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, 2018

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 (State or Other Jurisdiction of Incorporation or Organization)	**59-3843182** (I.R.S. Employer Identification No.)
1505 Adams Drive, Suite D, Menlo Park, California (Address of principal executive offices)	**94025** (Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: **Common Stock, $0.001 Par Value.**

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 ☐ (Do not check if a smaller reporting company)	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, 2017, 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 $17.5 million, based upon the closing price of the Registrant’s common stock as reported on the NYSE American on July 31, 2017. 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 April 15, 2018, there were outstanding 191,518,731 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.

PART I

ITEM 1. BUSINESS

Overview

We are a specialty pharmaceutical company focused on utilizing our proprietary drug delivery technologies to develop and commercialize novel prescription and over-the-counter, or OTC, products that address large markets in dermatology and women's health. Our objective is to develop products that treat health or age-related conditions that: (1) are not presently being addressed or treated or (2) are currently treated with drug therapies or drug delivery approaches that are sub-optimal. Our strategy is designed to bring new products to market by identifying optimal delivery mechanisms and/or alternative applications for United States Food and Drug Administration, or FDA, approved active pharmaceutical ingredients, or APIs, and biological materials, while, in appropriate circumstances, reducing the time, cost and risk typically associated with new product development by repurposing drugs 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 the FDA's findings of safety and/or effectiveness for a similar previously-approved product. We believe these approaches may reduce drug development risk and could reduce the time and resources we spend during development. Our current platform technologies include innovative delivery mechanisms for antibiotics, biologic materials and molecular iodine (I_2).

The product candidates in our current portfolio target significant market opportunities and include three clinical-stage product candidates, BPX01, a topical antibiotic for the treatment of inflammatory lesions of acne based on a unique formulation of minocycline, BPX04, a topical antibiotic for the treatment of inflammatory lesions of rosacea, and BPX03, a molecular iodine (I_2) tablet for the treatment of benign breast pain associated with fibrocystic breast condition, or FBC, and cyclic mastalgia, as well as one development-stage product candidate, BPX02, an injectable product utilizing biological materials for aesthetic dermatology applications. We presented comprehensive BPX01 Phase 2b clinical data for the treatment of acne and received positive FDA feedback regarding our BPX01 Phase 3 clinical study plans. We are considering strategic partnership alternatives to fund our Phase 3 clinical program in this indication. We expect to begin a Phase 3 clinical trial, should we raise the necessary additional capital or enter into a strategic partnership to fund the trial. A Phase 2 study for BPX04 in rosacea is currently in the planning stage, with study initiation expected in the second quarter of this year. We have initiated a pre-Phase 2 feasibility study of BPX04 for the treatment of rosacea. We conducted an interim analysis of 19 subjects who have completed a 12-week pre-Phase 2 feasibility study in the BPX04 for rosacea study, which suggested good tolerability and promising efficacy of BPX04 for this indication. The molecular iodine project includes a marketed OTC dietary supplement version, or VI_2OLET, for the alleviation of symptoms of FBC, as well as an investigational prescription drug version for the treatment of moderate to severe, periodic breast pain associated with FBC and cyclic mastalgia.

Products, Delivery Systems and Product Candidates

We have developed our product portfolio using our proprietary drug delivery technologies, including innovative delivery mechanisms for antibiotics, biologic materials and molecular iodine. We currently have one marketed product, our VI_2OLET iodine dietary supplement, three clinical-stage product candidates, BPX01, BPX03 and BPX04, and one development-stage product candidate, BPX02. The following table presents a summary of our marketed product and product candidates:

Dermatology Pipeline

Product/ Product Candidates	Delivery Mechanism	Platform Technology/Application	Product Type	Stage of Development
BPX01	Topical	Topical antibiotic for treatment of inflammatory lesions of acne	Prescription Drug	Phase 2b Completed
BPX04	Topical	Topical antibiotic for treatment of inflammatory lesions of rosacea	Prescription Drug	Pre-Phase 2 Feasibility in Progress
BPX02	Injectable	Injectable product for aesthetic dermatology applications	Injectable Product	Internal Development

Women's Health Pipeline

Product/ Product Candidates	Delivery Mechanism	Platform Technology/Application	Product Type	Stage of Development
VI_2OLET	Oral	Molecular iodine (I_2) for the alleviation of symptoms of FBC	OTC Dietary Supplement	Currently Marketed
BPX03	Oral	Molecular iodine (I_2) for treatment of moderate to severe periodic breast pain associated with FBC and cyclic mastalgia	Prescription Drug	Pre-Phase 3 Clinical Trial Completed

Iodine Delivery System

VI_2OLET Iodine

VI_2OLET, is an OTC molecular iodine dietary supplement that addresses cyclic breast discomfort and is clinically demonstrated to selectively deliver iodine to breast tissue, which helps to alleviate the symptoms associated with FBC, including tenderness, aches and swelling. Women who suffer from menstrual-related breast discomfort are recommended to take one to two tablets per day on an empty stomach for at least 60 days to realize initial symptom relief. Our molecular iodine formula is delivered to breast tissue and is intended to reduce the fibrocystic changes that results in breast discomfort caused by such fibrocystic changes. We commercially launched VI_2OLET in December 2014 in online stores and have expanded into approximately 7,000 retail pharmacies, specialty chain outlet and grocery chain outlet stores throughout the United States. We recently entered into an agreement to distribute VI_2OLET in Mexico and Central America. We are exploring commercial growth opportunities for the expansion of VI_2OLET revenue, which may include strategic partnerships and/or sublicense with women's and/or consumer health companies. To date, we have generated a de minimus amount of revenue from product sales.

BPX03 and Iodine Research

BPX03 is a prescription drug version of our molecular iodine tablet for the treatment of moderate to severe, periodic breast pain associated with FBC and cyclic mastalgia. We in-licensed this prescription iodine drug candidate, which was previously under development by the licensors, and refer to both the prior sponsor's investigational drug and our investigational drug as BPX03. We completed a clinical trial (using VI_2OLET) under Health Canada and institutional review board oversight to provide additional insight on how to design a Phase 3 safety and efficacy clinical trial. We are currently seeking a partner(s) to pursue any necessary clinical development and additional regulatory approvals for the product using the learnings from that clinical trial.

Hydrophilic Topical Delivery System

Our topical delivery system uses an anhydrous hydrophilic gel formulation that allows for the stabilization, solubilization and rapid absorption of API into the skin rather than remaining on the surface, a common problem with oil-based ointments and suspensions. The first expression of this delivery system's capabilities is demonstrated with minocycline. The nature of the platform design makes it suitable for multiple APIs.

BPX01 - Acne

BPX01 is a hydrophilic 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 acne with a proprietary anhydrous hydrophilic topical delivery system specifically designed to localize the delivery of the drug while minimizing systemic exposure and the resultant side effects. This proprietary topical delivery system allows a lower dosage of drug by improving the bioavailability with enhanced and 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 swelling 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 BPX01 for the treatment of acne. The multi-center study evaluated two concentrations of BPX01 (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 (59% reduction vs. 44%, respectively, at week 12, p=0.03).

This Phase 2b study also measured improvement on a five-point investigator's global assessment (IGA) scale. 25% of subjects treated with BPX01 2% showed at least a two-grade improvement and an IGA of clear (0) or almost clear (1), a secondary efficacy endpoint in the study, compared to 17.6% for vehicle (p=0.54). Although the study was not powered to measure statistical significance for improvement in IGA, a clear numerical trend was observed in the BPX01 2% arm compared to vehicle. IGA was included as a secondary endpoint in our Phase 2b study as this information supports dose selection and 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 or almost clear for drug compared to vehicle as well as being powered to show a reduction in inflammatory lesion counts.

Researchers also found that no subjects experienced serious treatment-related adverse side effects. Random 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 – Rosacea

BPX04 is a hydrophilic topical antibiotic gel with fully soluble minocycline for the treatment of inflammatory lesions of rosacea. We initiated a 30 subject, single center, open-label pre-Phase 2 feasibility study of BPX04 to assess the safety and efficacy of BPX04 at 0% (vehicle), 1% and 2% minocycline for the treatment of rosacea. An interim analysis of the 19 subjects who have completed the 12-week feasibility study suggests good tolerability and promising efficacy of BPX04 for this indication. Lesion counts were reduced in the 1% and 2% minocycline treatment arms by a mean of 90% at 12 weeks compared to baseline and 89% of the subjects demonstrated an improvement in IGA scores to clear (0) or almost clear (1) compared to their baseline scores of moderate (3) or severe (4) with no serious drug-related adverse events. We expect to complete this 30 subject study in the second half of this year, and also expect to initiate a Phase 2 study in the second quarter of this year.

