a timely manner.

We have also made various representations and warranties to the RDO investors in connection with the RDO Transaction Documents, including those related to solvency, no integrated offerings, maintenance of our stock exchange listing, internal controls, and absence of liens, among others. In the event any of our representations or warranties in the RDO Transaction Documents are determined to be inaccurate, or if we are deemed to have otherwise violated any provisions of the RDO Transaction Documents, we may be found to be in breach of the RDO Transaction Documents. This in turn may result in litigation against us, which could be costly and time-consuming, divert management's attention and resources, damage our reputation and otherwise harm our business, results of operations and financial condition.

Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates, in particular BPX-01 and BPX-04.

Our portfolio of product candidates includes two clinical-stage drug product candidates, BPX-01, a topical antibiotic for the treatment of inflammatory lesions of acne vulgaris, and BPX-04, a topical antibiotic for the treatment of papulopustular rosacea. The success of our business, including our ability to finance the company, form strategic partnerships and generate revenues in the future, will primarily depend on the successful development, regulatory approval and commercialization of these product candidates. In the future, we may become dependent on one or more of

our early-stage product candidates or any of our product candidates that we may in-license, acquire or develop. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise additional capital on acceptable terms, or at all;
- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary and secondary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety and efficacy of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects experienced in connection with the use of our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- our ability to enter into a potential collaboration or partnership to fund the continued development of our product candidates;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to (i) manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, (ii) remain in good standing with regulatory agencies and (iii) develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMPs;
- a continued acceptable safety profile during clinical development and subsequent to approval of our product candidates or any future product candidates, if any;
- our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved, for marketing, sale and distribution in such countries or territories, whether alone or in collaboration with others;
- acceptance by physicians and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- our ability to avoid third-party patent interference or intellectual property infringement claims; and
- our ability to in-license or acquire additional product candidates or commercial-stage products that we believe can successfully develop and commercialize.

If we are unable to achieve any of the above factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or fail to obtain regulatory approvals or commercialize our product

candidates. Even if we obtain the necessary regulatory approvals, we may never successfully commercialize any of our product candidates. Accordingly, we may not generate revenue through the sale of our product candidates or any future product candidates sufficient to continue operations.

We have a limited operating history and have yet to obtain regulatory approvals for any of our product candidates, which makes it difficult to evaluate our future prospects and viability.

Our operations to date have been primarily limited to researching and developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have also not yet obtained regulatory approvals for any of our product candidates. Consequently, the ability to accurately assess and predict our future operating results or business prospects is more limited than if we had a longer operating history or FDA-approved products on the market. In November 2018, we divested our VI_2OLET dietary supplement, which was our only source of revenue to date.

We have experienced significant turnover in our senior management, and if we fail to attract and retain management and other key personnel, we may be unable to continue to develop successfully or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly-competitive pharmaceutical industry depends upon our ability to attract and retain highly-qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management, including: our Chief Executive Officer and Principal Financial Officer, Steven Bosacki, and our Chief Accounting Officer, Joyce Goto. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. The loss of the services of any of these individuals, along with other key executives or employees, could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. In order to retain valuable employees at the company, in addition to salary and cash incentives, we provide stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies.

In addition, over the past couple years, we experienced significant turnover in our senior management ranks, including the departure of our former President, Anja Krammer in October 2018, the departure of former Executive Vice President and Chief Financial Officer, Greg Kitchener, in October 2018 and the departure of Kin Chan, Executive Vice President of Research and Technology in July 2019. In September 2018, we appointed David S. Tierney, MD, to serve as President and Chief Executive Officer, in October 2018, we appointed Joyce Goto, Vice President and Controller, to serve as our Principal Accounting Officer, and in July 2019, we appointed Steven Bosacki to serve as Chief Operating Officer. In January 2020, Dr. Tierney resigned and Mr. Bosacki was named as Chief Executive Officer and Principal Financial Officer. This lack of management continuity could adversely affect our ability to successfully manage our clinical trials and execute our growth strategy, as well as result in operational and administrative inefficiencies and added costs and may make recruiting for future management positions more difficult.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in Campbell, California where we are headquartered. We could have difficulty attracting experienced personnel to the company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater and other resources, different risk profiles and longer histories in our industry than we do. They may also provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts

with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with it.

We currently have limited marketing and sales capabilities. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.

To successfully commercialize our product candidates, if approved, in the United States, Canada, the European Union and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Although our employees have experience in the marketing, sale and distribution of pharmaceutical products from prior employment at other companies, we, as a company have limited prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with additional third parties that have direct sales forces and established distribution systems, either to augment or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are unable to successfully commercialize our product candidates, either on our own or through collaborations with one or more third parties, our business, financial condition, operating results and prospects would suffer.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- delays in the commencement, enrollment and the timing of clinical testing for our product candidates;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- any delays in regulatory review and approval of product candidates in clinical development;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;

- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish and maintain an effective sales, marketing and distribution infrastructure;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates outside of the United States;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential litigation or other disputes;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Our ability to utilize our net operating loss, or NOL, carryforwards and research and development income tax credit carryforwards may be limited.

We have significant NOL carryforwards available to reduce future taxable income, if any, for federal and California state income tax purposes. If not utilized, both the federal and California state NOL carryforwards will begin expiring in 2030. Under Section 382 of the Internal Revenue Code of 1986, as amended, or Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We believe that, with the transactions that have occurred over the past three years, we may have triggered an "ownership change" limitation. We have not conducted a formal NOL carryforward analysis. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks Related to Development and Commercialization of Our Product Candidates and Regulatory Approval and Other Legal Compliance Matters

We rely on a single, qualified supplier to manufacture each of our product candidates.

We rely on one third-party manufacturer for our product and product candidate manufacturing needs. We are working towards qualifying a second vendor to carry out the manufacturing and testing of our clinical and commercial supplies, however there can be no assurance that we will be able to qualify a second vendor in a timely manner or at all.

Each of these third-party manufacturers is required by law to comply with the FDA's regulations, including the applicable cGMP regulations for the type of product manufactured. These regulations set forth standards for both quality assurance and quality control. Third-party manufacturers also must maintain records and other documentation as required by applicable laws and regulations. In addition to a legal obligation to comply, the manufacturer is contractually obligated to comply with all applicable laws and regulations. However, although we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs, we cannot guarantee that each of our manufacturing partners will so comply. Failure of these manufacturers to maintain compliance with applicable laws and regulations could result in delayed or rejected clinical studies, decreased sales of our products, decreased revenues and reputational harm to us and may subject us to sanctions by the FDA, including a request for a voluntary recall, warning letter, seizure of products, injunctions prohibiting some or all further sales and/or recalling product already on the market, possible decree imposing substantial fines, preclusion of government contracts, import alerts and criminal liability for us and our individual employees. In addition, failure of a contract manufacturer for a product undergoing review by the FDA to maintain an acceptable cGMP compliance status could result in a decision by the FDA not to approve any pending NDA.

Our manufacturing contract is a short-term agreement. We are dependent upon renewing agreements with each of our third-party manufacturers or finding replacement manufacturers to satisfy our requirements. If we do not renew our agreements with our manufacturing partners, there can be no assurance that we will be able to find or engage a replacement manufacturer on a timely basis on acceptable terms, if at all. As a result, we cannot be certain that manufacturing sources will continue to be available or that we can continue to outsource the manufacturing of our products on commercially reasonable or acceptable terms. Further, due to the short-term nature of our agreements, our expenses for manufacturing are not fixed and may change from contract to contract. If the cost of production increases, our gross margins could be negatively affected.

In addition, we rely on our outside manufacturers to provide us with an adequate and reliable supply of our products on a timely basis and in accordance with good manufacturing standards and applicable product specifications. As a result, we are subject to and have little or no control over delays and quality control lapses that our third-party manufacturers may suffer.

We and our third-party manufacturers rely on a limited number of suppliers of the raw materials and other components of our products. A disruption in supply of raw material and other components would be disruptive to our inventory supply.

We and the manufacturers of our products rely on suppliers of raw materials and other components used in the production of our products. Some of these materials are available from only one source. We try to maintain inventory levels that are no greater than necessary to meet our current projections, which could have the effect of exacerbating supply problems. Any interruption in the supply of finished products could hinder our ability to distribute timely our finished products. If we are unable to obtain adequate product supplies to satisfy our customers' orders, we may lose such orders and, possibly, our customers. This, in turn, could result in a loss of our market share and a corresponding reduction in our revenues. In addition, any disruption in the supply of raw materials or an increase in the cost of raw materials to our manufacturers could have a significant effect on their ability to supply us with our products, which would adversely affect our financial condition and operating results.

Clinical drug development is costly, time-consuming and uncertain, and we may suffer setbacks in our clinical development program that could harm our business.

Clinical drug development for our product candidates is costly, time-consuming and uncertain. Our product candidates are in various stages of development and while we expect that clinical trials for these product candidates will continue for several years, such trials may take significantly longer than expected to complete. In addition, we, the FDA,

an IRB, or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

- discovery of safety or tolerability concerns, such as serious or unexpected toxicities or side effects or exposure to otherwise unacceptable health risks, with respect to study participants;
- lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints;
- delays in subject recruitment and enrollment in clinical trials or inability to enroll a sufficient number of patients in clinical trials to ensure adequate statistical ability to detect statistically significant treatment effects;
- difficulty in retaining subjects and volunteers in clinical trials;
- difficulty in obtaining IRB approval for studies to be conducted at each clinical trial site;
- delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective contract research organizations, or CROs, clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper formulation and dosing;
- failure by us, our employees, our CROs or their employees or other third-party contractors to comply with contractual and applicable regulatory requirements or to perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- changes in applicable laws, regulations and regulatory policies.

As with other pharmaceutical and biotechnology companies, we may suffer significant setbacks in our clinical trials despite promising results in earlier trials. In the event that we abandon or experience delays in the clinical development efforts related to our product candidates, we may not be able to execute on our business plan effectively and our business, financial condition, operating results and prospects may be harmed.

We may be unable to obtain regulatory approval for our clinical-stage product candidates or other early-stage product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results.

We are not permitted to market any of our current product candidates in the United States until we receive approval of a NDA from the FDA. We are also not permitted to market any of our current product candidates in any foreign countries until we receive the requisite approval from the applicable regulatory authorities of such countries. Failure to obtain such regulatory approvals will delay or prevent us from commercializing any of our current or future product candidates.

To gain approval to market a new drug, we must provide the FDA and/or foreign regulatory authorities with, among other things, extensive preclinical and clinical data that adequately demonstrates the safety and efficacy of the drug in our intended indication and information to demonstrate the adequacy of the manufacturing methods to assure the drug's identity, strength, quality and purity. The development and approval of new drug product candidates involves a long, expensive and uncertain process, and delay or failure can occur at any stage. A number of companies in the pharmaceutical and biopharmaceutical industries have suffered significant setbacks in clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, observations during clinical trials regarding safety or efficacy, such as previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure success in later clinical trials, and the results of clinical trials by other parties may not be indicative of the results in trials it may conduct. Further, different results may be achieved depending upon which analysis population is used to analyze results. Regardless of the outcome of any Phase 2 trials, our Phase 3 trials, if commenced, may not be successful. For example, we reported that findings on a secondary endpoint in our Phase 2b clinical trial of BPX-01, the reduction in Investigator's Global Assessment, or IGA, which was defined as the proportion of subjects with at least a two-grade reduction in IGA to clear "0" or almost clear "1", were not statistically significant. While the BPX-01 2% arm demonstrated a clear numerical trend compared to vehicle, the BPX-01 1% arm showed a smaller separation from vehicle. While this trial was not powered to demonstrate statistical significance for IGA and, therefore, IGA was not expected to be statistically significant, there is no guarantee that our Phase 3 trial, if commenced, will produce statistically significant results on IGA, which will serve as a co-primary endpoint with inflammatory lesion reduction despite our plans to adequately power the Phase 3 study to achieve this endpoint. In addition, topline results of a clinical trial do not necessarily predict final results. For example, the topline results of the Phase 2b clinical study of BPX-01 1% and 2% reported that both concentrations statistically significantly reduced inflammatory lesions, the primary endpoint. The information reflected our preliminary review of the topline primary efficacy results based solely upon information available to it at that time. Since topline reporting, adjustments for multiple comparisons were made, resulting in a change to the p-value for the 1% and 2% concentrations, rendering the results of the 1% concentration no longer statistically significant. It is always a risk that further review of results may change the conclusions drawn from the preliminary review to less positive results than it anticipated.

In the case of our topical product candidates, BPX-01 and BPX-04, we are seeking to deliver sufficient concentrations of the API through the skin barrier to the targeted dermal tissue to achieve the intended therapeutic effect. The topical route of administration may involve new dosage forms, which can be difficult to develop and manufacture and may raise novel regulatory issues and result in development or review delays. For example, the antibiotic delivered in BPX-01 and BPX-04 is difficult to stabilize and prone to epimerization in most formulations and delivery systems and, as such, presents great challenges for transepidermal delivery. We believe potential competitors have attempted to resolve these problems by stabilizing the antibiotic in certain lipophilic formulation, but the solutions either failed to adequately deliver the antibiotic or required overly high concentration (i.e., dosage) for clinical efficacy. As a result, safety and efficacy of BPX-01 and BPX-04 may be difficult to establish.

The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons. The FDA or the applicable foreign regulatory body may:

- disagree with the design or implementation of one or more clinical trials;
- decline to deem a product candidate safe and effective for its proposed indication, or deem a product candidate's safety or other perceived risks to outweigh its clinical or other benefits;
- find that the data from preclinical studies and clinical trials does not sufficiently support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required for approval;
- disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties;
- determine the data collected from clinical trials are insufficient to support the submission or approval of an NDA or other applicable regulatory filing;
- require additional preclinical studies or clinical trials;
- identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates;
- grant approval contingent on the performance of costly additional post-approval clinical trials;
- approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested or with strong warnings that may affect marketability;
- decline to approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;
- require a Risk Evaluation and Mitigation Strategy, or REMS, with monitoring requirements or distribution limitations. For example, it is possible that the FDA could require distribution controls in the approval, if any, of our product candidates to prevent inadvertent exposure to pregnant women;
- decline to approve the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with whom we contract; or
- change our approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

Any delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results.

Delays or difficulties in the enrollment of patients in clinical trials may result in additional costs and delays in our ability to generate significant revenues, and may delay or prevent our receipt of any regulatory approvals necessary to commercialize our planned and future products.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors have completed clinical trial and product registration for product candidates that treat the same indications as our product candidates, and patients who are otherwise eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and impede our ability to obtain additional financing.

We intend to pursue Section 505(b)(2) regulatory approval filings with the FDA for at least one of our product candidates. If the FDA concludes that certain of our product candidates fail to satisfy the requirements under Section 505(b)(2), or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for such product candidates may take significantly longer, cost substantially more and entail greater complications and risks than anticipated and, in either case, may not be successful. In addition, if under certain circumstances, exclusivity of competitors would delay approval of our product candidates, then we may pursue approval through the Section 505(b)(1) regulatory pathway, which may require us to conduct additional preclinical or clinical trials or obtain a right to reference the preclinical or clinical data of others.

We are currently developing two product candidates, BPX-01 and BPX-04, for which we intend to seek FDA approval through the Section 505(b)(2) regulatory pathway, and may decide to seek FDA approval for other early-phase products through the Section 505(b)(2) regulatory pathway in the future. A Section 505(b)(2) NDA is a special type of NDA that enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing previously approved product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Such filings involve significant filing costs, including filing fees.

BPX-01 and BPX-04 are a topical formulations of minocycline (Solodyn), a previously approved oral antibiotic. Reliance on safety findings made by the FDA in approving Solodyn, the antibiotic we will reference in our NDA, could expedite the development program for our product candidates by decreasing the amount of preclinical or clinical data that we would need to generate in order to obtain FDA approval. BPX-01's and BPX-04's route of administration and dosage form, however, differ from Solodyn's and, as a result, the FDA may not permit us to use this approach to regulatory approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, or if the Section 505(b)(2) regulatory pathway fails to significantly decrease the amount of testing we must conduct, we may need to conduct additional preclinical or clinical trials, provide additional data and information and meet additional standards to obtain regulatory approval. In such case, the time and financial resources required to obtain FDA approval for BPX-01 and BPX-04, or any other product candidate for which we seek approval pursuant to the Section 505(b)(2) regulatory pathway in the future, and complications and risks associated with these product candidates, likely would increase substantially. Moreover, our inability to pursue the Section 505(b)(2) regulatory pathway could prevent us from introducing our product candidates into the market prior to our competitors, which could harm our competitive position and prospects. Further, even if the FDA allows us to pursue the Section 505(b)(2) regulatory pathway, we cannot guarantee that we would ultimately lead to faster product development, and our product candidates may not receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its

Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Furthermore, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs referenced in a Section 505(b)(2) NDA. As part of any NDA we would submit to the FDA, we would be required to make certifications to all patents listed in the Orange Book for Solodyn, the listed drug we intend to reference in our NDA. There are currently six patents listed in the Orange Book for Solodyn. If we make a Paragraph IV certification to any of the patents listed in the Orange Book, those patent certifications may give rise to patent litigation and mandatory delays in approval of our NDA for up to 30 months depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved referenced product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

Furthermore, award of three-year exclusivity by FDA to a competitor with a Section 505(b)(2) NDA could delay approval of a product candidate we submitted pursuant to Section 505(b)(2) of the FDC Act if the FDA were to determine that the products have overlapping conditions of approval, even if our Section 505(b)(2) NDA does not rely on the competing Section 505(b)(2) NDA. Alternatively, we may pursue approval through the Section 505(b)(1) regulatory pathway, which may require us to conduct additional preclinical or clinical trials or obtain a right to reference the preclinical or clinical data of others. These alternatives may increase the time and/or financial resources required to obtain approval.