In addition to BPX01 and BPX04, early data suggests that our anhydrous hydrophilic topical delivery system may also be utilized with other APIs, including other antibiotics, retinoids and combinations.

Injectable Delivery System

Our injectable delivery system allows for prolonged release of biologics, as well as, small and mid-sized molecules.

BPX02

We are developing BPX02, an injectable product utilizing biologic materials for aesthetic dermatology applications. This research stage product candidate is currently under internal development. We will likely pursue

regulatory approval for this product via a biologics license application, or BLA. As such, BPX02 would still be subject to regulation under the FDC Act, except the section of the FDC Act that governs the approval of NDAs. Instead, BPX02 would be subject to the marketing and exclusivity provisions of the Public Health Service Act for approval of BLAs. However, the application process and requirements for approval of BLAs are very similar to those for NDAs.

Encapsulation Delivery System

Our encapsulation delivery system is able to isolate the hydrophilic agent from the boundary layer between the hydrophlic and hydrophobic phases of emulsion. The emulsion of the hydrophilic delivery vehicle makes it feel smooth to the touch. We believe this new platform technology is an innovative way of delivering combinations of ingredients to cosmeceutical products for new market innovations. We have three patents issued in the United States.

Target Markets

We believe that the industry dynamics in the area of dermatology represent significant opportunities for innovative new products to emerge as solutions for unmet needs in multi-billion dollar therapeutic categories. In particular, we believe that the dermatology market is a large specialty market with significant global patient demand, and that our focus on this market coupled with our proprietary platform technologies should enable us to develop and commercialize attractive products within this category.

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 acne.

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, acne accounted for approximately $3.8 billion in sales in 2015 ($2.2 billion topical, $1.6 billion oral). Due to extensive consolidation in the dermatology market over the past decade, 64% (or $2.4 billion) of the $3.8 billion in 2015 acne sales was generated by three major pharmaceutical companies: Allergan Plc. (Allergan), Almirall S.A. (Almirall) and Valeant Pharmaceuticals International, Inc. (Valeant).

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. The biology of rosacea remains unclear, however 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 approximately $700 million in 2015 according to Torreya Insights, with more than 80% of this revenue being generated by a limited number of brands. The leading manufacturers are Galderma S.A. (Galderma) and Bayer Healthcare (Bayer).

Strategy and Competitive Strengths

We believe that the strength of our novel drug delivery system technologies 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 corporate strategy and competitive advantages include the following:

- Patented drug delivery platform technologies;
- Known actives, which potentially allow for shorter time to market, lower cost and lower risk for product introductions due to the Section 505(b)(2) regulatory pathway, and the ability to offer multiple actives using the same delivery platform; and

- An experienced medical advisory board providing thought leadership and clinical guidance within the dermatology communities.

Technology and Intellectual Property

Overview

Our success depends in large part upon our ability to obtain and maintain proprietary protection for our 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 and will perform in the future, particularly for each of the products in our development pipeline and each of the products we market. We rely on a combination of patent, copyright, trademark and trade secret laws in the United States and other countries to obtain and maintain our intellectual property. We protect our intellectual property by, among other methods, filing for patent applications on inventions that are important to the development and conduct of our business with the United States Patent and Trademark Office, or USPTO, and its foreign counterparts.

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 eight U.S. provisional and utility patent applications pending related to our topical compositions for dermatological conditions and novel iodine-based technologies for women's health. We have four issued patents. Three of these patents address a microparticle drug delivery technology. One of these relates to BPX. We also have 21 pending international patent applications, 18 of which relate to BPX01, two of which address a microparticle drug delivery technology and one of which addresses an iodine technology. These international patent applications resulted from development of our unique formulations of minocycline and iodine and were filed according to local national laws or 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.

On March 1, 2013, we entered into a collaboration and license agreement with Iogen LLC, or Iogen, to license certain patents, formulations, and know-how relating to molecular iodine formulations. Our license is an exclusive, royalty-bearing license agreement with the right to enforce and sublicense. These licensed patents have expiration dates of 2029.

Trademarks

We have applied for trademark protection for several trademarks in the United States. The USPTO has registered several of our trademarks: "VIOLET," "VI_2OLET," "BIOPHARMX," "GET IT OFF YOUR CHEST," "THE GIRLS HAVE SOMETHING TO SAY," "SMARTER DRUG DELIVERY," and the VI_2OLET logo.

We have also applied for trademark protection in three markets outside the United States. In the European Union, we have registered trademarks for "BIOPHARMX" and "VI_2OLET." In China, we have a registered trademark for "BIOPHARMX" and the VI_2OLET logo. In Mexico, we have applied for trademark protection for the VI_2OLET logo.

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 consultants specializing

in our various product development areas. Research and development expenses for the years ended January 31, 2018 and 2017 were approximately $9.1 million and $10.2 million, respectively.

As a Silicon Valley-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 will enable 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 commercial distribution. We have no plans to establish in-house manufacturing capabilities for large-scale production at this time.

We have a master service agreement in place with DPT Laboratories, Ltd., or DPT, to carry out the manufacturing of clinical supplies. DPT provides drug development services including formulation development, clinical and commercial manufacturing satisfying the FDA's current good manufacturing practices, or cGMPs, analytical methods development and stability testing. Additionally, we have a master service agreement with Dow Development Laboratories, LLC, to conduct formulation and analytical development and stability studies, among other services. We are evaluating a second vendor to carry out the manufacturing and testing of our clinical and commercial supplies.

We have in place a commercial supply agreement with UPM Pharmaceuticals, or UPM, a division of Gregory Pharmaceuticals Holdings, Inc. to manufacture and package our VI_2OLET dietary supplement tablets. UPM provides high-quality drug development services including formulation development, clinical and commercial manufacturing satisfying the cGMPs, analytical methods development, and stability testing. Our manufacturing agreement for VI_2OLET with UPM requires a minimum annual purchase of approximately $269,000 of iodine dietary supplement tablets. This agreement expires in 2020, and we are required to purchase the minimum annual amount regardless of market demand. The remaining minimum purchase commitment is $0.9 million through 2020. We have not recorded an obligation for the minimum purchase amount remaining since we have not assessed that the obligation will not be serviced in the normal course of business based on our market demand analysis. In the future, we may conclude that an obligation is required as the result of our market demand analysis and record such obligation. The recording of such obligation would negatively impact the results of our operations in the period recorded.

Marketing, Sales & Distribution

Our team has experience in the commercialization of prescription products. We have experience in branding and launching products in the United States, Europe and Asia. Our team understands channel strategies that include branded generic and licensed product strategies.

While BPX01 continues through clinical development, we have commenced our go-to-market strategic planning for the product 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 pricing strategy. While our commercialization plan for BPX01 will largely depend on the nature of the strategic partnership we enter into, following the successful enrollment of our Phase 3 clinical trial we will evaluate our needs and take steps toward building our sales, marketing and distribution infrastructure in anticipation of commercial launch. Although we continue to evaluate commercializing BPX01 directly in the United States, we may choose to pursue strategic partnerships to launch the product outside of the United States, pending the appropriate regulatory approvals in each country, in order to take advantage of well-established sales, marketing and distribution networks established by leading pharmaceutical companies in such countries. The same process will be considered as BPX04 advances through clinical trials.

VI_2OLET is sold through online stores, drug stores, grocery stores and specialty retail chains throughout the United States. We recently entered into an agreement to distribute VI_2OLET in Mexico and Central America, and the distributor is responsible for all marketing, sales and distribution activities. We are evaluating expanded or alternative channels for distributing the product by way of partnerships and/or sublicensing with women's health and/or consumer health companies. Should we sublicense VI_2OLET, the sublicensee would be responsible for all marketing, sales and distribution.

Customers

Potential customers for our products and product candidates include pharmaceutical companies, physician's practices, including obstetricians and gynecologists, dermatologists and general practitioners, and retail customers via retail sales channels and/or pharmacy outlets.

Competition

Acne

While the acne market has a number of competitive products, BPX01 is being developed to combine the most successful oral antibiotic drug (minocycline) for the treatment of moderate-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: Allergan, Almirall, Dr. Reddy's Laboratories Ltd., Galderma, Impax Laboratories, Lupin Pharmaceuticals, Inc., Mayne Pharma Group Limited (Mayne Pharma), Mylan N.V. (Mylan), Pfizer, Inc., Sun Pharmaceutical Industries, Ltd. (Sun Pharma), Teva Pharmaceutical Industries, Ltd. (Teva) and Valeant. 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 Allergan, Bayer, Galderma, Mayne Pharma, Mylan, Sun Pharma, Teva and Valeant. In addition to prescription acne therapies discussed above, there are numerous 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, by Ellipse, and a device, elos, by Syneron, that treats a combination of IPL and radiofrequency technologies. Combination drug-device treatments such as photodynamic therapy, or PDT, with Blu-U by Dusa Pharmaceuticals, has been used off-label for treating acne, while the Blu-U light source without its PDT drug has been indicated for acne treatment.