We have limited experience in the conduct of clinical trials and have never obtained approval of any product candidates and may be unable to do so successfully.

As a company, we have limited experience in conducting clinical trials or progressing a product candidate through to regulatory approval. In part because of this lack of experience, our clinical trials may require more time and incur greater costs than we anticipate. We cannot be certain that planned clinical trials will begin or conclude on time, if at all. Large-scale trials would require significant additional financial and management resources, and reliance on third-party clinical investigators, contract research organizations (“CROs”) and/or consultants. Any performance failure on the part of such third parties could delay clinical development or delay or prevent us from obtaining regulatory approval or commercializing our current or future product candidates, depriving us of potential product revenue and resulting in additional losses.

Any product candidates that we commercialize will be subject to ongoing and continued regulatory review.

Even after we achieve U.S. regulatory approval for a product candidate, if any, we will be subject to continued regulatory review and compliance obligations. For example, the FDA may impose significant restrictions on the approved indicated uses for which our product candidates may be marketed or on the conditions of approval. A product candidate’s approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials or a REMS to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, continued compliance with the FDA’s good clinical practice, or GCP, requirements and good laboratory practice requirements, which are regulations and guidelines the FDA would apply to all of our product candidates in clinical and preclinical development, along with any clinical trials that we conduct post-approval, and continued compliance with the FDA’s cGMP requirements pursuant to which manufacturing facilities are subject to continual review and periodic inspections by the FDA. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- commence criminal investigations and prosecutions;
- impose injunctions;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- delay or refuse to approve pending applications or supplements to approved applications filed by us;
- refuse to permit drugs or active ingredients to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change and new or additional statutes or government regulations may prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates, which would materially and adversely affect our ability to generate revenue and achieve or maintain profitability.

Our product candidates may cause serious or undesirable side effects or possess other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of approved labeling or result in post-approval regulatory action.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after marketing such product. Undesirable side effects caused by product candidates could cause us or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or issuance of field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;
- we may be subject to limitations as to how we promote the product;
- we may be required to change the way the product is administered or modify the product in some other way;
- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer.

Any of the above events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted off-label uses of any of our product candidates, we may receive warning or untitled letters and become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our brand and reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they determine our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from using our product candidates in ways that fall outside the scope of the approved indications, as he or she may deem appropriate in his or her medical judgment. Physicians may also

misuse our product candidates or use improper techniques, which may lead to adverse results, side effects or injury and, potentially, subsequent product liability claims. Furthermore, the use of our product candidates for indications other than those cleared by the FDA and/or other regulatory agencies may not effectively treat such conditions, which could harm our brand and reputation among both physicians and patients.

We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we conduct our business. The laws and regulations that may affect our ability to operate include:

- the federal healthcare program anti-kickback statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the United States False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, which prohibits 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 (i.e., public or private), knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense 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;

- HIPAA and related implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, or ACA, which require manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members, with such information published on a searchable website on an annual basis; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy

and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the federal anti-kickback statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of our operations, any of which could materially and adversely affect our ability to operate our business and our financial results.

Our employees, independent contractors, principal investigators, consultants, vendors and CROs may become insolvent or engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and CROs may become insolvent or engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to comply with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. 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, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, 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 operating results.

Even if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of any of our current or future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications, and may not be commercially successful. The degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the effectiveness of our product as compared to other available therapies;

- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved;
- the cost of treatment with our product candidates in relation to alternative treatments and willingness to pay for the product, if approved, on the part of patients;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience;
- the willingness of patients to pay for certain of our product candidates relative to other discretionary items, especially during economically challenging times;
- the revenue and profitability that our product candidate may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our product candidates or favorable publicity about competitive products; and
- potential product liability claims.

If any of our current or future product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our operations.

If we are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.

As to any of our product candidates that become available by prescription only, our success will depend on the availability of coverage and adequate reimbursement for our product from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates fail to demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. In addition, certain currently approved therapies for the treatment of dermatological-related issues have received limited or no reimbursement coverage by insurers and, accordingly, coverage for BPX-01

and BPX-04, if approved, may not be available. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our prescription-only products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for certain of our product candidates will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Further, third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions in both the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.

Our product candidates, if approved, will face significant competition and our failure to compete effectively may prevent us from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical companies, including generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than us. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, certain of our product candidates, if approved, may compete with other dermatological products, including OTC treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies and may need to compete with unregulated, unapproved and off-label treatments. Certain of our product candidates, if approved, will present novel therapeutic approaches for the approved indications and will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects.

Due to less stringent regulatory requirements in certain foreign countries, there are many more dermatological products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market them. As a result, we expect to face more competition in these markets than in the United States.

Our product candidates, including BPX-01 and BPX-04, if approved, will face intense competition and most of our competitors have significantly greater resources than we do.

If approved for the treatment of inflammatory lesions of acne, BPX-01 will face direct competition from numerous other topical products such as antimicrobials, retinoids or some combination of the two, and the existence of these products may limit the market size for BPX-01. In addition, BPX-01 will compete against oral systemic treatments for acne, which include isotretinoins, antibiotics, antimicrobials and contraceptives, and against a number of approved topical treatments for acne, including branded drugs and generic versions where available as well as treatments for both inflammatory and non-inflammatory lesions of acne. If approved for the treatment of rosacea, BPX-04 will face direct competition from numerous other topical products such as azelaic acids, brimonidine and ivermectin creams, and the existence of these products may limit the market size for BPX-04. In addition, BPX-04 will compete against oral systemic treatments for rosacea which include antibiotics and antimicrobials, and against a number of approved topical treatments for rosacea, including branded drugs and generic versions where available. Certain alternative treatments offered by competitors may be available at a lower price and may offer greater efficacy or a better safety profile. Even if a generic product or an OTC product is less effective than our product candidates, a less effective generic or OTC product may be more quickly adopted by health insurers, physicians and patients than our competing product candidates based upon cost or convenience.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury and possibly death to a patient. An inability to obtain sufficient insurance coverage on commercially reasonable terms or otherwise to protect against potential product liability claims could inhibit our business.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our brand and/or reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management’s attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or
- loss of revenue.

Although we maintain product liability insurance coverage for clinical trials, our insurance coverage may not be sufficient to cover all of our product liability-related expenses or losses and may not cover us for any expenses or losses we suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability, particularly if any of our product candidates receive regulatory approval. Further, a successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and harm our business, financial condition, operating results and prospects.

If we suffer negative publicity concerning the safety of our products, our sales and our reputation and the reputation of our products may be harmed and we may be forced to withdraw products.

Physicians and potential patients may have a number of concerns about the safety of our products, whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. Negative publicity concerning our products, whether accurate or inaccurate, could reduce market or governmental acceptance of our products and could result in decreased product demand or product withdrawal. In addition, significant negative publicity could result in an increased number of product liability claims, whether or not these claims are supported by applicable law.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development or commercialization of any of our products or product candidates for a variety of reasons, including the appearance of new technologies that render our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment, and we will have missed the opportunity to allocate those resources to potentially more productive uses.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Risks Related to Dependence on Third Parties, Employee Matters, Managing Growth and Macroeconomic Conditions

We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing our growth.

Our current management, personnel, systems and facilities are not adequate to support our future growth plans. We will need to further expand our scientific, sales and marketing, operational, financial and other resources to support our planned research, development and commercialization activities.

To manage our operations, growth and various projects effectively, we must:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- develop a marketing, sales and distribution capability;
- manage our commercialization activities for our product candidates effectively;
- establish and maintain relationships with development and commercialization partners;
- manage our preclinical and clinical trials effectively;
- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels; and
- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, we have utilized the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. We rely on consultants for certain functions of our business and will need to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to manage our growth effectively and expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might fail to achieve our research, development and commercialization goals.

Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.

Our strategy is to in-license and acquire product candidates and we may in-license and acquire commercial-stage products or engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We are currently exploring commercial growth opportunities, but there is no guarantee that such opportunities will materialize. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing, and approval by the FDA and applicable foreign regulatory authorities. All

product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

Business or economic disruptions or global health concerns could seriously harm our development efforts and increase our costs and expenses.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development activities. For example, in December 2019 an outbreak of a novel strain of coronavirus originated in Wuhan, China and has since spread to a number of other countries, including the United States. To date, this outbreak has already resulted in extended shutdowns of certain businesses in the Wuhan region and has had ripple effects to businesses around the world. While we do not source any of our product candidates or their active pharmaceutical ingredients from China, global health concerns, such as coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. It is also possible that global health concerns such as this one could disproportionately impact the hospitals and clinical sites in which we conduct any of our clinical trials, which could have a material adverse effect on our business and our results of operation and financial condition.

We may be adversely affected by natural disasters and other catastrophic events, and by man-made problems such as terrorism, that could disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. If any future facility, or if we experience a significant disruption in our operations for any other reason, our ability to continue to operate our business would be materially harmed.

If any future facility were to be damaged, destroyed or otherwise become unable to operate, whether due to war, acts of hostility, earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if performance of any of future facilities are disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved and we choose to manufacture all or any part of them internally, jeopardize our ability to timely manufacture our products, if at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our prospective customers' expectations, our business, prospects, financial results and reputation could be materially harmed.

Our contract manufacturers' and suppliers' facilities are located in multiple locations, where other natural disasters or similar events, such as blizzards, tornadoes, fires, explosions or large-scale accidents or power outages, could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. In addition, acts of terrorism and other geo-political unrest could cause disruptions in our business or the businesses of our partners, manufacturers or the economy as a whole. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution or commercialization of our product candidates, our business, financial condition, operating results and prospects would suffer.

Currently, we maintain insurance coverage totaling $10 million against product liability claims, $5 million against damage to our property and equipment and $1 million in worker's compensation coverage, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

Our business and operations would suffer in the event of failures in our internal computer systems or those of our collaborators.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access,

natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or clinical trial data from completed or future clinical trials could result in delays in our 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 liability and the further development of our product candidates could be delayed.

Security breaches, loss of data and other disruptions to us or our third-party service providers could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we and our third-party service providers collect and store sensitive data, including legally protected health information, personally identifiable information about our patients, credit card information, intellectual property, and our proprietary business and financial information. We manage and maintain our applications and data utilizing a combination of managed data center systems and cloud-based data center systems. We face a number of risks related to our protection of, and our service providers' protection of, this critical information, including loss of access, inappropriate disclosure and inappropriate access, as well as risks associated with our ability to identify and audit such events.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While we are not aware of any such attack or breach, if such event would occur and cause interruptions in our operations, our networks would be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under federal, state, and international laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our ability to conduct our clinical trials, conduct research and development activities, collect, process and prepare company financial information, provide information about our product candidates and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, we are subject to various state laws, including the California Consumer Privacy Act, or CCPA, which was enacted in California in 2018 and components of which were effective on January 1, 2020. The CCPA will, among other things, require covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and will give such consumers the right to opt-out of certain sales of personal information. Amendments to the CCPA have been made since its enactment, and it remains unclear what, if any, further amendments will be made to this legislation or how it will be interpreted. We cannot yet predict the impact of the CCPA on our business or operations, but it may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

Recent developments in Europe have created compliance uncertainty regarding the processing of personal data from Europe. For example, the General Data Protection Regulation, or GDPR, which became effective in the E.U. on May 25, 2018, applies to our activities conducted from an establishment in the EU or related to products and services that we offer to E.U. users. The GDPR creates new compliance obligations applicable to our business, which could cause us to change our business practices, and increases financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements). As a result, we may need to modify the way we treat such information.

Risks Related to Our Intellectual Property

We may not be able to obtain or enforce patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our product candidates and technologies will depend in part upon our ability to obtain and maintain patent protection in both the United States and other countries, to preserve and protect our trade secrets and to prevent third parties from infringing upon our proprietary rights. Our ability to protect any of our product candidates from unauthorized or infringing use by third parties depends in substantial part upon our ability to obtain and maintain valid and enforceable patents.

Our patent portfolio includes patent applications in the United States and other countries. Any patents that we could obtain may be narrow in scope and thus more easily circumvented by competitors. Further, in countries where we do not have granted patents, third parties may be able to make, use or sell products identical to or substantially similar to, our product candidates. Additionally, restrictive regulations governing the precise labeling of ingredients and percentages for supplements, the large number of manufacturers that produce products with many active ingredients in common and the rapid change and frequent reformulation of products may make patent protection impractical.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and any future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patent applications, such applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents issue, we cannot guarantee that the claims of these patents will be held valid or enforceable by a court of law or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us.

Competitors in the fields of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not currently own or license issued patents covering all of the recent developments in our technology and we are unsure of the extent to which we will obtain adequate patent protection, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. In particular, due to the extensive prior art relating to antibiotics for topical acne and topical rosacea and because BPX-01 and BPX-04 represent forms of such therapies, respectively, the patent protection available for BPX-01 and BPX-04 may not prevent competitors from developing and commercializing similar products or products that otherwise target similar indications. If the breadth or strength of protection provided by the patents we hold or

pursue with respect to our product candidates is challenged, companies may be dissuaded from collaborating with us to develop such products, or threaten our ability to advance and commercialize, our product candidates.

The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; and
- we may not develop additional proprietary technologies that are patentable.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, however, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may affect the profitability of our early-stage product candidates, in particular.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach or that our trade secrets and unpatented know-how will not otherwise become known or independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Further, enforcing a claim that a third-party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable.

Changes in patent law or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent United States Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office (the "USPTO") is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact(s) the AIA will have on the operation of our business. Moreover, the AIA and our

implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. One important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third-party who files a patent application with the USPTO after such date but prior to us may therefore be awarded a patent covering an invention of it even if we were the first to invent. This "first-inventor-to-file" system will require us both to remain cognizant, going forward, of the timing between invention and filing of a patent application.

Among some of the other changes introduced by the AIA are those that (i) limit where a patentee may file a patent infringement suit and (ii) provide opportunities for third parties to challenge any issued patent in the USPTO. Such changes apply to all of our U.S. patents, even those issued prior to March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings, as compared to the evidentiary standard applied in U.S. federal courts, necessary to invalidate a patent claim, a third-party could potentially present evidence in a USPTO proceeding sufficient for the USPTO to find a claim invalid, notwithstanding that the same evidence would be insufficient to invalidate a claim first presented in a district court action. Accordingly, a third-party may attempt opportunistically to use USPTO procedures to invalidate our patent claims.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' abilities to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

If we is unable to protect our trademarks from infringement, our business prospects may be harmed.

We have applied for trademark protection for, and registered, trademarks in the United States, the European Union and China. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and any remedy obtained may constitute insufficient redress relative to the damages we may suffer.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop own products and, further, may export otherwise infringing products to territories where we have patent protection insufficient to guard against such infringement. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals. In such instances, we may be unable to enjoin or otherwise prevent infringement of our patents or marketing of competing products in violation of our proprietary rights, generally. Proceedings to enforce our patent rights in foreign jurisdictions could (i) result in substantial costs and divert our efforts and attention from other aspects of our business, (ii) put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and (iii) provoke third parties to assert claims against it. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may be unable to seek adequate remedies to address infringement and/or material diminishment of the value of our patents, which could limit our potential revenue opportunities in such jurisdictions. Accordingly, our efforts to establish or enforce our intellectual property rights around the world may be inadequate to

obtain a significant commercial advantage from our intellectual property. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming and an unfavorable outcome in that litigation could have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot guarantee that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents issue, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, devices, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, due to the large number of patents issued and patent applications filed in our fields, third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, our product candidates or proprietary technologies may infringe patents owned by third parties or third parties may allege such infringement. Because (i) some patent applications in the U.S. may be maintained in secrecy until the patents are issued, (ii) patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing and (iii) publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to it. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the U.S., in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act. Such lawsuits can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are later invalidated. A court may, however, decide that we are infringing the third-party's patents and order us to cease the activities covered by the patents. In addition, there is a risk that a court will order us to pay to such third-party damages for having violated the other party's patents.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on commercially acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property, or such rights might be restrictive and limit our present and future activities. Ultimately, we or a licensee could be prevented from commercializing a product or forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

In addition to possible infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation, re-examination or other post-grant proceedings declared or granted by the USPTO, and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, generally. To date, no litigation asserting infringement claims has ever been brought against us. If a third-party claims that we infringe our intellectual property rights, we may face a number of issues, including:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third-party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court prohibiting us from selling or licensing the product or using the technology unless the third-party licenses our intellectual property rights to us, which it is not required to do;

- if a license is available from a third-party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our products or technologies; and

- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our ability to raise additional funds or otherwise adversely affect our business, financial condition, operating results and prospects.

Because we may rely on certain third-party licensors and partners in the future, and if any such licensors or partners are sued for infringing a third-party's intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we are sued directly.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive and time-consuming.

Competitors may infringe our intellectual property, including our patent applications or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Such proceedings and/or litigation can be expensive—particularly for a company of our size—and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to enjoin the other party from using the technology at issue on the grounds that our patent claims do not cover our technology or that the factors necessary to grant an injunction are not satisfied. An adverse determination in such case could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they fail to cover or otherwise protect our product candidates. Moreover, such adverse determinations could subject our patent applications to the risk that they will not issue, or issue with limited and potentially inadequate scope to cover our product candidates.

Interference, derivation or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that we may, intentionally or incidentally, disclose some of our confidential results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Risks Related to Our Common Stock

We expect the NYSE American to begin the delisting process for our common stock on March 24, 2020, which could affect our market price and liquidity.

Our common stock currently trades on the NYSE American. The NYSE American imposes various quantitative and qualitative requirements to maintain listing, including minimum stockholders' equity requirements and market price of our common stock. The continued listing standards for a NYSE American issuer are as follows:

- Stockholders' equity of $2.0 million or more if the issuer has reported losses from continuing operations and/or net losses in two of its three most recent fiscal years;

- Stockholders' equity of $4.0 million or more if the issuer has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years; and

- Stockholders' equity of $6.0 million or more if the issuer has reported losses from continuing operations and/or net losses in its five most recent fiscal years.

On September 24, 2018, we received a deficiency notice by the NYSE American that we were not in compliance with the stockholders' equity requirements set forth in the NYSE American Company Guide. The deficiency notice was based on our reported stockholders' equity of $4.3 million as of July 31, 2018 and net losses in our five most recent fiscal years ended January 31, 2018. On September 19, 2019, we received notification from the NYSE American that provided an extension until March 24, 2020 to regain compliance with certain NYSE American continued listing requirements. If we are unable to regain compliance by March 24, 2020 or the NYSE American determines that we are not making progress consistent with the plan during the plan period, the NYSE American may initiate suspension and delisting procedures. If delisting proceedings are commenced, the NYSE American rules permit it to appeal a staff delisting determination. Our common stock will continue to be listed and traded on the NYSE American during the plan period, subject to our compliance with the NYSE American's other applicable continued listing standards. As of January 31, 2020, our stockholders' deficit was $0.3 million.

Additionally, the declining market price of our common stock previously resulted in a 30-day average price of our common stock falling below $0.20, in violation of the share price requirements set forth in the NYSE American Company Guide. Following our 1-for-25 reverse stock split effected on April 25, 2019, we received notification from the NYSE American on April 30, 2019, that we had regained compliance with the applicable standard. However, there can be no assurance that our share price will not fall below $0.20 in the future, and if we are unable to maintain a minimum market price of our common stock, we may fall out of compliance with the listing standards again.

Additionally, if at any time our common stock trades below $0.06 per share, we will be automatically delisted from the NYSE American. If we are unable to satisfy the continued listing requirements of the NYSE American, our common stock will be subject to delisting. If our common stock loses our status on the NYSE American, we believe that our shares of common stock would likely be eligible to be quoted on the inter-dealer electronic quotation and trading system operated by Pink OTC Markets, Inc., commonly referred to as the Pink Sheets and now known as the OTCQB market. Our common stock may also be quoted on the Over-the-Counter Bulletin Board, an electronic quotation service maintained by the Financial Industry Regulatory Authority, Inc. These markets are generally not considered to be as efficient as, and not as broad as, the NYSE American. In the event of any delisting, it could be more difficult to buy or sell our common stock and obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting may also impair our ability to raise capital.

The stock price of our common stock may continue to be volatile or may decline.

Our stock price is likely to remain volatile. The market price of our common stock may continue to fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- limited daily trading volume resulting in the lack of a liquid market;
- the development status of our product candidates, in particular BPX-01 and BPX-04, including whether any of our product candidates receive regulatory approval;
- our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- regulatory or legal developments in the United States and foreign countries;
- the results of our clinical trials and preclinical studies;
- the clinical results of our competitors or potential competitors;
- the execution of our partnering and manufacturing arrangements;
- variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- variations in the level of expenses related to our commercialization activities, if any product candidates are approved;
- the success of, and fluctuations in any product candidates approved for commercialization in the future;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- overall performance of the equity markets;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions or trends in our industry or the economy as a whole;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC, and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, capital commitments, intellectual property, litigation or other disputes impacting us or our business;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- FDA or foreign regulatory actions affecting us or our industry;
- changes in the structure of healthcare payment systems;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- ratings downgrades by any securities analysts who follow our common stock;
- the development and sustainability of an active trading market for our common stock;

- the size of our public float;
- the expiration of market standoff or contractual lock-up agreements and future sales of our common stock by our officers, directors and significant stockholders;
- recruitment or departure of key personnel;
- changes in accounting principles;
- future issuances of our securities;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and
- any other factors discussed in this report.

In addition, the stock markets, and in particular the NYSE American, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders of pharmaceutical companies have instituted securities class action litigation following periods of market volatility. If we become involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

We have identified material weaknesses in our internal control over financial reporting since inception and, while we continue to work on remedying the situation, we have not yet been able to do so. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Ineffective internal control could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We have identified material weaknesses in our internal control over financial reporting since our inception as a company. As defined in Regulation 12b-2 under the Exchange Act, a “material weakness” is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Specifically, we determined that we had the following material weaknesses in our internal control over financial reporting: (i) inadequate segregation of duties; and (ii) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of both U.S. GAAP and SEC guidelines.

As of the date of this report, we have not remediated these material weaknesses. We are continuing to adopt and implement written policies and procedures for accounting and financial reporting. We plan to hire additional qualified personnel to address inadequate segregation of duties, although the timing of such hires is largely dependent on our securing additional financing to cover such costs. The implementation of these initiatives may not fully address any material weakness or other deficiencies that we may have in our internal control over financial reporting.

Even if we develop effective internal control over financial reporting, such controls may become inadequate due to changes in conditions or the degree of compliance with such policies or procedures may deteriorate, which could result in the discovery of additional material weaknesses and deficiencies. In any event, the process of determining whether our existing internal control over financial reporting is compliant with Section 404 of the Sarbanes-Oxley Act,

or Section 404, and sufficiently effective requires the investment of substantial time and resources, including by our Chief Executive Officer and other members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete. In addition, we cannot predict the outcome of this process and whether we will need to implement remedial actions in order to establish effective controls over financial reporting. The determination of whether or not our internal controls are sufficient and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. We may also fail to timely complete our evaluation, testing and any remediation required to comply with Section 404.

We are required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. However, for as long as we are a "smaller reporting company," our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. While we could be a smaller reporting company for an indefinite amount of time, and thus relieved of the above-mentioned attestation requirement, an independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Such undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

We will continue to incur significant costs as a result of and devote substantial management time to operating as a public company listed on the NYSE American.

As a public company listed on the NYSE American, we incurred and will continue to incur significant legal, accounting and other expenses. For example, we are subject to the rules and regulations required by the NYSE American, including changes in corporate governance practices and minimum listing requirements. These requirements have increased our legal and financial compliance costs and have and will continue to render some activities more time-consuming and costly. In addition, our management and other personnel have diverted and will continue to divert attention from operational and other business matters to devote substantial time to these listing requirements and failure to meet these requirements could lead to an adverse effect on the listing of our common stock on the NYSE American.

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

The trading market for our common stock depends in part upon the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage 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.

Future sales and issuances of our common stock or rights to purchase common stock could result in substantial dilution to the percentage ownership of our stockholders.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock or other securities convertible into or exchanged for our common stock in one or more transactions, and in a manner we determine from time to time and at prices that may not be the same as the price per share paid by other investors, and dilution to our stockholders could result. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by other investors. New investors could also receive rights, preferences and privileges senior to those of existing holders of our common stock. In addition, in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock, we may be required to proportionally adjust the conversion price, exercise price or number of shares issuable upon exercise of our outstanding warrants.

In addition, common stock with an aggregate offering price of up to $8.5 million (of which $4.6 million is available) may be issued and sold pursuant to an "at-the-market" offering of our common stock pursuant to a sales agreement between us and JonesTrading Institutional Services LLC ("JonesTrading"). Subject to certain limitations in the sales agreement and compliance with applicable law, we have the discretion to deliver a placement notice to JonesTrading at any time throughout the term of the sales agreement, which has a term equal to the term of the

registration statement on Form S-3 unless otherwise terminated earlier by us or JonesTrading pursuant to the terms of the sales agreement. The number of shares that are sold by JonesTrading after delivering a placement notice will fluctuate based on the market price of our common stock during the sales period and limits we set with JonesTrading. Because the price per share of each share sold will fluctuate based on the market price of our common stock during the sales period, it is not possible at this stage to predict the number of shares that will be ultimately issued. Issuances of such shares pursuant to the sales agreement will have a dilutive effect on our existing stockholders. Further, if we sell common stock, preferred stock, convertible securities and other equity securities in other transactions pursuant to our shelf registration statement on Form S-3, existing investors may be materially diluted by such subsequent sales and new investors could gain rights superior to our existing stockholders.

We may issue debt or debt securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.

In the future, we may attempt to increase our capital resources by entering into debt or debt-like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium-term notes, senior notes, subordinated notes, guarantees, preferred stock, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and securities would receive distributions of our available assets before distributions to the holders of our common stock. Because our decision to incur debt and issue securities in future financings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future.

Our directors, executive officers and principal stockholders exert significant influence over us and could impede a change of corporate control.

Our directors, executive officers and holders of more than 5% of our common stock, together with their affiliates, beneficially owned, in the aggregate, approximately 14% of our outstanding common stock as of February 29, 2020. As a result, these stockholders, acting together, have the ability to exert significant influence on matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have the ability to significantly influence the management and affairs of our company. Accordingly, this concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Delaware law and provisions in our certificate of incorporation and bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

The anti-takeover provisions of the DGCL may discourage, delay or prevent a change of control by prohibiting us from engaging in a business combination with stockholders owning in excess of 15% of our outstanding voting stock for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our certificate of incorporation and bylaws contain provisions that may make the acquisition of us more difficult, including the provisions that:

- provide that our board of directors has the right to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director;

- provide that only a majority of our board of directors or an officer instructed by the directors are authorized to call a special meeting of stockholders;

- authorize the issuance of undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval, and which may include rights superior to the rights of the holders of common stock; and

- provide that our board of directors is expressly authorized to make, alter or repeal our bylaws.

These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of its choosing and cause us to take certain actions you desire.

We are a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

We are a "smaller reporting company," meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a "smaller reporting company," and have either: (i) a public float of less than $250 million or (ii) annual revenues of less than $100 million during the most recently completed fiscal year and (A) no public float or (B) a public float of less than $700 million. As a "smaller reporting company," we are subject to lesser disclosure obligations in our SEC filings compared to other issuers, including being able to provide simplified executive compensation disclosures in our filings and only being required to provide two years of audited consolidated financial statements in our annual reports. In addition, because our public float is less than $75 million, we are a "non-accelerated filer" under Rule 12b-2 of the Exchange Act and are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting. Until such time as we cease to be a "smaller reporting company" or a "non-accelerated filer," as applicable, such decreased disclosure in our SEC filings may make it harder for investors to analyze our operating results and financial prospects.

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

We have never paid cash dividends on our capital stock. We currently intends to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any cash dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease a 11,793 square foot office and laboratory space at 115 Nicholson Lane, San Jose, California 95134. This lease expires in December 2023. On February 17, 2020, we executed a sublease agreement covering the entire space for the remaining term of the lease.

We also lease an approximately 100 square foot office at 900 E. Hamilton Ave., Suite 100, Campbell, California 95008. This is a month-to-month lease.

ITEM 3. LEGAL PROCEEDINGS

We may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. In addition, we may receive letters alleging infringement of patents or other intellectual property rights. We are not a party to any material legal proceedings, nor are we aware of any pending or threatened litigation that we believe is likely to

have a material adverse effect on our business, results of operations, cash flows or financial condition should such litigation be resolved unfavorably. These claims, even if not meritorious, could result in the expenditure of significant financial resources and diversion of management efforts.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Our common stock is traded on the NYSE American under the symbol "BPMX." The following table sets forth, for each of the fiscal periods indicated, the quarterly high and low sales prices for our common stock as reported by the NYSE American.

	High	Low
Fiscal Year Ended January 31, 2020		
First Quarter	$ 4.48	$ 1.23
Second Quarter	$ 1.40	$ 0.40
Third Quarter	$ 0.43	$ 0.28
Fourth Quarter	$ 1.05	$ 0.26
Fiscal Year Ended January 31, 2019		
First Quarter	$ 9.38	$ 3.38
Second Quarter	$ 7.35	$ 4.50
Third Quarter	$ 6.75	$ 3.15
Fourth Quarter	$ 4.80	$ 1.25

As of February 29, 2020, there were approximately 38 registered holders of record of our common shares, based upon information received from our stock transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees, including broker dealers. We believe that there are a significantly larger number of beneficial owners of our common shares than the number of record holders.

Transfer Agent and Registrar

The Transfer Agent for our common stock is Computershare Trust Company, N.A. located at 250 Royall Street, Canton, MA 02021.

Dividend Policy

We have not paid any cash dividends to our stockholders. Any future determination as to the declaration and payment of dividends on shares of our common stock will be made at the discretion of our board of directors out of funds legally available for such purpose. We are under no contractual obligations or restrictions to declare or pay dividends on our shares of common stock. We currently have no plans to pay such dividends.

Unregistered Sales of Equity Securities

None.

Equity Compensation Plan Information

The following table includes information as of January 31, 2020 for our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	1,234,492	$ 4.02	1,737,986(1)
Equity compensation plans not approved by security holders(2)	6,667	$ 4.75	—

(1) Includes shares of common stock that remain available for purchase under our 2016 Equity Incentive Plan.

(2) Includes shares outstanding under inducement option grants to one employee. All of these grants were made outside of a stockholder approved plan, pursuant to the exemption for inducement grants under the listing rules of the NYSE American, and have the same material terms as the options granted under our 2016 Equity Incentive Plan.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, is intended to help the reader understand our results of operations and financial condition. MD&A is provided as a supplement to, and should be read in conjunction with, our audited consolidated financial statements and the accompanying notes to the consolidated financial statements and other disclosures included in this Annual Report on Form 10-K. Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States and are presented in U.S. dollars.

Overview

We are a specialty pharmaceutical company focused on the dermatology market. Our focus is to develop products that treat dermatologic conditions that are not being adequately addressed or those where current therapies and approaches are suboptimal. Our strategy is to bring new products to market by identifying optimal delivery mechanisms and/or alternative applications for FDA-approved or well characterized active pharmaceutical ingredients, or APIs. We aim to reduce the time, cost and risks typically associated with new product development by utilizing APIs with demonstrated safety profiles and, when applicable, taking advantage of the regulatory approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. Section 505(b)(2) permits an applicant for a new product, such as a new or improved formulation or a new use of an approved product, to rely in part on literature and/or the FDA's findings of safety and/or effectiveness for a similar previously-approved product. Our approach is to identify the limitations of current treatment options and work to develop novel products using our proprietary HyantX™ topical drug delivery system.

Results of Operations

Revenue

Year ended January 31,			
2020	2019	Change	%
($ in thousands)			
$ —	$ 57	$ (57)	(100)%

Revenue was related to VI_2OLET, our iodine dietary supplement. We recognized revenue when control was transferred to the customer, which was typically upon shipment, net of reserves for product returns, pricing discounts or other concessions. In November 2018, we divested the rights to develop, manufacture, market and sell the VI_2OLET product, therefore we did not recognize revenues in fiscal year 2020 and do not expect to recognize revenues in the future from this product.

Cost of Goods Sold

Year ended January 31,			
2020	2019	Change	%
($ in thousands)			
$ —	$ 83	$ (83)	(100)%

Cost of goods sold included direct costs related to the sale of VI_2OLET, our iodine dietary supplement, and write-downs of excess and obsolete inventories. Following the divestiture of VI_2OLET, we did not incur any costs of goods sold and do not expect to incur cost of good sold in the future related to this product.

Research and Development Expenses

Year ended January 31,			
2020	2019	Change	%
($ in thousands)			
$ 4,690	$ 9,079	$ (4,389)	(48)%

Research and development expenses primarily include headcount-related costs, stock-based compensation and both internal and external research and development expenses. Research and development expenses are expensed as incurred.

Research and development expenses decreased $4.4 million for the year ended January 31, 2020 compared to the prior year primarily due to decreased headcount-related, clinical trial, product development and stock-based compensation expenses.

Sales and Marketing Expenses

Year ended January 31,			
2020	2019	Change	%
($ in thousands)			
$ 714	$ 2,157	$ (1,443)	(67)%

Sales and marketing expenses primarily include headcount-related costs, stock-based compensation and the market development related to our products candidates. Sales and marketing expenses are expensed as incurred.

Sales and marketing expenses decreased $1.4 million for the year ended January 31, 2020 compared to the prior year primarily due to decreased headcount-related and stock-based compensation expenses.

General and Administrative Expenses

Year ended January 31,			
2020	2019	Change	%
($ in thousands)			
$ 4,282	$ 5,244	$ (962)	(18)%

General and administrative expenses primarily include headcount-related costs, stock-based compensation and costs of our executive, finance and other administrative functions.

General and administrative expenses decreased $1.0 million for the year ended January 31, 2020 compared to the prior year primarily due decreased headcount-related, consulting and stock-based compensation expenses.

Change in Fair Value of Warrant and Stock Liabilities

Year ended January 31,			
2020	2019	Change	%
($ in thousands)			
$ 291	$ 28	$ 263	nm

The change in fair value of warrant and stock liabilities for the year ended January 31, 2020 primarily resulted from an exchange agreement with holders of certain warrants, such that warrants to purchase approximately 2.3 million shares of common stock were to be exchanged for 850,000 shares of common stock. The change in fair value of warrant and stock liabilities for the year ended January 31, 2019 primarily reflects the fair value re-measurement of certain warrants granted in fiscal year 2017 that are accounted for as derivative liabilities.