While there is no FDA-approved topical minocycline solution for acne (or otherwise), we are aware of one competitive product currently in Phase 3 clinical trials.

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. BPX04 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 acids and alpha-A agonists. Current treatments are marketed by companies such as Allergan, Bayer, Galderma, Mylan, Perrigo Company Plc., Sun Pharma and Valeant. In addition to prescription rosacea therapies, devices such as intense pulsed light and the pulsed dye laser can be helpful in treating telangiectasia and vascular erythema to some extent and also may reduce associated symptoms.

While there is no FDA-approved topical minocycline solution for rosacea (or otherwise), we are aware of two competitive products currently in Phase 2 and Phase 3 clinical trials.

FBC and Cyclic Mastalgia

In the area of women's health, many companies sell supplements containing iodide salts for the purpose of addressing hypothyroidism as iodine replacement therapy. We believe our competitive advantage is our solid dose proprietary formulation that delivers molecular iodine in a stable manner, allowing the consumer to ingest orally and specifically to address breast symptoms. Addressing an underserved condition, we believe that VI_2OLET is an innovative product that provides a new treatment option for millions of women.

While there is no single, established standard of care for FBC and cyclic mastalgia, physicians have typically recommended a range of treatments from changes in diet, abstaining from caffeine and methylxanthine and nutritional supplements, such as gamma-linolenic acid, for mild symptoms to prescription analgesics and hormone-based therapies, such as contraceptives, Danocrine, Tamoxifen and Bromocriptine, for more severe symptoms.

Some limitations of competitive approaches to addressing FBC and/or cyclic mastalgia include serious and sometimes dangerous side effects caused by prescription drugs and the temporary nature of relief provided by analgesics. Because optimal non-hormonal solutions do not exist, many women with this condition choose to live with chronic pain.

Government Regulation

In the United States, foods (including dietary supplements), drugs (including biological products), 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.

Regulation of Dietary Supplements

The formulation, manufacturing, packaging, labeling, advertising, distribution and sale (hereafter, “sale” or “sold” may be used to signify all of these activities) of dietary supplements are subject to regulation by one or more federal agencies, primarily the FDA and the Federal Trade Commission, or the FTC, and to a lesser extent the Consumer Product Safety Commission, or the CPSC.

All facilities that manufacture, process, package, or store food for human consumption must register with the FDA as a food facility. A dietary supplement is considered a food under the FDC Act and FDA regulations. Food facility registrations must be updated biennially. The FDA annually schedules inspections at a number of registered food facilities to determine whether the inspected facilities are in compliance with food-related FDA regulations.

The FDA, under the FDC Act, regulates the formulation, manufacturing, packaging, labeling, distribution and sale of food, including dietary supplements. The FTC regulates the advertising of these products. The National Advertising Division of the Council of Better Business Bureaus, or NAD, oversees an industry sponsored, self-regulatory system that permits competitors to resolve disputes over advertising claims. The NAD has no enforcement authority of its own, but may refer matters that appear to violate the Federal Trade Commission Act, or FTC Act, or the FDC Act to the FTC or the FDA for further action, as appropriate.

Federal agencies, primarily the FDA and the FTC, have a variety of procedures and enforcement remedies available to them, including initiating investigations, issuing warning letters and cease and desist orders, requiring corrective labeling or advertising, requiring consumer redress (for example, requiring that a company offer to repurchase products previously sold to consumers), seeking injunctive relief or product seizures, imposing civil penalties or commencing criminal prosecution. In addition, certain state agencies have similar authority.

The Dietary Supplement Health and Education Act, or DSHEA, was enacted in 1994 and amended the FDC Act. DSHEA establishes a statutory class of dietary supplements, which includes vitamins, minerals, herbs, amino acids and other dietary ingredients for human use to supplement the diet. Among other things, DSHEA prevents the FDA from regulating dietary ingredients in dietary supplements as food additives. Dietary ingredients marketed in the United States before October 15, 1994 may be marketed without the submission of a new dietary ingredient, or NDI, premarket notification, or NDIN, to the FDA. Dietary ingredients not marketed in the United States before October 15, 1994 may require the submission, at least 75 days before marketing, of an NDIN containing information establishing that the ingredient is reasonably expected to be safe for its intended use. Among other things, DSHEA prevents the FDA from regulating dietary ingredients in dietary supplements as food additives.

The FDA issued an updated draft guidance document in August 2016 that clarifies when the FDA believes a dietary ingredient is an NDI, when a manufacturer or distributor must submit an NDIN to the FDA, the evidence necessary to document the safety of an NDI and the methods for establishing the identity of an NDI. The FDA’s interpretation of what constitutes an NDI subject to an NDIN is extremely broad and seems to imply that virtually every

new dietary supplement requires an NDIN. In addition, the FDA may begin to take enforcement actions consistent with the interpretations in the draft guidance before issuing a final version.

The FDA's cGMPs regulations for dietary supplements apply to manufacturers and holders of finished dietary supplement products, including dietary supplements manufactured outside the United States that are imported for sale into the United States. Among other things, the FDA's cGMPs: (a) require identity testing on all incoming dietary ingredients, (b) call for a scientifically valid system for ensuring finished products meet all specifications, (c) include requirements related to process controls, including statistical sampling of finished batches for testing and requirements for written procedures and (d) require extensive recordkeeping.

Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act, the FDA requires, among other things, that companies that manufacture or distribute nonprescription drugs or dietary supplements report serious adverse events associated with their products to the FDA and institute recordkeeping requirements for all adverse events. Based on serious adverse event (or other) information, the FDA may take actions against dietary supplements or dietary ingredients that in its determination present a significant or unreasonable risk of illness or injury, which could make it illegal to sell those products. FDA publishes quarterly reports on serious adverse events it receives.

The FDA Food Safety Modernization Act, or FSMA, enacted January 4, 2011, amended the FDC Act to significantly enhance the FDA's authority over various aspects of food regulation, including dietary supplements. Under FSMA, the FDA may use the mandatory recall authority when the FDA determines there is a reasonable probability that a food (including a dietary supplement) is adulterated or misbranded and that the use of, or exposure to, the food will cause serious adverse health consequences or death to humans or animals. Also under FSMA, the FDA has expanded access to records; the authority to suspend food facility registrations and require high risk imported food to be accompanied by a certification; stronger authority to administratively detain food; the authority to refuse admission of an imported food if it is from a foreign establishment to which a United States inspector is refusing entry for an inspection; and the authority to require that importers verify that the foods they import meet domestic standards.

The new FSMA requirements, as well as the FDA enforcement of the NDI draft guidance, can result in the detention and refusal of admission of imported products, the injunction of manufacturing of any dietary ingredients or dietary supplements until the FDA determines that such ingredients or products are in compliance, and the potential imposition of fees for re-inspection of noncompliant facilities.

The FDC Act, as amended by DSHEA, permits statements of nutritional support often referred to as "structure/function claims" to be included in labeling for dietary supplements without FDA pre-market approval. FDA regulation requires that FDA be notified of those statements within 30 days of marketing. Among other things, the statements may describe the role of a dietary ingredient intended to affect the structure or function of the body or characterize the documented mechanism of action by which a dietary ingredient maintains such structure or function, but may not expressly or implicitly represent that a dietary supplement will diagnose, cure, mitigate, treat, or prevent a disease. A company that uses a statement of nutritional support in labeling must possess information substantiating that the statement is truthful and not misleading. If the FDA determines that a particular statement of nutritional support is an unacceptable drug claim or an unauthorized version of a health claim, or if the FDA determines that a particular claim is not adequately supported by existing information or is otherwise false or misleading, the claim could not be used and any product bearing the claim could be subject to regulatory action.

The FTC and the FDA have pursued a coordinated effort to challenge the scientific substantiation for dietary supplement claims. Their efforts to date have focused on manufacturers and marketers as well as media outlets and have resulted in a significant number of investigations and enforcement actions, some resulting in civil penalties under the FTC Act of several million dollars. If the FTC and the FDA continue to focus on health related claims, including structure/function claims for dietary supplements, dietary supplements could be the subject of FTC and/or FDA inquiries, inquiries from NAD, and states attorneys general, as well as private class action lawsuits.

All states regulate foods and drugs under laws that generally parallel federal statutes. These products are also subject to state consumer health and safety regulations, such as California Safe Drinking Water and Toxic Enforcement Act of 1986, or Proposition 65. Violation of Proposition 65 may result in substantial monetary penalties.

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 or BLAs, 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 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 or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, 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 very

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 or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or the BLA 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 and BLAs is additionally subject to a substantial application user fee, currently approximately $2,421,000 for fiscal year 2018. Under an approved NDA or BLA, the applicant is subject to an annual program fee, currently approximately $304,000 per prescription product for fiscal year 2018. Beginning in fiscal year 2018, this annual program fee replaces the annual product and establishment fees. These fees typically increase annually.

The FDA has 60 days from its receipt of an NDA or BLA 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 or BLA submission is filed, the FDA reviews the NDA or BLA 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 or BLAs. 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. For biologics, priority review is further limited to drugs intended to treat a serious or life-threatening disease relative to the currently approved products. 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 or BLA, 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 or BLA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA 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 or BLA, 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 or BLA 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 or BLA supplement before the change can be implemented. An NDA or BLA 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 or BLA supplements as it does in reviewing NDAs or BLAs.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs, BLAs or supplements to NDAs or BLAs 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 or BLA 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. For BLAs, the BPCA provides a six-month extension for non-patent exclusivity 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.

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 U.S. Patent and Trademark Office 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 or BLA 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 or BLA. 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.

Biologics

Biological products used for the prevention, treatment or cure of a disease or condition of a human being are subject to regulation under the FDC Act, except the section of the FDC Act which governs the approval of NDAs. Biological products are approved for marketing under provisions of the Public Health Service Act, or PHSA, via a BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer’s tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful

differences between the biological product and the reference product in terms of safety, purity and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical study, absent a waiver by the Secretary. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. To date, a handful of biosimilar products and no interchangeable products have been approved under the BPCIA. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, particularly with respect to interchangeability, are still being evaluated by the FDA.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) eighteen months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) eighteen months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

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, the Company 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 current 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 European Medicines Agency, or EMA, the new Clinical Trials Regulation will become 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:
  - acquired immune deficiency syndrome;
  - 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 in case 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 withdrawal of the U.K. from the E.U. will take effect either

on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the U.K. provides a notice of withdrawal pursuant to the E.U. Treaty. 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 the Company 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, particularly prescription drugs, 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 to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; 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, thus 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; 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, 2018, we had 27 employees, all of whom were full time, including 13 employees in research and development and one employee located outside of 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 are subject to the information requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Therefore, 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 Public Reference Room of the SEC at 100 F Street, NE, Washington, D.C. 20549 or by calling the SEC at 1-800-SEC-0330, by sending an electronic message to the SEC at publicinfo@sec.gov or by sending a fax to the SEC at 1-202-777-1027. In addition, the SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

ITEM 1A. RISK FACTORS

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations, future prospects and the trading price of our common stock. Our business could be harmed by any of these risks. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes.

Risks Related to our Financial Position and Need for Additional Capital

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 upon which you can evaluate our business and prospects. 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, 2018, we had an accumulated deficit of $61.3 million and incurred net losses available to common stockholders of $16.6 million and $18.5 million for the years ended January 31, 2018 and 2017, respectively. We expect to continue to incur net losses for the foreseeable future as we advance our current and potential additional product candidates through clinical development, seek regulatory approval for them and prepare for and proceed to commercialization. Because of the risks and uncertainties associated with developing and commercializing our product candidates, we are unable to predict when we may introduce additional products commercially, the extent of any future losses or when we will become profitable, if at all. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We will need substantial additional funding. If we are unable to raise capital when needed, we may need to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates.

We incurred a net loss available to common stockholders of $16.6 million and $18.5 million for the years ended January 31, 2018 and 2017, respectively. As of January 31, 2018, we had cash and cash equivalents of $7.6 million and significant liabilities and obligations. In April 2017, we raised net proceeds of $4.4 million through the sale of common stock and warrants to purchase common stock through a registered direct offering. In July 2017, we raised net proceeds of $1.9 million through the sale of common stock through an additional registered direct offering. In November 2017, we raised net proceeds of $9.7 million through the sale of common stock and warrants to purchase common stock in a public offering. We presented comprehensive BPX01 Phase 2b clinical data for the treatment of acne and received positive FDA feedback regarding our BPX01 Phase 3 clinical study plans. We will seek to enter into a strategic partnership to fund the continued clinical development of BPX01 for the treatment of inflammatory lesions of acne, and there is no assurance we will be successful in entering into such strategic partnership in a timely manner or on acceptable terms. If we are unable to enter into a strategic partnership to fund the continued development of BPX01, we may be unable to complete clinical development of BPX01. We recently initiated a pre-Phase 2 feasibility study to assess the safety and efficacy of BPX04 for the treatment of rosacea. Our existing resources may not be adequate to permit us to complete clinical development of BPX04 or to fund our operations over the longer term. We will need to secure

significant additional resources to complete such development and to support our continued operations and are exploring a variety of funding alternatives, including both dilutive and non-dilutive financing options and strategic partnerships. Absent additional funding, we believe that our cash will be sufficient to fund our operations only for a relatively short period of time.

The development of our business will require substantial additional capital in the future to conduct research and develop our other product candidates, as well as 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. Our clinical studies for our product candidates may not be successful or may not generate results that are compelling enough to support future funding or strategic partnerships. Delays in obtaining funding could adversely affect our ability to develop and commercially introduce products and cause us to be unable to comply with our obligations. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, 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 in us.

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 our product candidates, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for development of products. In particular, a part of our strategy is to seek to enter into enter into a strategic collaboration to fund the continued development of BPX01. 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 BPX01 because third parties may not view BPX01 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 its development program or one or more of our other development programs, delay its potential development schedule or reduce the scope of research activities, or increase our expenditures and undertake discovery or preclinical development activities at our own expense. If we fail to enter into collaborations and do 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 our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- 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 of ours is involved in a business combination, the collaborator might deemphasize or terminate the development of any of our product candidates. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our 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.

Our independent registered public accounting firm has expressed 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, 2018 and 2017 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 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, 2018 and 2017 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 us.

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 and July 2017, 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 BPX01, BPX04 and BPX03.

Our portfolio of product candidates includes three clinical-stage drug product candidates, BPX01, a topical antibiotic for the treatment of acne, BPX04, a topical antibiotic for the treatment of rosacea, and BPX03, a molecular iodine tablet for the treatment of moderate to severe, periodic breast pain associated with fibrocystic breast condition, or FBC, and cyclic mastalgia. The success of our business, including our ability to finance our 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 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 collaboration or partnership to fund the continued development of BPX01;
- 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 good manufacturing practices, or 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 we 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 recognize more than a de minimis amount of revenue from sales of VI$_2$OLET 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. While VI$_2$OLET went on the market in December 2014 in online stores and in drug, grocery and retail chains throughout the United States, we have only recognized a de minimis amount of revenue from sales to date. 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. Our manufacturing agreement for VI2OLET with UPM, requires a minimum annual purchase of approximately $269,000 of iodine supplement tablets. This agreement expires in 2020, and we are required to purchase the minimum annual amount regardless of market demand. The remaining minimum purchase commitment is $0.9 million through 2020. We have not recorded an obligation for the minimum purchase amount remaining, since we have determined that a loss on this obligation is not probable based on our market demand analysis. In the future, we may conclude that an obligation is required as the result of our market demand analysis and record such obligation. The recording of such obligation would negatively impact the results of our operations in the period recorded.

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 the dietary supplement or 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 products or product candidates.

We rely on one third-party manufacturer for our product and product candidate manufacturing needs. Currently, we engage with DPT, a subsidiary of Mylan N.V., as our clinical contract manufacturer for BPX01 and BPX04. We have identified a qualified second vendor to carry out the manufacturing and testing of our clinical and commercial supplies and are working on vendor assessments. UPM manufactures iodine supplement tablets for VI2OLET.

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 either manufacturer 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 with DPT is a short-term agreement. Our commercial supply agreement with UPM is through 2020. 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 agreement, 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 of our products. A disruption in supply of raw material would be disruptive to our inventory supply.

We and the manufacturers of our products rely on suppliers of raw materials 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 an NDA or BLA 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 its 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 we 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 BPX01, 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 BPX01 2% arm demonstrated a clear numerical trend compared to vehicle, the BPX01 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 BPX01 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 us 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 we anticipated.

In the case of our topical product candidates, BPX01 and BPX04, 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 BPX01 and BPX04 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 BPX01 and BPX04 may be difficult to establish.