Other Income (Expense), net

Year ended January 31,			
2020	2019	Change	%
($ in thousands)			
$ (290)	$ (778)	$ (488)	nm

Other income and expenses, net, decreased $0.5 million for the year ended January 31, 2020 compared to the prior year primarily due to expenses recorded for the incremental fair value related to the modification of warrants. Expenses related to the modification of warrants were approximately $308,000 and $874,000 for the years ended January 31, 2020 and 2019, respectively.

Liquidity and Capital Resources

A summary of the sources and uses of cash and cash equivalents is as follows (in thousands):

	Year ended January 31,	
	2020	2019
Net cash used in operating activities	$ (10,107)	$ (14,992)
Net cash used in investing activities	(30)	(43)
Net cash provided by financing activities	7,795	10,528
Net decrease in cash and cash equivalents	$ (2,342)	$ (4,507)

The following table summarizes total current assets, liabilities and working capital deficit (in thousands):

	As of January 31,	
	2020	2019
Current assets	$ 986	$ 3,385
Current liabilities	1,684	2,297
Working capital	$ (698)	$ 1,088

Historically, we have financed our operations primarily through the sale of debt and equity securities. The accompanying consolidated financial statements for the year ended January 31, 2020 have been prepared assuming that we will continue as a going concern, meaning we will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. As of January 31, 2020, we had cash and cash equivalents of $0.7 million and working capital deficit of $0.7 million. We raised $7.8 million and $10.5 million from financing activities in the years ended January 31, 2020 and 2019, respectively. We will require significant additional financing in the future. If the Merger is not consummated, we will likely be required to wind-down and dissolve as a company and would be required to pay all our debts and contractual obligations and set aside certain reserves for potential future claims. While we will also attempt to consummate a financing to allow us to continue as a going concern, based on our recent strategic process, we do not believe that we will be able to consummate a financing on reasonable terms sufficient to obtain such additional financial resources. These factors raise substantial doubt about our ability to continue as a going concern.

Our primary capital requirements are to fund working capital, including the transaction costs related to the Merger.

Net cash used for operating activities for the year ended January 31, 2020 was $10.1 million, which primarily resulted from a net loss of $9.7 million and changes in operating assets and liabilities of $1.3 million, partially offset by non-cash expenses of $0.9 million. Changes in operating assets and liabilities was primarily attributable to timing of payments to vendors and lower operating expenses.

Net cash used for operating activities for the year ended January 31, 2019 was $15.0 million, which primarily resulted from a net loss of $17.3 million and changes in operating assets and liabilities of $0.7 million, partially offset by non-cash expenses of $3.0 million. Changes in operating assets and liabilities was primarily attributable to timing of payments to vendors.

Net cash used for investing activities for the years ended January 31, 2020 and 2019 was approximately $30,000 and $43,000, respectively, resulting from the purchase of property and equipment.

Net cash provided by financing activities for the year ended January 31, 2020 was $7.8 million, which was primarily due to the $7.2 million of net proceeds from the issuance of common stock and $0.6 million from the Bridge Loan.

Net cash provided by financing activities for the year ended January 31, 2019 was $10.5 million, which was primarily from the exercise of warrants to purchase common stock.

Going Concern

The accompanying consolidated financial statements have been prepared assuming we will continue as a going concern, meaning we will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. As of January 31, 2020, we had cash and cash equivalents of $0.7 million and working capital deficit of $0.7 million.

We have incurred recurring losses and negative cash flows from operations since inception and have funded our operating losses through the sale of common stock in public and private offerings and the issuance of notes, Series A convertible preferred stock and warrants. We incurred a net loss of $9.7 million and $17.3 million for the years ended January 31, 2020 and 2019, respectively, and had an accumulated deficit of $88.2 million as of January 31, 2020.

We have a limited operating history and our prospects are subject to risks, expenses and uncertainties frequently encountered by companies in our industry. If the Merger is not consummated, we will likely be required to wind-down and dissolve as a company and would be required to pay all our debts and contractual obligations and set aside certain reserves for potential future claims. While we will also attempt to consummate a financing to allow us to continue as a going concern, based on our recent strategic process, we do not believe that we will be able to consummate a financing on reasonable terms sufficient to obtain such additional financial resources. These factors raise substantial doubt about our ability to continue as a going concern.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-02, *Leases*, and in July 2018, ASU No. 2018-11, *Targeted Improvements*, which requires entities to recognize assets and liabilities for leases with lease terms greater than twelve months. We adopted this standard as of February 1, 2019, and our leases are classified as operating leases and will continue to be classified as operating leases under the new accounting method. Adoption of the new standard resulted in the recording of an operating lease right-to-use asset of $1.2 million, which represents the present value of the remaining lease payments as of the date of adoption discounted using an incremental borrowing rate of 15%, and an operating lease liability of $1.3 million. The adoption did not have an impact on our consolidated statements of operations and comprehensive loss or cash flows.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. Effective February 1, 2019, we adopted ASU No. 2018-07, and the adoption did have a material impact on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which amended certain disclosure requirements over Level 1, Level 2 and Level 3 fair value measurements. The amendment is effective for annual and interim periods beginning after December 15, 2019, with early adoption permitted. We are currently evaluating the impact of adopting this amendment, but does not anticipate it will have a material impact on our disclosures.

We have reviewed other recent accounting pronouncements and concluded they are either not applicable to the business, or no material effect is expected on the consolidated financial statements as a result of future adoption.

Critical Accounting Policies

Our consolidated financial statements and related public financial information are based on the application of accounting principles generally accepted in the United States, or GAAP. GAAP requires the use of estimates, assumptions, judgments and subjective interpretations of accounting principles that have an impact on the assets, liabilities, revenues and expense amounts reported. These estimates can also affect supplemental information contained in our external disclosures including information regarding contingencies, risk and financial condition. We believe our use of estimates and underlying accounting assumptions adhere to GAAP and are consistently applied. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ materially from these estimates under different assumptions or conditions. We continue to monitor significant estimates made during the preparation of our consolidated financial statements.

Our significant accounting policies are summarized in Note 1 of our audited consolidated financial statements included elsewhere in this report. While all of these significant accounting policies impact our financial condition and results of operations, we view the warrant liability, common stock liability and stock-based compensation policies as critical. Policies determined to be critical are those policies that have the most significant impact on our financial statements and require management to use a greater degree of judgment and estimates. Actual results may differ from those estimates. Our management believes that given current facts and circumstances, it is unlikely that applying any other reasonable judgments or estimate methodologies would cause an effect on our results of operations, financial position or liquidity for the periods presented in this report.

We believe the following critical accounting policies, among others, affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Warrant Liability

We account for certain of our warrants as derivative liabilities based on provisions relating to cash settlement options. We recorded a liability for the fair value of the warrants at the time of issuance, and at each reporting date the warrant is revalued to the instrument's fair value. The fair value of the warrant is estimated using the Black-Scholes pricing model. This liability is subject to fair value re-measurement until the warrants are exercised or expired, and any change in fair value is recognized as other income or expense in our consolidated statements of operations and comprehensive loss.

Common Stock Liability

In January 2020, we entered into an exchange agreement with certain warrant holders, in which approximately 2.3 million shares of common stock underlying the warrants would be exchanged for 850,000 shares of common stock. As of January 31, 2020, the stock liability included the value of common stock to be issued in the exchange. The value of these shares was approximately $383,000 as of January 31, 2020 and is included in accrued expenses and other on the consolidated balance sheet.

Stock-based Compensation

We recognize stock-based compensation for equity awards on a straight-line basis over their vesting periods, based on the grant date fair value. We estimate the fair value of stock options granted using the Black-Scholes pricing model. This model also requires subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as "special purpose entities."

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated audited financial statements as of and for the years ended January 31, 2020 and 2019, together with the report of the independent registered public accounting firm thereon and the notes thereto, are presented beginning at page F-1.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

As required by Rule 13a-15 under the Exchange Act, we have carried out an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this annual report, January 31, 2020. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Accounting Officer.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our company's reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Accounting Officer, to allow timely decisions regarding required disclosure.

Based upon that evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that our disclosure controls and procedures were ineffective as of the end of the period covered by this annual report. This conclusion was based on the material weaknesses in our internal control over financial reporting further described below.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Management has assessed the effectiveness of our internal control over financial reporting as of January 31, 2020 based on criteria established in Internal Control-Integrated Framework 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission. As a result of this assessment, management concluded that, as of January 31, 2020, our internal control over financial reporting was not effective. Our management identified the following material weaknesses in our internal control over financial reporting, which are common in many small companies with small staff: (i) inadequate segregation of duties; and (ii) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of both GAAP and SEC guidelines.

We plan to continue to take steps to enhance and improve the design of our internal control over financial reporting. During the period covered by this annual report on Form 10-K, we have not remediated the material weaknesses identified above. To remediate such weaknesses, we are continuing to adopt and implement written policies and procedures for accounting and financial reporting. We plan to hire additional qualified personnel to address inadequate segregation of duties, although the timing of such hires is largely dependent upon our securing additional financing to cover such costs. If we are unsuccessful in securing such funds, remediation efforts may be adversely affected in a material manner.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm because as a smaller reporting company we are not subject to Section 404(b) of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control over Financial Reporting

No change in our system of internal control over financial reporting occurred during the fourth quarter of the year ended January 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets for certain information concerning our directors and named executive officers as of January 31, 2020. All directors hold office until the next annual meeting of stockholders or until their respective successors are elected, except in the case of death, resignation or removal:

Name of Director	Age	Position
Steven M. Bosacki	62	Chief Executive Officer
Michael Hubbard(1)	68	Director
Stephen Morlock(1)	66	Director
R. Todd Plott, MD(2)	58	Director
David S. Tierney, MD	57	Director

(1) Member of the Audit, Compensation and Nominating and Corporate Governance Committees.

(2) Member of the Compensation and Nominating and Corporate Governance Committees.

Steven M. Bosacki

Steven M. Bosacki has served as our Chief Executive Officer since January 2020. Mr. Bosacki joined us in July 2019 as our Chief Operating Officer. Mr. Bosacki has also served as a Member with On Target Consulting LLC, a pharmaceutical consulting company, with David S. Tierney, M.D., the our Chief Executive Officer, since October 2018. Prior to joining us, Mr. Bosacki served as a Member with Fairway Pharmaceuticals, LLC, a pharmaceutical and medical device consulting company, from July 2017 to October 2018. From May 2016 to June 2017, Mr. Bosacki served as an Executive Director at Mission Pharmacal Company, a pharmaceutical company. From August 2013 to May 2016, Mr. Bosacki was President and Chief Executive Officer of Lautus Pharmaceuticals, LLC, a pharmaceutical company focused on dermatology and aesthetics markets. From April 2008, Mr. Bosacki served as Senior Vice President and General Counsel of Oceana Therapeutics, Inc., a specialty pharmaceutical company through its sale to Salix Pharmaceuticals, Ltd. in December 2011. Prior to Oceana Therapeutics, Mr. Bosacki served as Senior Vice President and General Counsel for Esprit Pharma, Inc., a pharmaceutical company, which was acquired by Allergan, Inc., a pharmaceutical company, in 2007. Earlier in his career, Mr. Bosacki served in a variety of management positions at Cardinal Health, Inc., a healthcare services company. Mr. Bosacki holds a law degree from the University of Detroit School of Law, and a law degree, a Master of Business Administration and a Bachelor of Commerce degree from the University of Windsor in Canada.

Michael Hubbard

Michael Hubbard has served as the Chairman of the Board since May 2016 and has served as a director since January 2015. Mr. Hubbard served as a senior audit partner at Deloitte & Touche LLP from August 2007 until retiring in June 2014 and also at PricewaterhouseCoopers LLP from September 1986 to July 2007. In these roles, he served private and publicly-held clients across the life sciences, waste management, construction, and technology sectors, advising domestic and international issuer companies on complex transactions, including nineteen initial public offerings and numerous follow-on equity and debt offerings. Mr. Hubbard holds a BA degree in Business Administration with a concentration in Accounting and an MBA degree from Washington State University. He is a licensed certified public accountant in the states of Washington (retired) and California (retired) and is a certified practitioner of international financial reporting standards. We believe that Mr. Hubbard should serve on our Board of Directors due to his broad range of experience serving large public and private companies in the United States and internationally, including experience with the reporting requirements for complex transactions, including carve-outs and spin-offs, direct involvement with numerous SEC filings and significant experience working with SEC staff, including the pre-clearance of accounting issues, responses to comments letters on periodic filings and offering documents.

Stephen Morlock

Stephen Morlock has served as a director since March 2015. Mr. Morlock served as Executive Vice President and Chief Financial Officer at Otis Spunkmeyer, Inc. from May 1994 until his retirement in June 2004. He also served as Controller at Otis Spunkmeyer, Inc. from August 1992 to April 1994. Prior to that, he held various management

positions in accounting, financial planning and internal audit at Westinghouse Electric Supply Company from November 1977 to July 1992. Since his retirement in June 2004, Mr. Morlock has not been active in any business activities. Mr. Morlock holds a BS degree in Accounting from San Diego State University. We believe that Mr. Morlock should serve on our Board of Directors due to his extensive experience in the retail industry, including a variety of distribution channels, product merchandising, customer relationship management and brand name development, as well as his background in manufacturing capacity utilization and expansion, procurement and inventory management, compensation plan design and financial reporting.

R. Todd Plott

R. Todd Plott, MD has served as a director since February 2019. Dr. Plott currently serves as Chief Medical Officer for Epiphany Dermatology, P.A., a private practice dermatology group based in Austin, Texas, where he has held various positions since November 2017. Prior to Epiphany Dermatology's acquisition of his practice, Dr. Plott served as the owner of Dermatology Alliance-Keller, P.A., a private practice, from April 2011 to November 2017. Prior to building his own private practice, Dr. Plott served as Chief Medical Officer at Revance Therapeutics, Inc., a biotechnology company, from December 2007 to January 2009, and as Vice President of Clinical and Regulatory Affairs at Medicis Pharmaceutical Company, a medical-cosmetic dermatology pharmaceutical company, from September 2001 to December 2007. Dr. Plott has been appointed to the FDA Dermatologic and Ophthalmic Drug Advisory Committee. Dr. Plott holds a BS degree from South Nazarene University and a MD degree from the University of Texas Medical Branch, Galveston, Texas.

David S. Tierney

David S. Tierney, MD has served as a director since September 2018. Prior to his resignation on January 30, 2020, Dr. Tierney served as our President and Chief Executive Officer. Dr. Tierney currently is Chief Executive Officer of Pharma2B, a privately held clinical stage pharmaceutical company. Dr. Tierney was the President, Chief Executive Officer and director of Icon Biosciences, Inc., a privately held ophthalmic drug delivery company, from January 2014 to March 2018. From January 2013 to March 2014, he was a venture partner at Signet Healthcare Partners, a New York City based life science private equity fund. He served as President and Chief Operating Officer of Oceana Therapeutics, Inc., a specialty therapeutic company he co-founded in 2008 and was later acquired by Salix Pharmaceuticals, Ltd. in December 2011. Dr. Tierney served as the President, Chief Executive Officer and director of Valera Pharmaceuticals, Inc., a specialty pharmaceutical company, between August 2000 and April 2007, when Valera completed a merger with Indevus Pharmaceuticals, Inc. Dr. Tierney serves on the board of directors of Catalyst Pharmaceuticals, Inc., Kempharm, Inc. and Bimeda. Dr. Tierney received his medical degree from the Royal College of Surgeons in Dublin, Ireland and was subsequently trained in internal medicine.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and any persons who own more than 10% of our common stock, to file initial reports of ownership and reports of changes in ownership with the SEC. Such persons are required by SEC regulation to furnish us with copies of all Section 16(a) forms that they file. Based solely upon our review of the copies of such forms provided to us and written representations from our named executive officers and directors with respect to fiscal year 2019, we believe that all Section 16(a) filing requirements during fiscal year 2020 were complied with.

Audit Committee

Our Audit Committee is comprised of Mr. Hubbard and Mr. Morlock. Mr. Hubbard is the chairman of our Audit Committee. The composition of our Audit Committee meets the requirements for independence under the current NYSE American and SEC rules and regulations. Each member of our Audit Committee is financially literate. In addition, our board of directors has determined that Mr. Hubbard is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose on him any duties, obligations or liabilities that are greater than are generally imposed on members of our Audit Committee and our board of directors. Our Audit Committee is directly responsible for, among other things:

- selecting a firm to serve as the independent registered public accounting firm to audit our consolidated financial statements;

- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to submit anonymously concerns about questionable accounting or audit matters;
- considering the adequacy of our internal controls and internal audit function;
- reviewing material related party transactions or those that require disclosure; and
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm.

Code of Conduct

We have adopted a Code of Conduct that applies to all of our directors, officers and employees. Our Code of Conduct is posted on the investor relations section of our website located at http://biopharmx.investorroom.com/overview, by clicking on "Corporate Governance." Any amendments or waivers of our Code of Conduct pertaining to a member of our board of directors or one of our executive officers will be disclosed on our website at the above-referenced address.

ITEM 11. EXECUTIVE COMPENSATION

The following table presents summary information regarding the total compensation awarded to, earned by or paid to each of the named executive officers for services rendered in all capacities during fiscal years 2020 and 2019. Mr. Bosacki is the only executive officer of the Company as of January 31, 2020.