In the case of our research-phase product candidate, BPX02, because it is a biological product, it may be difficult to characterize the clinically active component(s) by testing methods available in the laboratory, and some of the components of the finished product may be unknown. Therefore, to ensure product consistency, quality, and purity, we must ensure the manufacturing process remains substantially the same over time. The systems used to produce biological products can be sensitive to very minor changes in the manufacturing process. Small process differences can significantly affect the nature of the finished biological product, and more importantly, the way it functions in the body. We will have to tightly control the source and nature of starting materials, and consistently employ hundreds of process

controls that assure predictable manufacturing outcomes. Our ability to ensure that the manufacturing process remains stable over time may be difficult to establish. In addition, for a novel biological product, there may be uncertainties regarding the size and design of the clinical trials to establish safety, efficacy, purity or potency, and there are no assurances that data generated in any clinical trials we might conduct will be acceptable to the FDA or foreign regulatory bodies to support marketing approval.

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. For example, the FDA has expressed concern over the risk-benefit profile of BPX03 and indicated to the prior sponsor that, due to potential thyroid toxicity and teratogenic effects, BPX03 should be used primarily for the management of severe breast pain that does not respond adequately to treatment with OTC analgesics and other conservative measures and that the proportion of responders in the treatment group should be at least two-fold greater than the proportion of responders in the placebo group;
- 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. For example, the FDA has stated that two adequate and well-controlled Phase 3 clinical trials would be required for submission of an NDA for BPX03 and that it would require a safety database of at least 1,500 patients exposed to the proposed formulation;
- 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 of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with whom we contract; or
- change its 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.

Our only commercialized product, VI2OLET, is subject to regulation by U.S. and international regulatory authorities.

Our first and only commercialized product, launched in December 2014, is our women's health dietary supplement distributed under the brand name "VI2OLET" iodine. We recently entered into an agreement to distribute VI2OLET in Mexico and Central America. The processing, formulation, safety, manufacturing, packaging, labeling, advertising and distribution of VI2OLET is subject to federal laws and regulation by one or more federal agencies, including the FDA, the FTC, the CPSC, the United States Department of Agriculture and the Environmental Protection Agency. These activities are also regulated by various state, local and international laws and agencies of the states and localities in which our products are or may be sold including non-governmental entities such as NAD. The NAD oversees an industry sponsored, self-regulatory system that permits competitors to resolve disputes over advertising claims. The NAD has no enforcement authority of its own, but may refer matters that appear to violate the FTC Act or the FDC Act to the FTC or the FDA for further action, as appropriate.

All facilities that manufacture, process, package, or store food for human consumption must register with the FDA as a food facility. A dietary supplement is considered a food substance under the FDC Act and FDA regulations. We are registered with the FDA as a food facility and we renew our registration every two years. The FDA annually schedules inspections at a number of registered food facilities to determine whether the inspected facilities are in compliance with food-related FDA regulations. While the FDA has not yet inspected or scheduled an upcoming inspection at our facility, the FDA could choose to conduct such an inspection at any time. If the FDA observed any evidence of violation or noncompliance during an inspection, we would be required to respond adequately to the observations, typically by developing and executing appropriate corrective and preventive actions. Any inspection of our facility could entail inspection of our third-party manufacturer, UPM, which is responsible for production of VI_2OLET under the terms of our commercial supply agreement. Any observations related to the third-party manufacturer as a result of an FDA inspection may require the third-party manufacturer to implement significant corrective or preventive measures related to its production process, which could impact our commercial supply of VI_2OLET. Any uncorrected violation or noncompliance could lead to further regulatory action by the FDA.

Although dietary supplements may generally be marketed without FDA premarket review and approval, the FDA regulates, among other things, the manufacturing, labeling, and claims for such products. We cannot represent, expressly or implicitly, that a dietary supplement will diagnose, cure, mitigate, treat or prevent a disease, or the FDA will consider such products as drugs. The FDA could determine that a particular statement of nutritional support is an unacceptable drug claim, is not substantiated, is an unauthorized version of a health claim or that the product is otherwise misbranded and/or adulterated. In addition, claims on labeling and promotional materials for our dietary supplement products could be challenged by the FDA, the FTC, self-regulatory bodies such as the NAD, competitors or consumers. For example, we make certain claims relating to VI2OLET that may be alleged to be non-compliant with FDA or FTC regulations. If the FDA or the FTC determines that particular claims relating to our products are violative, we could be subject to regulatory action, such as investigations, warning or untitled letters and cease and desist orders, corrective labeling or advertising orders, consumer redress (for example, offers to repurchase products previously sold to consumers), injunctive relief or product seizures, civil penalties or criminal prosecution. Enforcement action by the FDA or the FTC, or class action lawsuits stemming from an enforcement action or allegation, could materially and adversely affect our business, financial position and operating results and could cause the market value of our common stock to decline.

In addition, the FDA regulates the manufacturing and safety of dietary supplements. The manufacturing of dietary supplements is subject to dietary supplement cGMPs. We are also required to submit to the FDA serious adverse reports, and the FDA may determine that a particular dietary supplement or ingredient presents an unacceptable health risk based on the required submission of this information or other information about the product. During development of BPX03 by the prior sponsor, the FDA expressed concern about the potential for teratogenicity of molecular iodine in a use similar to that of VI2OLET. If the FDA determines that our dietary supplement is unsafe or adulterated or otherwise in violation of FDA requirements, the FDA could take regulatory action as described above.

From time to time, the above-mentioned agencies and lawmakers consider the implementation of more stringent laws and regulations of dietary supplements and other products. These developments could require reformulation of some products to meet new standards, recalls or discontinuance of some products unsusceptible to reformulation, additional recordkeeping requirements, increased documentation of the properties of some products, additional or different labeling, additional scientific substantiation or other new requirements. Any of these developments could increase our costs significantly. In addition, regulators' evolving interpretation of existing laws could have similar

effects. For example, in August 2016, the FDA issued updated draft guidance explaining its interpretation of the requirement for the notification to the FDA of certain new dietary ingredients. Although FDA guidance is not mandatory, and companies are free to use an alternative approach if the approach satisfies the requirements of applicable laws and regulations, FDA guidance is a strong indication of the FDA's current thinking on the topic discussed in the guidance, including its position on enforcement. At this time, it is difficult to determine whether the draft guidance, if finalized, would have a material impact on our operations. However, if the FDA were to enforce the applicable statutes and regulations in accordance with the draft guidance as written, we would incur significant additional expenses, which could materially and adversely affect our business in several ways, including, but not limited to, the enjoinment of manufacturing of our products if and until the FDA determines that we are in compliance and can resume manufacturing, which would reduce our growth prospects.

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 are currently conducting clinical trials 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 our 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, BPX01 and BPX04, 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.

BPX01 and BPX04 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. BPX01's and BPX04'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 BPX01 and BPX04, 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 it 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 for BPX01, 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 of ours 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.

Use of PROs in our BPX03 clinical trials may delay the development of BPX03 or increase our development costs.

Due to the difficulty of objectively measuring the symptoms of FBC, patient-reported outcome instruments, or PROs, may have an important role in the development and regulatory approval of our BPX03 product candidate. PROs involve patients' subjective assessments of efficacy, and this subjectivity increases the uncertainty in determining clinical endpoints. Such assessments can be influenced by factors outside of our control, and can vary widely from day-to-day for a particular patient, and from patient-to-patient and site-to-site within a clinical trial. Furthermore, if we pursue a Phase 3 clinical program for BPX03, we anticipate that we would use PROs in such a program, and if the FDA does not accept or requires changes to the PRO, this could delay clinical development of BPX03, increase our costs and necessitate additional clinical trials.

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, 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 health care benefit program, willfully

obstructing a criminal investigation of a health care 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 health care 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;
- in the case of FBC, patients' perceptions of the condition as one for which medical treatment may be appropriate and a prescription therapy may be available;
- 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 and women's health—related issues have received limited or no reimbursement coverage by insurers and, accordingly, coverage for BPX03, BPX01 and BPX04, 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 BPX01, BPX04 and BPX03, 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, BPX01 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 BPX01. In addition, BPX01 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, BPX04 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 BPX04. In addition, BPX04 will compete against oral systemic treatments for rosacea which include antibiotics and antimicrobials, and against a number of approved topical treatments for acne, including branded drugs and generic versions where available. If approved for the treatment of FBC, BPX03 will face direct competition from numerous other products such as Danocrine, Tamoxifen and Bromocriptine and the existence of these products may limit the market size for BPX03. 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 consumers, 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 and continue to utilize 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.

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 pharmaceuticals industry depends upon our ability to attract and retain highly-qualified managerial, scientific, medical, sales and marketing and other personnel. In May 2016, our Chief Executive Officer resigned from the Company. We are highly dependent on our management and scientific personnel, including: our President and Secretary, Anja Krammer, our Executive Vice President of Research and Technology, Kin F. Chan, PhD, our Chief Financial Officer, Greg Kitchener and our Executive Vice President of Clinical and Regulatory Affairs, AnnaMarie Daniels. 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 our 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.

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 the San Francisco Bay Area where we are headquartered. We could have difficulty attracting experienced personnel to our 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 ours.

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, which may include strategic partnerships with women's health companies, 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.

We currently develop our clinical drug products exclusively in one research and development facility and may utilize this facility in the future to support commercial production if our product candidates are approved. If this or any future facility or our equipment were damaged or destroyed, 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.

We currently research and develop our product candidates exclusively in a single laboratory located in our corporate headquarters in Menlo Park, California. If this or 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 our research and development facility is 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.

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.

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.

Our corporate headquarters are located in Menlo Park, California, near major earthquake and fire zones. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as enterprise financial systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. 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.

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 commercialization and development of our products and product candidates could be delayed.

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 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. Any patents that we may obtain may be narrow in scope and thus 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 our current or 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 our current licensors, 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 our current licensors, or 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 and women’s health 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, topical rosacea and iodine for breast health and because BPX01, BPX04 and VI$_2$OLET represent forms of such

therapies, respectively, the patent protection available for BPX01, BPX04 and VI2OLET 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, or threaten our ability to 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. In addition, courts outside the United States may be less willing to protect trade secret information.

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

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 its 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 ours 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 United States 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 are 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 their 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 us. 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 fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business and development of our product candidates.

We are a party to certain license agreements that impose various royalty and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. Our license agreement with NuTech expires when both parties cease to produce or research an applicable product for a period of five years and our license agreement with Iogen is intended to be of perpetual duration. Both agreements may be terminated in the event of a breach. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects.

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, biologics, 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 and/or filed by third parties, or third parties may allege such infringement. Because (i) some patent applications in the United States may be maintained in secrecy until the patents are issued, (ii) patent applications in the United States 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 ours. 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 United States, 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 its 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 its 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 rely on certain third-party licensors and partners, and will continue to do so in the future, if one of our licensors or partners is 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. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than our technology alone would otherwise suggest.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, 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 its 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 United States.

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

Our stock may be delisted from the NYSE American, which could affect its market price and liquidity.

Our common stock trades on the NYSE American. The NYSE American imposes various quantitative and qualitative requirements to maintain listing, including minimum stockholders' equity requirements. On July 20, 2016, we received a staff deficiency notice from the NYSE American that we were not in compliance with the stockholders' equity requirements set forth in the NYSE American Company Guide. 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.

We were provided until August 22, 2016 to submit a plan to regain compliance with the NYSE American continued listing standards by January 20, 2018. On January 16, 2018, we informed the NYSE American that our stockholders' equity was $6.3 million, and on January 22, 2018 the NYSE American informed us that we were back in compliance with this standard. We reported stockholders' equity of $5.1 million as of January 31, 2018 and net losses in our five most recent fiscal years ended January 31, 2018. Additionally, we received $7.0 million from the exercise of outstanding warrants to purchase common stock after January 31, 2018 through the date of the filing of this Annual Report on Form 10-K. As a result, we believe that our stockholders' equity is above $6.0 million as of the date of the filing of this Annual Report on Form 10-K, after also giving consideration to results of operations and other items that impact stockholders' equity during the period subsequent to January 31, 2018.

While we regained compliance with the continued listing standards in January 2018, there can be no assurance that we will be able to maintain this status. If the NYSE American finds that we are not in compliance in the future, the NYSE American may initiate suspension and delisting procedures. If delisting proceedings are commenced, the NYSE American rules permit us 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.

Additionally, as a result of our operating losses in recent years and the declining market price of our common stock, our continued eligibility for listing on the NYSE American is under review. For example, on December 1, 2017, we received an additional notification from the NYSE American that the 30-day average price of our common stock fell below $0.20 as of November 30, 2017. Pursuant to the NYSE American Company Guide, the NYSE American staff determined that the Company's continued listing requires us to effect a reverse stock split of our common stock or otherwise demonstrate sustained price improvement by June 1, 2018. Additionally, if at any time our common stock trades below $0.06 per share, we will be automatically delisted from the NYSE American. Our stock price has ranged from a low of $0.11 per share to a high of $0.39 per share during the period from August 1, 2017 to the date of this report. Although we intend to regain compliance with the NYSE American listing standards by effecting a reverse stock split if we are not otherwise able to bring our stock price in compliance with NYSE American listing standards, there is

no assurance our stockholders would approve the amendment to our certificate of incorporation required to effect a reverse stock split. If we are unable to satisfy the continued listing requirements of the NYSE American, our common stock could be subject to delisting. If our common stock loses its 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. 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 BPX01 and BPX04, 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 and in particular, our success in seeking to enter into a strategic collaboration for the continued development of BPX01;
- 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, the commercial sales of VI_2OLET and 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 have not remedied these weaknesses. 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 generally accepted accounting principles in the United States of America, or 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 President 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.

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 26% of our outstanding common stock as of March 31, 2018. 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.

Investment funds managed by Franklin Advisers collectively beneficially own approximately 7% of the aggregate voting power of the Company as of March 31, 2018, which includes warrants exercisable for 3,551,250 shares of common stock. Investment funds managed by Franklin Advisers could acquire up to 25% in the aggregate of the voting power through open-market purchases of our common stock and purchase up to an aggregate of 20% of the securities offered by us in any private placement of our securities. Investment funds managed by Vivo Capital beneficially own approximately 15% of the aggregate voting power of the Company as of March 31, 2018, which includes warrants exercisable for 13,498,169 shares of common stock.

Franklin Advisers and Vivo Capital could have considerable influence over matters such as approving a potential acquisition of us. Franklin Advisers' and Vivo Capital's investments in and position in our company could also

discourage others from pursuing any potential acquisition of us, which could have the effect of depriving the holders of our common stock of the opportunity to sell their shares at a premium over the prevailing market price.

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 Delaware General Corporation Law, or 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 our company 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 your 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," have a public float of less than $75 million and have annual revenues of less than $50 million during the most recently completed fiscal year. As a "smaller reporting company," we are subject to lesser disclosure obligations in our SEC filings compared to other issuers. Specifically, "smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings, 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 and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited consolidated financial statements in annual reports. Decreased disclosures in our SEC filings due to our status a "smaller reporting company" 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 intend 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

Our principal executive office and laboratory is located at 1505 Adams Drive, Suite D, Menlo Park, California 94025, where the we occupy 12,203 sq. ft. of research and development and administration facilities that are nearby to external formulation, clinical and preclinical testing facilities. Our lease expires in December 2018. We believe that our existing property is in good condition and suitable for our current needs until replacement space can be obtained. We intend to look for replacement space in the San Francisco Bay Area, and believe we will be able to identify suitable space prior to the expiration of our lease.

ITEM 3. LEGAL PROCEEDINGS

On September 26, 2017, two purported shareholders filed a lawsuit in the Superior Court for the State of California, San Mateo County, against the Company and James Pekarsky, the Company's former Chief Executive Officer. The lawsuit alleges that certain investments were not exempt from registration under the federal securities laws, alleges a violation of the California Corporations Code and asserts a claim for breach of fiduciary duty. The complaint seeks unspecified rescissionary damages, interest thereon, punitive damages, and other relief. The Company continues to deny plaintiffs' allegations and believes the claims lack merit.

We may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. In addition, we may receive allegations of infringement of patents or other intellectual property rights. Subject to the above-mentioned lawsuit, we are not a party to any material legal proceedings, nor are we aware of any pending or threatened litigation that would have a material adverse effect on our business, operating results, cash flows or financial condition should such litigation be resolved unfavorably.

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 currently 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 as reported by the NYSE American.