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Steven M. Bosacki *Chief Executive Officer*	2020	163,094	—	21,777	—	184,871
David S. Tierney, MD	2020	450,774	—	158,953	—	609,727
Former Chief Executive Officer, Former President and Director(2)	2019	168,750	—	957,723	—	1,126,473
Kin F. Chan, PhD	2020	167,761	—	34,043	10,000	211,804
Former Executive Vice President of Research and Technology(3)	2019	270,000	—	—	—	270,000
Anja Krammer *Former President and Director(4)*	2019	248,803	—	102,671	238,875	590,349
Greg Kitchener *Former Executive Vice President and Chief Financial Officer(5)*	2019	173,769	—	—	—	173,769

(1) Amounts represent the aggregate fair value amount computed as of the grant date of each award in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718. Assumptions used in the calculation of these amounts are included in Note 7 to our consolidated financial statements contained in this annual report on Form 10-K for the year ended January 31, 2020.

(2) Effective as of January 30, 2020, Dr. Tierney resigned from his role as President and Chief Executive Officer. He remains as a member of the board of directors.

(3) Effective as of July 26, 2019, Dr. Chan resigned from his role as Executive Vice President of Research and Technology. Other compensation includes amounts earned under his consulting agreement.

(4) Effective as of October 10, 2018, Ms. Krammer was terminated from her roles as President and Secretary. Effective March 24, 2019, Ms. Krammer resigned as a member of the board of directors. Amount for fiscal year

2020 includes payments made as a board member. Amount for fiscal year 2019 includes termination benefits of $232,500 and $6,375 for the reimbursements of self-sourced health care insurance premiums.

(5) Effective as of October 10, 2018, Mr. Kitchener resigned from his roles as Executive Vice President and Chief Financial Officer.

Narrative Disclosure to Summary Compensation Table

Employment Arrangements with Our Named Executive Officers

We have entered into employment offer letters with each of the named executive officers in connection with his commencement of employment with us. These offers of employment were each subject to execution of our standard confidential information and invention assignment agreement.

Steven Bosacki's Employment Agreement

On July 16, 2019, we entered into an employment agreement with Steven M. Bosacki as Chief Operating Officer. On January 30, 2020, Mr. Bosacki was named Chief Executive Officer and Principal Financial Officer. The offer letter provides the following:

- A base salary of $300,000 per year.
- An initial annual bonus target of 40% of base salary.
- Eligibility to participate in our employee benefit plans and entitled to paid vacation in accordance with our vacation policy on the same basis as other executive employees.
- An incentive stock option to purchase 91,000 shares of our common stock with an exercise price equal to $0.44, which was equal to the closing price of our common stock on the NYSE American on the date of grant. The option will vest as to one thirty-sixth (1/36) of the shares subject to this option on the last day of each calendar month until all such shares have vested, subject to Mr. Bosacki’s continued employment or service with us. If the option or any other then-outstanding equity awards are not assumed, continued or substituted in a Change in Control (as defined in the Offer Letter), then such unvested equity awards shall accelerate and become vested and exercisable (to the extent applicable) as to 100% of the then-unvested shares subject to the equity awards in effect immediately prior to the Change in Control.
- Under the terms of the Offer Letter, Mr. Bosacki will receive the following payments in event of a separation from us:
    - In the event of Mr. Bosacki’s termination of employment (a) by us (i) on account of Mr. Bosacki’s death, (ii) on account of Mr. Bosacki’s disability, (iii) for Cause (as defined in the Offer Letter or (b) by Mr. Bosacki without Good Reason (as defined in the Offer Letter), we are obligated to pay Mr. Bosacki (1) any unpaid salary through the date of termination; (2) the amount of any actual bonus earned and payable from a prior period which remains unpaid by us as of the date of termination, (3) reimbursement for any unreimbursed expenses incurred through the date of termination; and (3) all other payments and benefits to which Mr. Bosacki is entitled upon a termination of employment under the terms of any applicable compensation arrangement or benefit or equity plan or program (collectively, the “Accrued Compensation”).
    - In the event of Mr. Bosacki’s termination of employment by us without Cause or is terminated by Mr. Bosacki due to his resignation by Good Reason, (as defined in the Offer Letter), in either case more than one month before or more than twelve months following a Change in Control, and provided that Mr. Bosacki delivers a signed Release (as defined in the Offer Letter) and satisfies all conditions to make the Release effective, Mr. Bosacki will be entitled to receive (1) the Accrued Compensation, (2) a lump sum cash payment in an amount equal to nine months of Mr. Bosacki’s then current annual base salary, and (3) payment of the Consolidated Omnibus Budget Reconciliation Act of 1985

("COBRA") premiums (provided Mr. Bosacki timely elect COBRA coverage) for continued health coverage until the earlier of (a) nine months and (b) the date that Mr. Bosacki is covered under the health plan of another employer.

- In the event a Change in Control occurs and if we terminate Mr. Bosacki's employment without Cause or if Mr. Bosacki resigns for Good Reason, in each case within the period beginning one month before, and ending twelve months following, such Change in Control, and provided that Mr. Bosacki delivers a signed Release and satisfies all conditions to make the Release effective, Mr. Bosacki will be entitled to receive (1) the Accrued Compensation, (2) a lump sum cash payment in an amount equal to eighteen (18) months of Mr. Bosacki's then current base salary, (3) payment of COBRA premiums (provided Mr. Bosacki timely elect COBRA coverage) for continued health coverage until the earlier of (a) eighteen months and (b) the date that Mr. Bosacki is covered under the health plan of another and (4) full acceleration of all outstanding equity awards.

Notwithstanding the forgoing, Mr. Bosacki has agreed to waive any change of control payments that would have been due to him pursuant to the Offer Letter upon the closing of the Merger.

Outstanding Equity Awards

The following table includes information as of January 31, 2020 for outstanding equity awards held by our named executive officers:

	Option Awards				
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Steven M. Bosacki	15,167	75,833(1)	—	0.44	7/16/2029
David S. Tierney, MD	98,668	197,333(2)	—	5.50	9/11/2028
	70,000	290,000(3)	—	0.84	6/12/2029
Kin F. Chan, PhD	—	—	—	—	—
Anja Krammer	—	—	—	—	—
Greg Kitchener	—	—	—	—	—

(1) The stock option was granted on July 16, 2019, and the shares subject to this option vest 1/36 of the shares on the last day of each full calendar month.

(2) The stock option was granted on September 11, 2018, and the shares subject to this option vest one-fourth on the one year anniversary of the grant date and 1/36 of the remaining shares vest each month thereafter.

(3) The stock option was granted on June 12, 2019, and the shares subject to this option vest 1/36 of the shares on the last day of each full calendar month.

Employment Arrangements and Potential Payments upon Termination or Change in Control

See employment arrangements discussed above in "Employment Arrangements with Our Named Executive Officers".

Director Compensation

The following table provides the total compensation for each person who served as a non-employee member of our board of directors during fiscal year 2020, including all compensation awarded to, earned by or paid to each person

who served as a non-employee director for some portion or all of fiscal year 2020. Dr. Tierney, our former President and Chief Executive Officer, received no compensation for his service as a member of our board of directors during fiscal year 2020, and is not included in this table. The compensation received by Dr. Tierney as an employee of the Company is presented in "Summary Compensation Table".

Director Compensation Fiscal Year 2020

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Michael Hubbard	113,500	—	113,500
Stephen Morlock	82,000	—	82,000
R. Todd Plott, MD	56,000	—	56,000
Anja Krammer(2)	5,914	—	5,914

(1) For information regarding the number of stock options held by each non-employee director as of January 31, 2020, see the column "Number of Securities Underlying Stock Options Held as of January 31, 2019" in the table below.

(2) Ms. Krammer received compensation for her service as a member of our board of directors after she no longer held the positions as our President and Secretary.

Each person who served as a non-employee member of our board of directors during fiscal year 2020 held the following aggregate number of shares of our common stock subject to outstanding stock options as of January 31, 2020:

Name	Number of Securities Underlying Stock Options Held as of January 31, 2020
Michael Hubbard	80,700
Stephen Morlock	79,900
R. Todd Plott, MD	49,420
David S. Tierney, MD	656,001

Retainer Fees. We provide a quarterly cash retainer fee to each of our non-employee directors for their services on the committees of our board of directors.

Our non-employee directors were compensated as follows:

- $40,000 annual retainer;
- $35,000 for service as the chair of the board;
- $12,500 for service as the chair of our Audit Committee;
- $10,000 for service as the chair of our Compensation Committee;
- $6,000 for service as the chair of our Nominating and Corporate Governance Committee;
- $10,000 for service as a member of the Audit Committee;
- $10,000 for service as a member of the Compensation Committee; and
- $6,000 for service as a member of the Nominating and Corporate Governance Committee.

Equity Awards. Each newly-elected or appointed non-employee director will be granted a stock option, as determined by the Compensation Committee, to purchase our common stock. Each stock option award will vest and become exercisable in equal monthly installments over two years from the vesting commencement date, subject to such

non-employee director's continued service on our board of directors. The awards will have 10-year terms and will terminate three years following the date the director ceases to be one of our directors or consultants.

In addition, all non-employee directors will be granted an annual stock option, as determined by the Compensation Committee, to purchase our common stock. Each stock option award will vest and become exercisable in equal monthly installments over one year from the vesting commencement date, subject to such non-employee director's continued service on our board of directors. The awards will have 10-year terms and will terminate three years following the date the director ceases to be one of our directors or consultants.

Compensation Committee Interlocks and Insider Participation

The members of our Compensation Committee during fiscal year 2020 were Mr. Hubbard and Mr. Morlock. No member of our Compensation Committee in fiscal year 2020 was at any time during fiscal year 2020 or at any other time an officer or employee of BioPharmX Corporation or any of its subsidiaries, and none had or have any relationships with BioPharmX Corporation that are required to be disclosed under Item 404 of Regulation S-K. None of our executive officers has served as a member of the board of directors, or as a member of the compensation or similar committee, of any entity that has one or more executive officers who served on our board of directors or Compensation Committee during fiscal year 2020.

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

Equity Compensation Plan Information is described above in Item 5.

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of February 14, 2020 by:

- each person, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of our common stock;
- each of our directors or director nominees;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

Percentage ownership of our common stock is based on 18,278,219 shares of common stock outstanding as of February 14, 2020. We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. We have deemed shares of our common stock subject to options and warrants that are currently exercisable or exercisable within 60 days of February 14, 2020 to be outstanding and to be beneficially owned by the person holding the option and warrant for the purpose of computing the percentage ownership of that person but have not treated them as outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each of the individuals and entities named below is c/o BioPharmX Corporation, 900 E. Hamilton Ave., Suite 100, Campbell, California 95008.

	Shares Beneficially Owned	
Name of Beneficial Owner	Shares of Common Stock	%
Directors and Named Executive Officers:		
Steven M. Bosacki(1)	20,223	*
David S. Tierney(2)	211,167	1.1%
Michael Hubbard(3)	75,250	*
Stephen Morlock(4)	100,506	*
R. Todd Plott(5)	39,787	*
All executive officers and directors as a group (5 persons)(6)	446,933	2.4%
5% or Greater Stockholders		
Timber Pharmaceuticals LLC(7)	2,200,328	12.0%

* Represents holdings of less than one percent

(1) Includes options exercisable for 20,223 shares of common stock within 60 days of February 14, 2020.

(2) Includes options exercisable for 207,167 shares of common stock within 60 days of February 14, 2020.

(3) Includes options exercisable for 75,250 shares of common stock within 60 days of February 14, 2020.

(4) Includes options exercisable for 74,450 shares of common stock within 60 days of February 14, 2020 and warrants exercisable for 26,056 shares of common stock within 60 days of February 14, 2020.

(5) Includes options exercisable for 39,787 shares of common stock within 60 days of February 14, 2020.

(6) Includes options exercisable for 416,877 shares of common stock within 60 days of February 14, 2020 and warrants exercisable for 26,056 shares of common stock within 60 days of February 14, 2020.

(7) The shares of common stock held by Timber will become treasury stock of BioPharmX if the Merger is consummated.

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

In addition to the executive officer, president and director compensation arrangements discussed above under “Executive Compensation,” the following is a description of transactions since February 1, 2019 to which we have been a participant, in which the amount involved in the transaction exceeds or will exceed the lesser of (i) $120,000 or (ii) 1% of the average of our total assets at year end for the last two completed fiscal years, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest or such other persons as may be required to be disclosed pursuant to Item 404 of Regulation S-K, which we refer collectively refer to as related parties.

During fiscal year 2019, we employed a family member related to Ms. Krammer in the marketing department. For fiscal year 2019, we paid the family member aggregate compensation, including salary and termination benefits, of approximately $142,000.

Review, Approval or Ratification of Transactions with Related Parties

The charter of our Audit Committee requires that any transaction with a related party that must be reported under applicable rules of the SEC, other than compensation related matters, must be reviewed and approved or ratified by our Audit Committee. The Audit Committee has adopted a related party transactions policy to set forth the procedures for the identification, review, consideration and approval or ratification of these transactions, and a copy of such policy is available on our website at http://biopharmx.investorroom.com/corporate-governance by clicking on "Related Person Transaction Policy".

Director Independence

Our board of directors determines the independence of our directors by applying the independence principles and standards established by the NYSE American LLC, or NYSE American, including those published in the NYSE American LLC Company Guide. These provide that a director is independent only if our board of directors affirmatively determines that such director has no relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of such director. They also specify that a director who is an executive officer or employee of the Company precludes a determination of independence with respect to such director. Under the rules of the NYSE American, independent directors must comprise at least 50% of our board of directors. In addition, the rules of NYSE American require that, subject to specified exceptions, each member of our Audit, Compensation and Nominating and Corporate Governance committees must be independent.

Applying the standards above, our board of directors annually reviews the independence of the Company's directors, taking into account all relevant facts and circumstances. In its most recent review, our board of directors reviewed and discussed, among other things, information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them, and all other facts and circumstances our board of directors deemed relevant in determining their independence. Based on this review, our board of directors determined that, aside from David S. Tierney, each member of our board of directors is currently considered an "independent director" as defined under the applicable rules and regulations of the SEC and the listing requirements and rules of NYSE American.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

In addition to performing the audit of our consolidated financial statements, BPM LLP provided various other services during fiscal years 2020 and 2019. Our Audit Committee has determined that BPM LLP's provisioning of these services, which are described below, does not impair BPM LLP's independence from us. The aggregate fees billed for fiscal years 2020 and 2019 for each of the following categories of services are as follows:

Fees Billed to BioPharmX Corporation	2020	2019
	(in thousands)	
Audit fees(1)	$ 215	$ 205
Audit related fees(2)	—	4
Tax fees(3)	—	—
All other fees(4)	—	—
Total fees	$ 215	$ 209

(1) *"Audit fees"* include fees for professional services rendered in connection with the audit of our annual consolidated financial statements, review of our quarterly condensed consolidated financial statements and advisory services on accounting matters that were addressed during the annual audit and quarterly review. This category also includes fees for services that were incurred in connection with statutory and regulatory filings or

engagements, such as comfort letters related to our public offerings, consents and review of documents filed with the SEC.

(2) *"Audit related fees"* include fees for professional services rendered that are reasonably related to the performance of the audit or review of our consolidated financial statements.

(3) *"Tax fees"* include fees for tax compliance and advice. Tax advice fees encompass a variety of permissible services, including technical tax advice related to federal and state income tax matters; assistance with sales tax; and assistance with tax audits.

(4) "*All other fees*" consist of the aggregate fees billed for products and services provided by BPM LLP, other than included in "Audit Fees," "Audit Related Fees" and "Tax Fees."

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our Audit Committee's policy is to pre-approve all audit and permissible non-audit services provided by the independent registered public accounting firm regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date. These services may include audit services, audit related services, tax services and other services. Pre-approval is detailed as to the particular service or category of services. The independent registered public accounting firm and management are required to periodically report to the audit committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date.

All of the services relating to the fees described in the table above were approved by our Audit Committee.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

1. Financial Statements

The list of consolidated financial statements set forth in the accompanying Index to the Consolidated Financial Statements at page F-1 of this Annual Report on Form 10-K is incorporated herein by reference. Such consolidated financial statements are filed as part of this Annual Report on Form 10-K.

2. Financial Statement Schedules

All schedules have been omitted because the required information is either not required, not applicable or because the information required is included in the consolidated financial statements or notes thereto.

(b) Exhibits

EXHIBIT INDEX

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
2.1	Form of Share Exchange Agreement dated January 23, 2014 by and among Thompson Designs, Inc., BioPharmX, Inc. and BioPharmX, Inc. Stockholders	8-K	000-54871	1/27/2014	2.1	
2.2*	Agreement and Plan of Merger and Reorganization, dated January 28, 2020, among BioPharmX, Timber and Merger Sub	8-K	001-37411	1/29/2020	2.1	
3.1	Certificate of Incorporation	S-8	333-201708	1/26/2015	4.01	
3.2	Amended and Restated Bylaws	8-K	001-37411	4/26/2019	3.2	
3.3	Certificate of Elimination of Certificate of Designations, Preference and Rights of Series A Preferred Stock	8-K	001-37411	3/18/2016	3.1	
3.4	Certificate of Designations of Preferences, Right and Limitations of Series A Convertible Preferred Stock	S-1/A	333-214116	11/18/2016	3.3	
3.5	Certificate of Elimination of Certificate of Designations, Preference and Rights of Series A Preferred Stock	8-K	001-37411	3/9/2018	3.1	
3.6	Certificate of Amendment to the Certificate of Incorporation	10-K	001-37411	4/21/2017	3.5	
3.7	Certificate of Amendment to the Certificate of Incorporation	8-K	001-37411	4/26/2019	3.1	
4.1	Specimen Stock Certificate	S-8	333-201708	1/26/2015	4.03	
4.2	Registration Rights Agreement, dated December 10, 2015 by and between the Company, Strategic Series—Franklin Biotechnology Discovery Fund and Franklin Templeton Investment Funds—Franklin Biotechnology Discovery Fund	8-K	001-37411	12/11/2015	4.1	
4.3	Purchase Agreement, dated December 9, 2015, by and between the Company, Strategic Series—Franklin Biotechnology Discovery Fund and Franklin Templeton Investment Funds—Franklin Biotechnology Discovery Fund	8-K	001-37411	12/11/2015	4.1	

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
4.4	Standstill Agreement, dated August 12, 2016, by and among the Company and Franklin Templeton Investment Funds – Franklin Biotehnology Diversity Fund, and Franklin Strategic Series – Franklin Biotechnology Discovery Fund	8-K	001-37411	8/18/2016	4.1	
4.5	Form of Common Stock Purchase Warrant (issued in connection with April 2016 stock offering)	8-K	011-37411	3/29/2016	4.1	
4.6	Form of Common Stock Purchase Warrant (issued in connection with Series A stock offering)	10-K	000-54871	3/31/2014	Exh. B to Exh. 10.11	
4.7	Form of Underwriters' Warrant Agreement (issued in connection with June 2015 stock offering)	S-1/A	333-203317	6/1/2015	4.4	
4.8	Assignment and Acceptance, dated September 8, 2016 by and among BioPharmX Corporation, RTW Master Funds, Ltd. and RTW Innovation Master Fund, Ltd.	S-1	333-214116	10/14/2016	4.5	
4.9	Form of Common Stock Warrant	8-K	001-37411	11/22/2016	4.1	
4.10	Form of Warrant	8-K	001-37411	4/26/2017	4.1	
4.11	Form of Representative's Warrant	S-1/A	333-221027	11/17/2017	4.18	
4.12	Form of Series A Common Warrant	S-1/A	333-221027	11/17/2017	4.19	
4.13	Form of Pre-funded Warrant	S-1/A	333-221027	11/17/2017	4.20	
4.14	Form of Series B Common Warrant	S-1/A	333-221027	11/20/2017	4.21	
4.15	Form of Warrant	10-Q	001-37411	12/7/2018	4.1	
4.16	Form of Warrant Exercise Agreement	8-K	001-37411	11/21/2018	10.1	
4.17	Bridge Warrant To Purchase Common Stock, dated January 28, 2020, made by BioPharmX in favor of Timber	8-K	001-37411	1/29/2020	4.1	
4.18	Description of Capital Stock					X
10.1#	Offer letter between Steven Bosacki and BioPharmX Corporation, effective as of July 16, 2019	8-K	001-37411	7/17/2019	10.1	

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
10.2	Lease Agreement entered into on October 30, 2018 between BioPharmX, Inc. and The Irvine Company LLC.	8-K	000-37411	10/31/2018	10.1	
10.3#	2014 Equity Incentive Plan	8-K	000-54871	1/27/2014	10.7	
10.4#	Form of 2014 Equity Incentive Plan award agreement	S-8	333-201708	1/26/2015	4.05	
10.5#	2016 Equity Incentive Plan (as amended)	S-8	333-227262	9/10/2018	99.1	
10.6#	Form of Stock Option Agreement	S-8	333-213627	9/14/2016	4.05	
10.7#	Form of Restricted Stock Unit Award Agreement	S-8	333-213627	9/14/2016	4.06	
10.8#	Form of Stock Bonus Award Agreement	S-8	333-213627	9/14/2016	4.07	
10.9#	Form of Restricted Stock Agreement	S-8	333-213627	9/14/2016	4.08	
10.10#	Form of Stock Appreciation Right Award Agreement	S-8	333-213627	9/14/2016	4.09	
10.11	Form of Indemnification Agreement	S-1/A	333-203317	5/14/2015	10.16	
10.12	Purchase Agreement, dated August 12, 2016, by and among BioPharmX Corporation and the purchasers listed on Schedule I thereto	8-K	001-37411	8/18/2016	10.1	
10.13	Letter Agreement, dated August 12, 2016, by and among BioPharmX Corporation, Franklin Strategic Series – Franklin Biotechnology Discovery Fund and Franklin Templeton Investment Funds – Franklin Biotechnology Discovery Fund	8-K	001-37411	8/18/2016	10.2	
10.14	Form of Common Stock Purchase Warrant	8-K	001-37411	9/27/2016	4.1	
10.15	Form of Securities Purchase Agreement	8-K	001-37411	9/27/2016	10.1	
10.16	Form of Amendment to Securities Purchase Agreement dated April 25, 2017 by and between the Registrant and certain purchasers	10-Q	001-37411	6/14/2017	10.1	
10.17	Form of Securities Purchase Agreement	8-K	001-37411	4/26/2017	10.1	
10.18	Form of Securities Purchase Agreement	8-K	001-37411	7/24/2017	10.1	
10.19	Form of Securities Purchase Agreement	8-K	001-37411	3/21/2019	10.1	

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
10.20	Placement Agency Agreement	8-K	001-37411	3/21/2019	10.2	
10.21#	Consulting Agreement between Kin Chan and BioPharmX, Inc., as amended	10-Q	001-37411	9/9/2019	10.1	
10.22	Bridge Loan Credit Agreement, dated January 28, 2020, between BioPharmX and Timber	8-K	001-37411	1/29/2020	10.1	
10.23	Note, dated January 28, 2020, made by BioPharmX in favor of Timber	8-K	001-37411	1/29/2020	10.2	
10.24	Form of Stockholder Support Agreement	8-K	001-37411	1/29/2020	10.3	
10.25	Form of Exchange Agreement, dated January 28, 2020, between BioPharmX and the Holders	8-K	001-37411	1/29/2020	10.4	
10.26	Sublease Agreement, dated as of February 14, 2020, by and between BioPharmX and Full Cycle Bioplastics, Inc.	8-K	001-37411	2/18/2020	10.1	
21.1	Subsidiaries of the Registrant					X
23.1	Consent of BPM LLP, independent registered public accounting firm					X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended					X
32.1	Certification of Chief Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350					X
32.2	Certification of Chief Accounting Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Schema Linkbase Document					X

Exhibit Number	Description of Document	Incorporated by Reference				Filed Herewith
		Form	File No.	Filing Date	Exhibit	
101.CAL	XBRL Taxonomy Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Labels Linkbase Document					X
101.PRE	XBRL Taxonomy Presentation Linkbase Document					X

* All schedules and exhibits to the agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

\# Management compensatory plan or arrangement

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in Campbell, California, on March 23, 2020.

BIOPHARMX CORPORATION

By: /s/ STEVEN M. BOSACKI
Name: Steven M. Bosacki
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ STEVEN M. BOSACKI Steven M. Bosacki	Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)	March 23, 2020
/s/ JOYCE GOTO Joyce Goto	Chief Accounting Officer (Principal Accounting Officer)	March 23, 2020
/s/ MICHAEL HUBBARD Michael Hubbard	Director	March 23, 2020
/s/ STEPHEN MORLOCK Stephen Morlock	Director	March 23, 2020
/s/ R. TODD PLOTT R. Todd Plott	Director	March 23, 2020
/s/ DAVID S. TIERNEY David S. Tierney	Director	March 23, 2020

BIOPHARMX CORPORATION
CONSOLIDATED FINANCIAL STATEMENTS
Years ended January 31, 2020 and 2019

CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
BioPharmX Corporation

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of BioPharmX Corporation and its subsidiary (the "Company") as of January 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the two years in the period ended January 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of January 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended January 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that BioPharmX Corporation and its subsidiary will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company's recurring losses from operations, available cash and accumulated deficit raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for leases in 2020 due to the adoption of the new lease standard.

Basis for Opinion

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

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

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

We have served as the Company's auditor since 2014.

/s/ BPM LLP

San Jose, California
March 23, 2020

BIOPHARMX CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	January 31, 2020	January 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 727	$ 3,069
Prepaid expenses and other	259	316
Total current assets	986	3,385
Property and equipment, net	93	148
Operating lease right-of-use asset, net	936	—
Other	115	121
Total assets	$ 2,130	$ 3,654
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 564	$ 1,363
Accrued expenses and other	942	934
Note payable, net of discount and issuance costs of $522	178	—
Total current liabilities	1,684	2,297
Long-term liabilities:		
Non-current operating lease liability	761	—
Other	24	59
Total liabilities	2,469	2,356
Commitments and contingencies (Note 5)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; none issued and outstanding as of January 31, 2020 and 2019	—	—
Common stock, $0.001 par value; 450,000,000 shares authorized; 15,227,891 and 8,732,612 shares issued and outstanding as of January 31, 2020 and 2019, respectively	15	9
Additional paid-in capital	87,867	79,823
Accumulated deficit	(88,221)	(78,534)
Total stockholders' equity (deficit)	(339)	1,298
Total liabilities and stockholders' equity (deficit)	$ 2,130	$ 3,654

Note: Share amounts as of January 31, 2019 have been adjusted to reflect the impact of a 1-for-25 reverse stock split effected in April 2019 as discussed in Note 1.

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

BIOPHARMX CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)

	Year ended January 31,	
	2020	2019
Revenues, net	$ —	$ 57
Cost of goods sold	—	83
Gross margin	—	(26)
Operating expenses:		
Research and development	4,690	9,079
Sales and marketing	714	2,157
General and administrative	4,282	5,244
Total operating expenses	9,686	16,480
Loss from operations	(9,686)	(16,506)
Change in fair value of warrant and stock liabilities	291	28
Other income (expense), net	(290)	(778)
Loss before provision for income taxes	(9,685)	(17,256)
Provision for income taxes	2	2
Net loss and comprehensive loss	$ (9,687)	$ (17,258)
Basic and diluted net loss per share	$ (0.75)	$ (2.23)
Shares used in computing basic and diluted net loss per share	12,921,000	7,727,000

Note: Share and per share amounts for the year ended January 31, 2019 have been adjusted to reflect the impact of a 1-for-25 reverse stock split effected in April 2019 as discussed in Note 1.

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

BIOPHARMX CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands, except share data)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	(Deficit)
Balance as of February 1, 2018	6,402,500	$ 6	$ 66,344	$ (61,278)	$ 5,072
Cumulative-effect adjustment from adoption of new accounting pronouncement	—	—	—	2	2
Issuance of common stock due to exercise of options	5,602	1	1	—	2
Issuance of common stock due to exercise of warrants	2,324,510	2	10,543	—	10,545
Stock-based compensation expense	—	—	2,061	—	2,061
Fair value of modification of warrants			874	—	874
Net loss	—	—	—	(17,258)	(17,258)
Balance as of January 31, 2019	8,732,612	9	79,823	(78,534)	1,298
Issuance of common stock due to exercise of options	1,667	—	4	—	4
Issuance of common stock, net of issuance costs of $0.6 million	6,493,612	6	7,194	—	7,200
Fair value of common stock liability reclassed to accrued expenses and other			(663)		(663)
Fair value of modification of warrants			308		308
Fair value of warrant issued with note payable			460		460
Stock-based compensation expense			741		741
Net loss				(9,687)	(9,687)
Balance as of January 31, 2020	15,227,891	$ 15	$ 87,867	$ (88,221)	$ (339)

Note: Share amounts as of January 31, 2019 and February 1, 2018 have been adjusted to reflect the impact of a 1-for-25 reverse stock split effected in April 2019 as discussed in Note 1.

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

BIOPHARMX CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year ended January 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (9,687)	$ (17,258)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	741	2,061
Fair value of modification of warrants	308	874
Depreciation expense	61	62
Amortization of note discount	13	—
Change in fair value of warrant and stock liabilities	(291)	(28)
Impairment loss on property and equipment	78	—
Other non-cash expense	—	3
Changes in assets and liabilities:		
Prepaid expenses and other assets	63	(32)
Accounts payable	(799)	(13)
Accrued expenses and other liabilities	(594)	(661)
Net cash used in operating activities	(10,107)	(14,992)
Cash flows from investing activities:		
Purchases of property and equipment	(30)	(43)
Net cash used in investing activities	(30)	(43)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	7,200	—
Proceeds from exercises of common stock warrants	—	10,546
Proceeds from exercises of stock options	4	1
Payments on financing lease obligation	(34)	(19)
Proceeds from issuance of note payable	625	—
Net cash provided by financing activities	7,795	10,528
Net decrease in cash and cash equivalents	(2,342)	(4,507)
Cash and cash equivalents as of beginning of year	3,069	7,576
Cash and cash equivalents as of end of year	$ 727	$ 3,069
Non-cash investing activities:		
Property and equipment acquired through finance lease	$ 54	$ 61
Non-cash financing activities:		
Issuance of warrants in connection with note payable	$ 460	$ —
Fair value of common stock liability reclassed to accrued expenses and other	$ 663	$ —
Supplemental disclosures:		
Income taxes paid	$ 2	$ 2

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

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

BioPharmX Corporation (the Company) is incorporated under the laws of the state of Delaware and originally incorporated on August 30, 2010 in Nevada under the name Thompson Designs, Inc. The Company has one wholly-owned subsidiary, BioPharmX, Inc., a Nevada corporation. The Company is a specialty pharmaceutical company focused on the dermatology market. Its focus is to develop products that treat dermatologic conditions that are not being adequately addressed or those where current therapies and approaches are suboptimal. Its strategy is to bring new products to market by identifying optimal delivery mechanisms and/or alternative applications for United States Food and Drug Adminstration (FDA) approved or well characterized active pharmaceutical ingredients (API). The Company aims to reduce the time, cost and risks typically associated with new product development by utilizing APIs with demonstrated safety profiles and, when applicable, taking advantage of the regulatory approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. Section 505(b)(2) permits an applicant for a new product, such as a new or improved formulation or a new use of an approved product, to rely in part on literature and/or the FDA's findings of safety and/or effectiveness for a similar previously-approved product. The Company's approach is to identify the limitations of current treatment options and work to develop novel products using our proprietary HyantX™ topical drug delivery system.

Since the Company's inception, substantially all of the Company's efforts have been devoted to developing its product candidates, including conducting preclinical and clinical trials, and providing general and administrative support for its operations. The Company has financed its operations primarily through the sale of equity and convertible notes.

On January 28, 2020, the Company entered into an Agreement and Plan of Merger and Reorganization (the Merger Agreement), with Timber Pharmaceuticals LLC, a Delaware limited liability company (Timber), and BITI Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of BioPharmX (Merger Sub). Subject to the terms and conditions contained in the Merger Agreement, including approval of the transactions contemplated therein by the Company's stockholders and by Timber's members, Merger Sub will be merged with and into Timber (the Merger), with Timber surviving the Merger as a wholly-owned subsidiary of BioPharmX. As a condition to the closing of the Merger, Timber has agreed to secure $20 million of financing for the combined company. The Merger is currently expected to be completed in the first quarter of fiscal year 2021.

Under the Merger Agreement, following the Merger, the Timber members, including the investors funding the $20 million investment, will own approximately 88.5% of the outstanding common stock of BioPharmX and the BioPharmX stockholders will own approximately 11.5% of the outstanding common stock, subject to certain adjustments as more particularly set forth in the Merger Agreement. The holder of a preferred membership interest in Timber of approximately $1.7 million will receive shares of newly designated preferred stock of BioPharmX which, other than conversion rights, shall have economic terms which are substantially the same as the economic terms of the preferred units of Timber currently outstanding. In addition, as part of the financing transaction, post-closing the Company will become obligated to issue warrants to purchase additional shares of common stock to the financing source, which may further dilute the holders of interests in the combined company. Upon completion of the Merger, the Company will change its name to Timber Pharmaceuticals, Inc. and the officers and directors of Timber will become the officers and directors of BioPharmX.

In connection with the Merger Agreement, the Company entered into a Credit Agreement with Timber, pursuant to which Timber has agreed to make a bridge loan to the Company (the Bridge Loan), in an aggregate amount of $2.25 million with $250,000 original issue discount. As of the date of this report, the Company has received $1,250,000 under the Bridge Loan and the remaining $1,000,000 is expected upon closing of the Merger. As of January 31, 2020, the Company had received $625,000 with $75,000 original issue discount.

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 of America (GAAP). The accompanying consolidated financial

statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of revenues and expenses recognized during the reported period. Actual results could differ from those estimates.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation. Accounts receivable have been included in prepaid expenses and other current assets in the consolidated balance sheets. The amount for the prior period has been reclassified to be consistent with the current year presentation and has no impact on previously reported total assets, total stockholders' equity (deficit) or net loss.

Reverse Stock Split

On April 25, 2019, the Company effected a 1-for-25 reverse stock split of its common stock. As a result of the reverse stock split, every twenty-five shares of the Company's pre-reverse split outstanding common stock was combined and reclassified into one share of common stock. Par value per share remained unchanged at $0.001 per share. Proportionate voting rights and other rights of common stockholders were not affected by the reverse stock split. No fractional shares were issued in connection with the reverse stock split; stockholders who would otherwise hold a fractional share of common stock received cash in an amount equal to the product obtained by multiplying (i) the closing price of the Company's common stock on the last trading day prior to the effective date of the reverse stock split, by (ii) the number of shares of the Company's common stock held by the stockholder that would otherwise have been exchanged for the fractional share interest. All stock options and warrants outstanding and common stock reserved for issuance under the Company's equity incentive plans immediately prior to the reverse stock split were adjusted by dividing the number of affected shares of common stock by 25 and, as applicable, multiplying the exercise price by 25, as a result of the reverse stock split. All of the share numbers, share prices and exercise prices have been adjusted on a retroactive basis as if such 1-for-25 reverse stock split occurred on the first day of the first period presented. Certain amounts in the notes to the financial statements may be slightly different than previously reported due to rounding of fractional shares as a result of the reverse stock split.