	High	Low
Fiscal Year Ended January 31, 2018		
First Quarter	$ 0.90	$ 0.39
Second Quarter	$ 0.90	$ 0.32
Third Quarter	$ 0.39	$ 0.18
Fourth Quarter	$ 0.30	$ 0.10
Fiscal Year Ended January 31, 2017		
First Quarter	$ 1.78	$ 0.75
Second Quarter	$ 0.97	$ 0.50
Third Quarter	$ 1.22	$ 0.27
Fourth Quarter	$ 0.58	$ 0.19

As of April 1, 2018, there were approximately 79 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, 2018 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	24,724,663	$ 0.41	1,884,878(1)
Equity compensation plans not approved by security holders(2)	660,000	$ 1.44	—

(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 three employees in fiscal year 2016. 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 financial statements and the accompanying notes to the financial statements and other disclosures included in this Annual Report on Form 10-K. Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

Overview

We are a specialty pharmaceutical company focused on utilizing our proprietary drug delivery technologies to develop and commercialize novel prescription and over-the-counter, or OTC, products that address large markets in dermatology and women's health. Our objective is to develop products that treat health or age-related conditions that: (1) are not presently being addressed or treated or (2) are currently treated with drug therapies or drug delivery approaches that are sub-optimal. Our strategy is designed to bring new products to market by identifying optimal delivery mechanisms and/or alternative applications for United States Food and Drug Administration, or FDA, approved active pharmaceutical ingredients, or APIs, and biological materials, while, in appropriate circumstances, reducing the time, cost and risk typically associated with new product development by repurposing drugs 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. We believe these approaches may reduce drug development risk and could reduce the time and resources we spend during development. Our current platform technologies include innovative delivery mechanisms for antibiotics, biological materials and molecular iodine (I_2).

Since inception, we have developed our product candidates, including conducting preclinical and clinical trials, and providing general and administrative support for these operations. We began shipping VI_2OLET through online stores in December 2014. We recently entered into an agreement to distribute VI_2OLET in Mexico and Central America. We continue to pursue additional channel distribution expansion for VI_2OLET by way of partnerships and/or sublicensing opportunities with women's health and/or consumer companies to provide broader access to consumers. To date, we have generated a de minimis amount of revenue from product sales while we focus on product acceptance and partnering opportunities.

Results of Operations

Revenue

Year ended January 31,			
2018	2017	Change	%
($ in thousands)			
$ 73	$ 100	$ (27)	(27)%

We recognize revenue on a sell-through basis if we do not have sufficient historical information to estimate product returns, pricing discounts or other concessions. If sufficient historical information is available, we recognize revenue upon shipment, net of reserves. We shipped our first product to an online retailer in December 2014 and recognized our first revenue in January 2015. The year over year decrease in revenues was primarily due to the timing of revenue recognized on a sell-through basis.

Cost of Goods Sold

Year ended January 31,			
2018	2017	Change	%
($ in thousands)			
$ 250	$ 516	$ (266)	(52)%

Cost of goods sold includes direct costs related to the sale of VI_2OLET, our iodine dietary supplement, write-downs of excess and obsolete inventories and amortization of our intangible assets. The year over year decrease in cost of goods sold was primarily related to the decrease in recognized revenue and related cost of our product, as well as the decrease in inventory reserves and amortization of our intangible assets.

Research and Development Expenses

Year ended January 31,			
2017	2016	Change	%
($ in thousands)			
$ 9,140	$ 10,158	$ (1,018)	(10)%

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 $1.0 million for the year ended January 31, 2018 compared to the prior year primarily due to decreased clinical study costs and nonclinical study costs, as we completed our Phase 2b clinical study for BPX01, partially offset by an increase in headcount-related and consulting expenses. We expect research and development expenses to increase period over period as we commence our Phase 2 study for BPX04, our topical antibiotic for the treatment of rosacea, and continue to advance research and development on other projects. We expect to begin the Phase 3 clinical trials for BPX01, our topical antibiotic for the treatment of acne, if we raise the necessary additional capital or enter into a strategic partnership to fund the trials.

Sales and Marketing Expenses

Year ended January 31,			
2018	2017	Change	%
($ in thousands)			
$ 2,415	$ 3,198	$ (783)	(24)%

Sales and marketing expenses primarily include headcount-related costs, stock-based compensation, costs related to establishing our corporate brand and efforts related to promoting VI_2OLET and the market development related to our acne drug candidate, BPX01. Sales and marketing expenses are expensed as incurred.

Sales and marketing expenses decreased $0.8 million for the year ended January 31, 2018 compared to the prior year primarily due to decreased advertising and promotional activities related to VI_2OLET, as we continue to pursue additional channel distribution expansion by way of partnerships with women's health or consumer companies. This decrease was partially offset by higher costs related to the market development activities of BPX01.

General and Administrative Expenses

Year ended January 31,			
2018	2017	Change	%
($ in thousands)			
$ 5,144	$ 4,654	$ 490	11 %

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 increased $0.5 million for the year ended January 31, 2018 compared to the prior year primarily due to higher legal, litigation and stock-based compensation costs.

Change in Fair Value of Warrant Liability

Year ended January 31,				
2018	2017	Change	%	
($ in thousands)				
$ 364	$ 163	$ 201	123	%

The change in fair value of warrant liability reflects the fair value re-measurement of certain warrants granted in fiscal year 2017 that are accounted for as derivative liabilities.

Other Expense, net

Year ended January 31,				
2018	2017	Change	%	
($ in thousands)				
$ (126)	$ (141)	$ (15)	(11)	%

For the year ended January 31, 2018, other expense primarily included interest income on our cash and cash equivalents and approximately $151,000 of expense for the incremental fair value related to the modification of warrants. For the year ended January 31, 2017, other income and expense primarily included non-cash interest expense recorded for debt issuance costs and interest expense related to our convertible notes.

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,	
	2018	2017
Net cash used in operating activities	$ (15,587)	$ (15,746)
Net cash used in investing activities	(41)	(45)
Net cash provided by financing activities	16,703	18,253
Net increase in cash and cash equivalents	$ 1,075	$ 2,462

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

	As of January 31,	
	2018	2017
Current assets	$ 7,981	$ 6,827
Current liabilities	2,979	3,727
Working capital	$ 5,002	$ 3,100

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, 2018 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, 2018, we had cash and cash equivalents of $7.6 million and working capital of $5.0 million. We raised $16.7 million and $18.3 million from financing activities in the years ended January 31, 2018 and 2017, respectively. We will require significant additional financing in the future. There can be no assurance that such financing will be available or on terms which are favorable to us. While our management believes that we have a plan to fund ongoing operations, there is no assurance that our plan will be successfully implemented. Failure to generate sufficient cash flows from operations, raise additional capital through one or more financings, entering into a strategic partnership, or reduce certain discretionary spending could have a material adverse effect on our ability to achieve our intended business objectives. 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 development of our products and product candidates, and any acquisitions or investments in businesses, products or technologies that are complementary to our own that we make that require cash consideration or expenditures.

Net cash used for operating activities for the year ended January 31, 2018 was $15.6 million, which primarily resulted from a net loss of $16.6 million and changes in operating assets and liabilities of $0.7 million, partially offset by non-cash expenses of $1.7 million. Changes in operating assets and liabilities was primarily attributable to timing of payments to vendors and decreased operating expenses.

Net cash used for operating activities for the year ended January 31, 2017 was $15.7 million, which primarily resulted from a net loss of $18.4 million, partially offset by non-cash expenses of $1.7 million and changes in operating assets and liabilities of $0.9 million. Changes in operating assets and liabilities was primarily attributable to timing of payments to vendors and increased operating expenses.

Net cash used for investing activities for the years ended January 31, 2018 and 2017 was approximately $41,000 and $45,000, respectively, resulting from the purchase of property and equipment.

Net cash provided by financing activities for the year ended January 31, 2018 was $16.7 million, which was due to the $16.0 million of net proceeds from the issuance of common stock, preferred stock and warrants to purchase common stock in our public and private offerings, $0.6 million from the exercise of warrants to purchase common stock and $10,000 from the exercise of stock options. Additionally, we received $7.0 million from the exercise of warrants to purchase common stock after January 31, 2018 through the date of this report.

Net cash provided by financing activities for the year ended January 31, 2017 was $18.3 million, which was due to the $16.7 million of net proceeds from the issuance of common stock, preferred stock and warrants to purchase common stock in our public and private offerings, $1.5 million of net proceeds from the issuance of convertible notes payables and approximately $41,000 from the exercise of stock options.

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, 2018, we had cash and cash equivalents of $7.6 million and working capital of $5.0 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 convertible notes, Series A convertible preferred stock and warrants. We incurred a net loss available to common stockholders of $16.6 million and $18.5 million for the years ended January 31, 2018 and 2017, respectively, and had an accumulated deficit of $61.3 million as of January 31, 2018.