Fair Value of Financial Instruments

Carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, prepaid and other current assets, accounts payable, accrued expenses, notes payable and other liabilities approximate fair value due to their short maturities.

Property and Equipment, net

Property and equipment is stated at cost less accumulated depreciation. Depreciation is recognized using the straight-line method. Repairs and maintenance costs are expensed as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. When such an event occurs, management determines whether there has been an impairment by comparing the anticipated undiscounted future net cash flows to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. For the year ended January 31, 2020, the Company recorded an impairment loss of approximately $78,000 on property and equipment, net as result of the closure of the office and laboratory space in San Jose, California. The Company did not identify any impairment losses for the year ended January 31, 2019.

Warrant Liability

The Company accounts for certain of its warrants as derivative liabilities based on provisions relating to cash settlement options. The Company recorded a liability for the fair value of the warrants at the time of issuance, and at each reporting date the warrants are revalued to the instrument's fair value. The fair value of the warrants are estimated using the Black-Scholes pricing model. This liability is subject to fair value re-measurement until the warrants are exercised or expired, and any change in fair value is recognized as other income or expense in the consolidated statements of operations and comprehensive loss.

Common Stock Liability

In January 2020, the Company entered into an exchange agreement with certain warrant holders, in which approximately 2.3 million warrants to purchase shares of common stock will be exchanged for 850,000 shares of common stock. As of January 31, 2020, the common stock liability included the value of common stock to be issued in the exchange. The value of these shares was approximately $383,000 as of January 31, 2020 and is included in accrued expenses and other on the consolidated balance sheets.

Revenue Recognition

Revenue is related to the iodine dietary supplement, VI_2OLET, which was divested in November 2018. Effective February 1, 2018, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), using the modified retrospective transition method. The cumulative effect of the initial application of ASC 606 of approximately $2,000 was recognized as an adjustment to accumulated deficit and a decrease to deferred revenue as of February 1, 2018. The adoption of ASC 606 did not have a material impact on the Company's consolidated balance sheets, or statements of operations and comprehensive loss and cash flows for the year ended January 31, 2019.

Cost of Good Sold

Cost of goods sold is related to the iodine dietary supplement, VI_2OLET, which was divested in November 2018. Cost of good sold includes direct costs related to the sale of VI_2OLET, write-downs of excess and obsolete inventories and amortization of intangible assets.

Research and Development Expenses

Research and development expenses are expensed as incurred and consist primarily of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations, product development, consulting, materials, supplies, and facilities and other overhead allocations.

Income Taxes

The Company accounts for income taxes using the liability method whereby deferred tax asset and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are established to reduce deferred tax assets when management estimates, based on available objective evidence, that it is more-likely-than-not that the benefit will not be realized for the deferred tax assets.

The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. No interest expense was recognized during the periods presented.

Stock-Based Compensation

The Company recognizes stock-based compensation for equity awards on a straight-line basis over their vesting periods based on the grant date fair value. The Company estimates the fair value of stock options granted using the Black-Scholes pricing model. This model also requires subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

Comprehensive Loss

Comprehensive loss is the change in equity of an enterprise, except those resulting from stockholder transactions. Accordingly, comprehensive loss includes certain changes in equity that are excluded from net loss. For the years ended January 31, 2020 and 2019, the Company's comprehensive loss is equal to its net loss. There were no components of other comprehensive loss for any of the periods presented.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated based on the weighted average number of shares of the Company's common stock outstanding during the period. The weighted average shares outstanding for the years ended January 31, 2020 and 2019 exclude 7,733 shares of unvested restricted common stock. Diluted net loss per share attributable to common stockholders is calculated based on the weighted average number of shares of the Company's common stock outstanding and other dilutive securities outstanding during the period.

As of January 31, 2020 and 2019, approximately 8,421,000 and 7,308,000, potentially dilutive securities, respectively, were excluded from the computation of diluted loss per share because their effect on net loss per share would be anti-dilutive.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update (ASU) 2016-02, *Leases*, and in July 2018, ASU No. 2018-11, *Targeted Improvements*, which requires entities to recognize assets and liabilities for leases with lease terms greater than twelve months. The Company adopted this standard as of February 1, 2019, and the Company's leases are classified as operating leases and will continue to be classified as operating leases under the new accounting method. Adoption of the new standard resulted in the recording of an operating lease right-to-use asset of $1.2 million, which represents the present value of the remaining lease payments as of the date of adoption discounted using an incremental borrowing rate of 15%, and an operating lease liability of $1.3 million. The adoption did not have an impact on the Company's consolidated statements of operations and comprehensive loss or cash flows. See Note 10 for further information.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. Effective February 1, 2019, the Company adopted this standard, and the adoption did not have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which amended certain disclosure requirements over Level 1, Level 2 and Level 3 fair value measurements. The amendment is effective for annual and interim periods beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the impact of adopting this amendment, but does not anticipate it will have a material impact on its disclosures.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business, or no material effect is expected on the consolidated financial statements as a result of future adoption.

2. GOING CONCERN

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern and will continue to conduct operations for the foreseeable future and realize assets and discharge liabilities in the ordinary course of operations. As of January 31, 2020, the Company had cash and cash equivalents of $0.7 million and working capital deficit of $0.7 million.

The Company has incurred recurring losses and negative cash flows from operations since inception and has funded its operating losses through the sale of common stock, preferred stock, warrants to purchase common stock and

the issuance of notes. The Company incurred a net loss of $9.7 million and $17.3 million for the years ended January 31, 2020 and 2019, respectively, and had an accumulated deficit of $88.2 million as of January 31, 2020.

The Company has a limited operating history and its prospects are subject to risks, expenses and uncertainties frequently encountered by companies in its industry. The Company will require significant additional financing in the future. If the Merger is not consummated, it will likely be required to wind-down and dissolve as a company and would be required to pay all its debts and contractual obligations and set aside certain reserves for potential future claims. While the Company will also attempt to consummate a financing to allow it to continue as a going concern, based on its recent strategic process, it does not believe that it will be able to consummate a financing on reasonable terms sufficient to obtain such additional financial resources. These factors raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainties.

3. BALANCE SHEET DETAILS

	January 31,	
	2020	2019
	(in thousands)	
Property and equipment, net:		
Laboratory equipment	$ 214	$ 196
Computer and equipment	96	129
	310	325
Less: accumulated depreciation	(217)	(177)
	$ 93	$ 148

Depreciation expense for the years ended January 31, 2020 and 2019 was approximately $61,000 and $62,000, respectively. In the fourth quarter of fiscal year 2020, the Company recorded a write-down of approximately $78,000 for certain property and equipment as result of the closure of the office and laboratory space in San Jose, California.

	January 31,	
	2020	2019
	(in thousands)	
Accrued expenses and other current liabilities:		
Fair value of common stock liability	$ 383	$ —
Operating lease liability - current portion	260	—
Legal	138	45
Compensation	51	371
Research and development	49	399
Other	61	119
	$ 942	$ 934

4. FAIR VALUE MEASUREMENTS

The Company recognizes and discloses the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). Each level of input has different levels of subjectivity and difficulty involved in determining fair value.

- Level 1—Inputs used to measure fair value are unadjusted quoted prices that are available in active markets for the identical assets or liabilities as of the reporting date.

- Level 2— Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.

- Level 3— Unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of the assets or liabilities.

As of January 31, 2020, the Company recorded a $0.4 million common stock liability, which is classified as Level 1 within the fair value hierarchy.

The fair value of the warrant liability was classified as a Level 3 liability, as the Company uses unobservable inputs to value it. The table below presents the activity within Level 3 of the fair value hierarchy (in thousands):

	Warrant Liability
Balance as of February 1, 2018	$ 39
Change in fair value of warrants	(28)
Balance as of January 31, 2019	11
Change in fair value of warrants	(11)
Balance as of January 31, 2020	$ —

The warrant liability is included in accrued expenses and other current liabilities on the consolidated balance sheets.

5. COMMITMENTS AND CONTINGENCIES

Commitments

As part of the Merger process, the Company's board of directors approved a retention bonus plan totaling $120,000 to be paid to employees. Payments under the retention bonus plan are based on meeting certain objectives. As of January 31, 2020, none of these objectives had been met. In the event the remaining employees are terminated as part of the Merger, severance payment obligations of approximately $75,000 are expected to be paid.

See Note 10 for discussion regarding the Company's operating and financing lease commitments.

Legal Proceedings

The Company may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. In addition, the Company may receive letters alleging infringement of patents or other intellectual property rights. The Company is not a party to any material legal proceeding, nor is it aware of any pending or threatened litigation that the Company believes is likely to have a material adverse effect on its business, results of operations, cash flows or financial condition should such litigation be resolved unfavorably. These claims, even if not meritorious, could result in the expenditure of significant financial resources and diversion of management efforts.

Indemnification

The Company enters into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third-party with respect to the Company's technology. The term of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable because it involves claims that may be made against the Company in the future, but have not yet been made.

The Company has entered into indemnification agreements with its directors, officers and certain of its medical advisors that may require the Company to indemnify its directors, officers and such medical advisors against liabilities that may arise by reason of their status or service in these roles, other than liabilities arising from willful misconduct of the individual. The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. No liability associated with such indemnifications has been recorded to date.

6. STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock

In March 2019, the Company issued 1,745,800 shares of common stock at a price per share of $0.09 resulting in net proceeds of $3.6 million in a registered direct offering.

On May 16, 2019, the Company entered into a Capital on Demand™ Sales Agreement (Sales Agreement) with JonesTrading Institutional Services LLC, as agent (JonesTrading), pursuant to which the Company may offer and sell, from time to time through JonesTrading, shares of the Company's common stock, par value $0.001 per share (the Common Stock), having an aggregate offering price of up to $8.5 million. As of January 31, 2020, the Company had sold an aggregate of 4,747,812 shares of Common Stock pursuant to the terms of such Sales Agreement for aggregate net proceeds of $3.6 million.

Warrants

A summary of warrants outstanding as of January 31, 2020 is as follows:

	Total	Price per Share	Expiration Date
Warrants related to June 2015 financing	4,363	$ 68.75	June 2020
Warrants related to April 2016 financing	70,581	$ 30.00	April 2021
Warrants related to September 2016 financing (1)(4)	51,466	$ 18.75	September 2021 to March 2022
Warrants related to November 2016 financing	1,216,230	$ 8.75	November 2024
Warrants related to November 2016 financing	35,818	$10.938	November 2022
Warrants related to November 2016 financing	7,926	$ 8.25	November 2022
Warrants related to April 2017 financing	32,053	$ 22.50	October 2022
Warrants related to October 2017 financing	153,848	$ 7.50	October 2022
Warrants related to November 2017 financing (4)	2,277,412	$ 5.00	November 2022
Warrants related to November 2018 financing (2)(4)	1,066,670	$ 4.10	May/June 2021
Warrants related to note payable (3)	2,255,336	$ 0.01	July 2022
	7,171,703		

(1) In connection with the sale of common stock in September 2016, warrants to purchase 51,466 shares of common stock were issued at an exercise price of $18.75 per share. These warrants included a cash settlement option requiring the Company to record a liability for the fair value of the warrants at the time of issuance and at each reporting period with any change in the fair value reported as other income or expense. At the time of issuance, approximately $566,000 was recorded as a warrant liability. To value the warrant liability, the Company used the Black-Scholes pricing model with the following assumptions: risk-free interest rate of 1.1%, contractual term of 5 years, expected volatility of 95.8% and a dividend rate of 0%. As of January 31, 2020, there was no fair value related to these warrants.

(2) On November 20, 2018, the Company entered into agreements with holders of certain of its warrants to purchase common stock with an exercise price per share of $6.25 originally issued on November 24, 2017 (Existing Warrants), whereby the holders and the Company agreed that the holders would cash exercise 1,066,670 shares of common stock underlying such Existing Warrants at a reduced price of $3.50, and the Company would issue new warrants to such holders to purchase up to an aggregate of 1,066,670 shares of common stock (New Warrants). The New Warrants are exercisable after the six-month anniversary of their issuance and terminate on the 30-month anniversary following their issuance. The New Warrants have an exercise price per share of $4.10. The Company recorded a charge for the incremental fair value of approximately $874,000 in the other expense line item in the consolidated statements of operations and comprehensive loss. The fair value of the warrants exercised was computed as of the date of exercise using the following assumptions: risk-free interest rate of 2.51%, contractual term of 6 months, expected volatility of 78.4% and a dividend rate of 0%.

(3) On January 28, 2020, in connection with the Bridge Loan, the Company issued a warrant to purchase common stock. See Note 11 for discussion regarding the accounting treatment of this warrant.

(4) On January 28, 2020, the Company entered into an exchange agreement with certain warrant holders, in which approximately 2.3 million warrants to purchase shares of common stock will be exchanged for 850,000 shares of common stock. These certain warrants contained language that would have allowed the warrant holders to convert the warrants into shares of common stock at the time of the consummation of the Merger based on a Black-Scholes value of these certain warrants. On January 28, 2020, the Company revalued the warrants for the shares of common stock to be issued resulting in a charge to other income and expense of approximately $308,000 due to the incremental value between the warrants and exchanged shares of common stock. To value the warrants for approximately 2.3 million shares of common stock to be exchanged, the Company used the Black-Scholes pricing model with the following assumptions: risk-free interest rate of 1.47%, remaining contractual term of warrant, average expected volatility of 106% and a dividend rate of 0%. On January 31, 2020, the Company revalued the common stock liability and due to the lower closing stock price of the Company's common stock, the common stock liability was reduced by approximately $280,000. As of January 31, 2020, the common stock liability was approximately $383,000. The exchange was effected on February 3, 2020.

Equity Incentive Plan

On July 5, 2016, the Company adopted the 2016 Equity Incentive Plan ("2016 Plan"), which permits the Company to grant equity awards to directors, officers, employees and consultants. In connection with the adoption of the 2016 Plan, the Company ceased to grant equity awards under its 2014 Equity Incentive Plan ("2014 Plan"), which was adopted on January 23, 2014. All grants and awards under the 2014 Plan, including stock options previously issued under BioPharmX, Inc.'s 2011 Equity Incentive Plan that were substituted with stock options issued under the 2014 Plan, remain in effect in accordance with their terms. Stock options generally vest in one to four years and expire ten years from the date of grant. In March 2017, the 2016 Plan was amended and the shares reserved for issuance was increased by 800,000 shares to a total of 960,000 shares. In August 2018, the 2016 Plan was amended and the shares reserved for issuance were increased by 2,000,000 shares to a total of 2,960,000 shares of common stock. The 2014 Plan and 2016 Plan are referred to collectively as the "Plans."

The following table summarizes the Company's stock option activities under the Plans:

	Available for Grant	Shares	Weighted Average Exercise Prices	Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Balance as of February 1, 2018	75,396	988,452	$ 10.30	9.17	$ 304
Shares authorized for issuance	2,000,000	—			
Granted	(417,660)	417,660	$ 5.23		
Exercised	—	(11,129)	$ 2.53		
Canceled and returned to the 2016 Plan	449,839	(449,839)	$ 7.52		
Canceled subsequent to termination of the 2014 Plan	—	(27,199)	$ 25.33		
Balance as of January 31, 2019	2,107,575	917,945	$ 9.02	7.92	$ 23
Granted	(893,820)	893,820	$ 0.84		
Exercised	—	(1,667)	$ 2.50		
Canceled and returned to the 2016 Plan	524,231	(524,231)	$ 5.26		
Canceled subsequent to termination of the 2014 Plan	—	(51,375)	$ 25.43		
Balance as of January 31, 2020	1,737,986	1,234,492	$ 4.02	8.37	$ 1
Vested and exercisable		508,154	$ 6.43	7.30	$ —
Vested and expected to vest		1,069,509	$ 4.27	8.25	$ 1

Inducement Grants

The Company has also awarded inducement option grants to purchase common stock to new employees outside of the 2016 Plan as permitted under Section 711(a) of the NYSE American Company Guide. Such options vest at the rate of 25% of the shares on the first anniversary of the commencement of such employee's employment with the

Company, and then one forty-eighth (1/48) of the shares monthly thereafter subject to such employee's continued service. The following table summarizes the Company's inducement grant stock option activities:

	Shares	Weighted Average Exercise Prices	Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Balance as of February 1, 2018	26,400	$ 35.90	7.72	$ —
Granted	16,000	$ 4.75		
Canceled	(11,400)	$ 41.22		
Balance as of January 31, 2019	31,000	$ 17.86	6.6	$ —
Canceled	(24,333)	$ 21.46		
Balance as of January 31, 2020	6,667	$ 4.75	—	$ —
Vested and exercisable	6,667	$ 4.75	—	$ —
Vested and expected to vest	6,667	$ 4.75	—	$ —

The following table summarizes significant ranges of outstanding and exercisable options as of January 31, 2020:

	Options Outstanding			Options Vested and Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Prices	Number Vested and Exercisable	Weighted Average Exercise Prices
$0.44 - $0.84	666,764	9.21	$ 0.79	175,072	$ 0.81
$0.85 - $4.00	95,094	6.59	$ 2.54	82,206	$ 2.54
$4.01 - $10.50	388,625	8.06	$ 5.62	172,205	$ 5.84
$10.51- $18.50	69,893	4.70	$ 16.78	64,555	$ 16.69
$18.51 - $28.50	6,400	6.30	$ 20.19	6,400	$ 20.19
$28.51 - $75.00	14,383	4.33	$ 51.17	14,383	$ 51.17
	1,241,159	8.33	$ 4.02	514,821	$ 6.41

The total intrinsic value of stock options exercised during the year ended January 31, 2020 was di minimus. The total intrinsic value of stock options exercised during the year ended January 31, 2019 was approximately $26,000. During the year ended January 31, 2019, certain stock options were exercised pursuant to net exercise provisions, resulting in 138,157 shares of common stock retired in exchange of the total exercise price. The weighted average grant date fair values of the stock options granted during the years ended January 31, 2020 and 2019 was $0.44 and $3.00, respectively.

7. STOCK-BASED COMPENSATION

The following table summarizes the stock-based compensation expenses included in the statements of operations and comprehensive loss (in thousands):

	Year ended January 31,	
	2020	2019
Research and development	$ 238	$ 654
Sales and marketing	57	414
General and administrative	446	993
Total	$ 741	$ 2,061

The Company estimates the fair value of stock options granted using the Black-Scholes pricing model. This model also requires subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values. For employee grants, the fair value is amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period. As of January 31, 2020, total compensation costs related to unvested, but not yet recognized, stock-based awards was $0.8 million, net of estimated forfeitures. This

cost will be amortized on a straight-line basis over a weighted average remaining period of 2.29 years and will be adjusted for subsequent changes in estimated forfeitures.

Valuation Assumptions

The following assumptions were used to calculate the estimated fair value of awards granted:

	Year ended January 31,	
	2020	2019
Expected volatility	68.3% - 70.8%	78.8% - 91.0%
Expected term in years	4.0	4.0
Risk-free interest rate	1.88% - 2.51%	2.43% - 2.98%
Expected dividend yield	—	—

Expected Term

The expected term represents the period that the Company's stock-based awards are expected to be outstanding. For awards granted subject only to service vesting requirements, the Company utilizes the simplified method for estimating the expected term of the stock-based award, instead of historical exercise data.

Expected Volatility

The Company uses the historical volatility of the price of shares of common stock of selected public companies, including the Company's stock price, in the biotechnology sector due to its limited trading history.

Risk-Free Interest Rate

The Company bases the risk-free interest rate used in the Black-Scholes pricing model upon the implied yield curve currently available on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term used as the assumption in the model.

Expected Dividend

The Company has never paid dividends on its common shares and currently does not intend to do so and, accordingly, the dividend yield percentage is zero for all periods.

8. EMPLOYEE BENEFIT PLAN

The Company sponsors a 401(k) defined contribution plan for its employees. This plan provides for tax-deferred salary deductions for all full-time employees. Employee contributions are voluntary. Employees may contribute up to 100% of their annual compensation to this plan, as limited by an annual maximum amount as determined by the Internal Revenue Service. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. The Company has made no contributions to the plan for the years ended January 31, 2020 and 2019.

9. INCOME TAXES

No federal income taxes were paid during the years ended January 31, 2020 and 2019 due to the Company's net losses. The provision of income taxes consist of state minimum income taxes.

As of January 31, 2020, the Company had available federal net operating loss ("NOL") carryforwards of $77.4 million which will begin to expire in 2030 and California state NOL carryforwards of $70.8 million which will begin to expire in 2033. As of January 31, 2020 and 2019, the net deferred tax assets of approximately $24.0 million and $21.1 million, respectively, generated primarily by NOL carryforwards, have been fully reserved due to the uncertainty surrounding the realization of such benefits. The net valuation allowance increased by $2.6 million and $4.9 million during the years ended January 31, 2020 and 2019, respectively.

Current tax laws impose substantial restrictions on the utilization of NOL and credit carryforwards in the event of an "ownership change," as defined by the Internal Revenue Code. If there should be an ownership change, the Company's ability to utilize its carryforwards could be limited. Although the Company has not conducted a formal NOL carryforward analysis, as a result of the registered direct offering in March 2019, pending ownership change that will result from the Merger and prior financing transactions, the NOL and credit carryforwards amounts of $21.1 million and $1.2 million, respectively, may be materially limited.

Significant components of the Company's deferred tax assets were as follows (in thousands):

	January 31, 2020	January 31, 2019
Deferred tax assets:		
Net operating loss carryforwards	$ 21,101	$ 18,769
Stock-based compensation expense	1,251	1,163
Tax credit carryforwards	1,203	1,022
Operating lease liability	285	—
Other	121	160
Total deferred tax assets	23,961	21,114
Less: valuation allowance	(23,700)	(21,114)
Net deferred tax assets	261	—
Deferred tax liability:		
Operating lease right-of-use asset	(261)	—
Total deferred tax liability	(261)	—
Net deferred tax assets	$ —	$ —

A reconciliation of income taxes provided at the federal statutory rate (21% in 2019) to the actual income tax provision was as follows (in thousands):

	Year ended January 31, 2020	Year ended January 31, 2019
Income tax benefit computed at U.S. statutory rate	$ (2,034)	$ (3,624)
State income tax (net of federal benefit)	(645)	(1,478)
Change in valuation allowance	2,586	4,857
Research and development credits	(86)	(158)
Other	181	405
Provision for income taxes	$ 2	$ 2

As of January 31, 2020 and 2019, the Company did not have any material unrecognized tax benefits. The tax years from 2010 to 2020 remain open for examination by the federal and state authorities.

10. LEASES

On October 30, 2018, the Company signed a lease for 11,793 square feet of office and laboratory space in San Jose, California. The lease commenced in December 2018 and will terminate in December 2023. The lease requires payment of maintenance, utilities, taxes, insurance and other operating expenses associated with the leased space. On February 14, 2020, the Company entered into a sublease agreement for its 11,793 square feet office and laboratory space in San Jose, California. The sublease covers the term of the master lease. Payments from the sublease are expected to materially offset the costs for lease and related operating expenses.

Effective February 1, 2019, the Company adopted ASC 842, *Leases*, which resulted in the recording of an operating lease right-to-use asset of $1.2 million and corresponding short-term and long-term liabilities of $0.3 million and $1.0 million, respectively. The right-to-use asset and corresponding liability for the facility lease have been measured at the present value of the future minimum lease payments using a 15% rate which was considered the Company's incremental borrowing rate at the time of adoption. The Company has an option to extend the lease for an additional 36 months, but, as the renewal is not reasonably certain, the Company has not included this renewal option in its accounting for the lease. Lease expense is recognized on a straight-line basis over the lease term and was approximately $370,000 and $586,000 for the years ended January 31, 2020 and 2019, respectively. Cash paid for

amounts included in the measurement of the operating lease liability for the year ended January 31, 2020 was approximately $338,000 and was included in net cash used in operating activities in the statement of cash flows.

The future minimum payments under the Company's operating lease as of January 31, 2020 are as follows (in thousands):

	Operating Lease
Fiscal years ending January 31,	
2021	$ 372
2022	382
2023	392
2024	334
Total future minimum lease payments	1,480
Less: present value discount	(459)
Present value of operating lease liabilities	$ 1,021

The Company recorded financing leases related to laboratory equipment purchased in March 2018 and May 2019. The leased asset values were approximately $61,000 and $54,000, respectively, and the corresponding current and long-term liabilities were recorded in accrued expenses and other current liabilities and other long-term liabilities, respectively. Total future payments representing interest until the termination of leases were approximately $6,000 as of January 31, 2020.

The following table summarizes the Company's financing lease commitment as of January 31, 2020 (in thousands):

	Financing Leases
Fiscal years ending January 31,	
2021	$ 43
2022	22
2023	5
Total	$ 70

11. NOTE PAYABLE

In connection with the Merger Agreement, the Company and Timber entered into a Credit Agreement, dated as of January 28, 2020, pursuant to which Timber has agreed to make a Bridge Loan to the Company in an aggregate amount of $2.25 million. Pursuant to the terms of the Credit Agreement, Timber will make the Bridge Loan to the Company in three tranches: (i) a $625,000 initial advance ($700,000 less $75,000 of original issue discount (OID)) made on the closing date of the Credit Agreement; (ii) $625,000 ($700,000 less $75,000 of OID) 30 days thereafter; and (iii) $1,000,000 ($1,100,000 less $100,000 of OID) upon the closing of the Merger. The Bridge Loan bears interest at a rate of 12% per annum and is repayable on June 15, 2020, subject to extension for an additional month under certain circumstances, the termination (without completion) of the Merger or upon a liquidity event, as defined in the Credit Agreement. The Company has also issued to Timber a promissory note setting forth the terms of repayment (the Note).

The Bridge Loan is collaterized by a lien on all of the Company's assets. Further, in connection with the Bridge Loan, on January 28, 2020 the Company issued to Timber a warrant to purchase approximately 2.3 million shares of common stock at an exercise price of $0.01 (the Bridge Warrant). The Bridge Warrant was exercised on a cashless basis on February 10, 2020 for a total amount of 2,200,328 shares of the Company's common stock.

As of January 31, 2020, the Company received the initial tranche of $625,000 and recorded the note payable based on the relative fair values of the Bridge Warrant and Note. To value the Bridge Warrrant, the Company used the Black-Scholes pricing model with the following assumptions: risk-free interest rate of 1.44%, contractual term of 30 months, expected volatility of 70.3% and a dividend rate of 0%. The fair value of the Bridge Warrant was approximately $460,000 and was recorded as additional paid-in capital and a discount on the Bridge Loan. The debt discount and issuance costs of $522,000 as of January 31, 2020 will be amortized through June 15, 2020. The Company recorded

$13,000 in note discount in interest expense for the year ended January 31, 2020. On February 28, 2020, the Company received the second tranche payment of $625,000.

12. SUBSEQUENT EVENTS

Except as noted in Note 11, there are no subsequent events that have occurred since January 31, 2020 that required recognition or disclosure in the financial statements.

Exhibit 4.18

DESCRIPTION OF CAPITAL STOCK

The following description of BioPharmX Corporation capital stock is only a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to the applicable provisions of Delaware law, our amended and restated certificate of incorporation and amended and restated by-laws, which are subject to future amendment in accordance with the provisions thereof.

General

BioPharmX is authorized to issue 460,000,000 shares of all classes of capital stock, of which 450,000,000 shares is common stock, $0.001 par value per share, and 10,000,000 shares are undesignated preferred stock, $0.001 par value per share. As of February 29, 2020, BioPharmX had 18,278,219 outstanding shares of common stock and no outstanding shares of preferred stock.

Common Stock

Dividend Rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of BioPharmX common stock are entitled to receive dividends out of funds legally available if the board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

Voting Rights

Holders of BioPharmX common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. BioPharmX has not provided for cumulative voting for any matter in its certificate of incorporation. Accordingly, pursuant to the certificate of incorporation, holders of a majority of the shares of our common stock will be able to elect all of BioPharmX's directors.

No Preemptive or Similar Rights

BioPharmX common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon liquidation, dissolution or winding-up, the assets legally available for distribution to BioPharmX stockholders would be distributable ratably among the holders of the common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Options

As of February 29, 2020, BioPharmX had outstanding options to purchase an aggregate of 1,206,286 shares of common stock, with a weighted-average exercise price of $3.98 per share.

Warrants

As of February 29, 2020, BioPharmX had outstanding warrants to purchase an aggregate 2,644,708 shares of common stock, with a weighted-average exercise price of $7.98 per share.

Registration Rights

In connection with BioPharmX's August 2016 private placement offering and issuance of convertible notes, the holders of common stock underlying such convertible notes (the ''2016 Shares'') were entitled to rights with respect to the registration of such 2016 Shares under the Exchange Act. In connection with BioPharmX's September 2016 public offering of warrants, or the 2016 Warrants, to Roth Capital Partners and certain designees of Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC, the holders of common stock underlying such warrants were entitled to rights with respect to the registration of such shares under the Securities Act. In January 2017, BioPharmX issued additional warrants, or the 2017 Warrants, to Rodman & Renshaw pursuant to a letter agreement. In September 2016, a shelf registration statement with respect to the 2016 Shares was filed and declared effective by the SEC. In August 2017, a shelf registration statement with respect to the 2017 Warrants was filed and declared effective by the SEC.

We are required to use commercially reasonable efforts to cause such registration statements to remain continuously effective for a period that will terminate upon the earlier of (i) the date on which all such common stock has been disposed of pursuant to such registration statement, or (ii) the date on which all such common stock is sold in a transaction that is exempt from registration pursuant to Rule 144 or a transaction in which such selling stockholders' rights under the registration rights agreement are not assigned; provided, however, that such requirement shall not apply during any period in which all the shares of common stock then outstanding and held by selling stockholders may be sold under Rule 144 without restriction, including volume limitations or manner of sale restrictions.

Preferred Stock

As of February 29, 2020, no shares of BioPharmX preferred stock are issued and outstanding and no such shares were subject to outstanding options or other rights to purchase or acquire. However, shares of preferred stock may be issued in one or more series from time to time by our board of directors, and the board of directors is expressly authorized to fix by resolution or resolutions the designations and the powers, preferences and rights, and the qualifications, limitations and restrictions thereof, of the shares of each series of preferred stock. Subject to the determination of our board of directors, any shares of our preferred stock that may be issued in the future would generally have preferences over our common stock with respect to the payment of dividends and the distribution of assets in the event of our liquidation, dissolution or winding up.

Anti-Takeover Effect of Unissued Shares of Capital Stock

Common Stock. Shares of BioPharmX's authorized and unissued common stock are available for future issuance without additional stockholder approval. While these additional shares are not designed to deter or prevent a change of control, under some circumstances BioPharmX could use the additional shares to create voting impediments or to frustrate persons seeking to effect a takeover or otherwise gain control by, for example, issuing those shares in private placements to purchasers who might side with our board of directors in opposing a hostile takeover bid.

Preferred Stock. BioPharmX's certificate of incorporation grants our board of directors the authority, without any further vote or action by its stockholders, to issue preferred stock in one or more series and to fix the number of shares constituting any such series and the preferences, limitations and relative rights, including dividend rights, dividend rate, voting rights, terms of redemption, redemption price or prices, conversion rights and liquidation preferences of the shares constituting any series. The existence of authorized but unissued preferred stock could reduce BioPharmX's attractiveness as a target for an unsolicited takeover bid since it could, for example, issue shares of preferred stock to parties who might oppose such a takeover bid or shares that contain terms the potential acquirer may find unattractive. This may have the effect of delaying or preventing a change in control, may discourage bids for the common stock at a premium over the market price of the common stock, and may adversely affect the market price

of, and the voting and other rights of the holders of, common stock.

Anti-Takeover Provisions

The provisions of Delaware law, BioPharmX's certificate of incorporation and its bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. BioPharmX believes that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire BioPharmX because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

BioPharmX is subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless:

• Prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

• The interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding, for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

• At or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. BioPharmX expects the existence of this provision to have an anti-takeover effect with respect to transactions its board of directors does not approve in advance. BioPharmX also anticipates that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Certificate of Incorporation and Bylaw Provisions

BioPharmX's certificate of incorporation and its bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of BioPharmX, including the following:

• Board of Directors Vacancies. The bylaws authorize the board of directors to fill vacant directorships, including newly created seats. This provision could prevent a stockholder from gaining control of our board of directors by filling vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

• Special Meetings of Stockholders. The bylaws provide that special meetings of our stockholders may be called only by a majority of the board of directors or an officer instructed by the directors to call a special

meeting, thus prohibiting a stockholder from calling a special meeting. This provision might delay the ability of stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

• No Cumulative Voting. The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. BioPharmX's certificate of incorporation and bylaws do not provide for cumulative voting.

• Amendment of Bylaw Provisions. Any of the above provisions in our bylaws may be amended or repealed by unanimous written consent of BioPharmX's board of directors.

• Issuance of Undesignated Preferred Stock. BioPharmX's board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock enables the board of directors to render more difficult or to discourage an attempt to obtain control by merger, tender offer, proxy contest or other means.

Transfer Agent and Registrar

The transfer agent and registrar for BioPharmX common stock is Computershare Trust Company, N.A.

Listing

BioPharmX common stock is listed on the NYSE American market under the trading symbol ‘‘BPMX’’.

EXHIBIT 21.1

SUBSIDIARY OF BIOPHARMX CORPORATION

As of January 31, 2020, BioPharmx Corporation’s sole subsidiary was BioPharmx, Inc., a Nevada corporation.

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-227262, 333-217419, 333-213627 and 333-201708), the Registration Statements on Form S-3 (Nos. 333-229459, 333-220012, 333-213635 and 333-212015) and the Registration Statements on Form S-1 (Nos. 333-221686 and 333-221027) of BioPharmX Corporation of our report (which contains an explanatory paragraph relating to BioPharmX Corporation's ability to continue as a going concern as described in Note 2 to the consolidated financial statements) dated March 23, 2020 relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K.

/s/ BPM LLP

San Jose, California
March 23, 2020

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Steven M. Bosacki, certify that:

(1) I have reviewed this annual report on Form 10-K of BioPharmX Corporation;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 23, 2020

/s/ STEVEN M. BOSACKI
Steven M. Bosacki
Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF ACCOUNTING OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Joyce Goto, certify that:

(1) I have reviewed this annual report on Form 10-K of BioPharmX Corporation;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 23, 2020

/s/ JOYCE GOTO
Joyce Goto
Chief Accounting Officer (Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of BioPharmX Corporation (the "Company") on Form 10-K for the fiscal year ended January 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of the officer's knowledge:

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

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

Date: March 23, 2020

/s/ STEVEN M. BOSACKI
Steven M. Bosacki
Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of BioPharmX Corporation (the "Company") on Form 10-K for the fiscal year ended January 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of the officer's knowledge:

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

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

Date: March 23, 2020

/s/ JOYCE GOTO
Joyce Goto
Chief Accounting Officer (Principal Accounting Officer)