We have a limited operating history and our prospects are subject to risks, expenses and uncertainties frequently encountered by companies in our industry. To date, we have generated a de minimis amount of revenue from the sale of VI_2OLET, our iodine dietary supplement. We continue our research and development efforts for our product candidates, which will require significant funding. If we are unable to obtain additional financing in the near-term or research and development efforts require higher than anticipated capital, there may be a negative impact on our financial viability. We plan to increase working capital by managing our cash flows and expenses and raising additional capital through either private or public equity or debt financing. We also continue to pursue additional channel distribution expansion for VI_2OLET through partnerships with women's health companies to provide broader access to consumers. Risks include, but are not limited to, the uncertainty of availability of additional financing and the uncertainty of achieving future profitability. We intend to raise additional funds through the issuance of equity securities. We have an effective shelf registration statement on file with the SEC to allow us to sell up to approximately $79.0 million of our securities from time to time prior to February 2019, subject to regulatory limitations. For example, pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities pursuant to the shelf registration statement with a value of more than one third of the aggregate market value of our common stock held by non-affiliates in any 12 month period, so long as the aggregate market value of our common stock held by non-affiliates is less than $75.0 million. There can be no assurance that such financing will be available or on terms which are favorable to us. While our management believes that we have a plan to fund ongoing operations, there is no assurance that our plan will be successfully implemented. Failure to generate sufficient cash flows from operations, raise additional capital through one or more financings, enter into a strategic partnership or reduce certain discretionary spending could have a material adverse effect on our ability to achieve our intended business objectives. These factors raise substantial doubt about our 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.

Recent Accounting Pronouncements

In May 2014, as part of its ongoing efforts to assist in the convergence of GAAP and International Financial Reporting Standards, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The new guidance sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed in GAAP. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in the prior accounting guidance. The ASU provides alternative methods of initial adoption and is effective for annual and interim periods beginning after December 15, 2017. The FASB has issued several updates to the standard which i) defer the original effective date, while allowing for early adoption (ASU 2015-14); ii) clarify the application of the principal versus agent guidance (ASU 2016-08); iii) clarify the guidance on inconsequential and perfunctory promises and licensing (ASU 2016-10); and clarify the guidance on certain sections of the guidance providing technical corrections and improvements (ASU 2016-10). In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers (Topic 606) Narrow-Scope Improvements and Practical Expedients*, to address certain narrow aspects of the guidance including collectibility criterion, collection of sales taxes from customers, noncash consideration, contract modifications and completed contracts. This issuance does not change the core principle of the guidance in the initial topic issued in May 2014. We implemented this new guidance as of February 1, 2018. We have completed our evaluation of the impact of this standard and based on this analysis, we do not believe adoption of this standard will have a material impact on our consolidated financial statements. We expect to use the modified retrospective method upon adoption.

In February 2016, FASB issued ASU No. 2016-02, *Leases*, which requires entities to recognize assets and liabilities for leases with lease terms greater than twelve months. The new guidance also requires quantitative and qualitative disclosures regarding the amount, timing and uncertainty of cash flows arising from leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. We are in process of evaluating the impact of adoption on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting*, which relates to the accounting for employee share-based payments. This standard provides guidance on simplifying several aspects of the accounting for employee share-based payment transactions, including the income tax consequences, accounting for forfeitures and classification of excess tax benefits on the statement of cash flows. This standard is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. We adopted this standard on February 1, 2017, and there was no material impact on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This amendment gives guidance and reduces diversity in practice with respect to certain types of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. We are in the process of evaluating the impact of adoption on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. This amendment impacts entities that change the terms or conditions of a share-based payment award. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. This amendment should be applied prospectively to an award modified on or after the adoption date. We adopted this guidance as of February 1, 2018 for any awards that are modified after that date.

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 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 revenue recognition, inventory 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:

Revenue Recognition

Revenue is recognized provided that persuasive evidence of a sales arrangement exists, the price is fixed or determinable, title and risk of loss has transferred, collectibility of the resulting receivable is reasonably assured, there are no customer acceptance requirements and we do not have any significant post-shipment obligations. We recognize revenue on a sell-through basis for customer arrangements in which we do not have historical information to estimate product returns, pricing discounts or other concessions upon shipment. For these product shipments, we invoice the reseller, record deferred revenue at the gross invoice sales price and classify the cost basis of the product held by the wholesaler as a component of inventory. We recognize revenue when product is sold by the reseller to the end user, on a FIFO basis. For customer arrangements in which we can reasonably estimate returns, price discounts and other concessions, revenue is recognized upon shipment and a reserve is recorded for returns, price discounts and other concessions.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using the standard cost method which approximates actual cost on a first-in, first-out basis. Market value is determined as the lower of replacement cost or net realizable value. We regularly review inventory quantities in consideration of actual loss experiences, projected future demand and remaining shelf life to record a provision for inventory, which may have become obsolete or are in excess of anticipated demand or net realizable value, when appropriate. If future demand or market conditions for the products are less favorable than forecasted, we may be required to record additional write-downs, which would negatively affect our results of operations in the period when the write-downs were recorded. We must order components for our products and build inventory in advance of product shipments. We have a purchase commitment relating to the manufacturing of VI_2OLET finished product and is non-cancelable. We assess our purchase commitment based on demand forecasts and establish a liability for quantities deemed in excess of these forecasts.

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.

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, 2018 and 2017, 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, 2018. This evaluation was carried out under the supervision and with the participation of our management, including our President and Chief Financial 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 President and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Based upon that evaluation, our President and Chief Financial 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, 2018 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, 2018, 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, 2018 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 March 31, 2018. 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
Anja Krammer	50	President and Director
Greg Kitchener	47	Executive Vice President and Chief Financial Officer
Kin F. Chan	45	Executive Vice President of Research and Technology
Michael Hubbard(1)	66	Director
Stephen Morlock(1)	64	Director

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

Anja Krammer

Anja Krammer has served as our President, Secretary and a director since January 2014. Since September 2011, she has served as the President, Secretary and director of BioPharmX, Inc. Ms. Krammer has served as Chief Marketing Officer/Founder of MBI, Inc., a management consulting firm from January 1998. While at MBI, Inc., Ms. Krammer also served as Vice President Global Marketing from April 2006 to August 2008 for Reliant Technologies, a venture-backed startup in aesthetic medicine. From April 2004 to April 2006, Ms. Krammer served as Sr. Director of Strategic Marketing for Medtronic Corporation. From December 2000 to September 2001, Ms. Krammer was Vice President, Solutions Marketing for Getronics Corporation, a global IT services company. From April 1999 to December 2000, Ms. Krammer served as Vice President, Indirect Channel Sales and Worldwide Industry Partnership Marketing in the Itronix Division of Acterna Corporation, an optical communications company. Ms. Krammer's other prior roles include serving as Director of Worldwide Marketing and Communications for Tektronix Corporation in its Color Printing and Imaging Division from October 1997 to April 1999. From October 1995 to October 1997, Ms. Krammer was Director of Worldwide Sales and Marketing with KeyTronic Corporation, a computer equipment manufacturer. Ms. Krammer holds a BAIS degree with a focus on Marketing/Management from the University of South Carolina and an International Trade Certificate from the University of Paris—Sorbonne.

Greg Kitchener

Greg Kitchener has served as our Executive Vice President and Chief Financial Officer since August 2015. Prior to joining the Company, he served as Vice President of Finance at Cepheid, a publicly-traded healthcare company, from October 2011 to July 2015, after having served as Executive Director of Finance from April 2011 to October and as Senior Director of Finance from July 2008 to April 2011. He also previously held financial leadership positions at Synopsys from January 2005 to July 2008, culminating in the position of Director of Corporate Planning/FP&A and M&A, and held various finance positions at Cisco Systems from 2000 to January 2005. He started his career as an account representative at Charles Schwab from 1997 to 1998. Mr. Kitchener holds a Master of Business Administration from Cornell University and a Bachelor of Science in mathematics from University of California, Santa Cruz.

Kin F. Chan

Kin F. Chan, PhD has served as our Executive Vice President of Research and Technology since February 2014. Since September 2011, Dr. Chan has served as Vice President of Technology of BioPharmX, Inc. He was also the founder and President of Fourier Biotechnologies, LLC, which provides services in optical engineering and preclinical research, from 2009 to January 2014. In addition, from April 2012 to January 2014, he was Vice President of Engineering at Demira, Inc., a biopharmaceutical company focusing on dermatology products. Prior to that, he was the Managing Director of Advanced Research at Solta Medical, Inc. from 2003 to 2009, and was an optical research and development engineer at Ball Semiconductor, Inc. from 2000 to 2003. Dr. Chan holds BS, MS and PhD degrees in Electrical and Computer Engineering from the University of Texas at Austin.

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 IPOs 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 CPA 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.

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 2017, we believe that all Section 16(a) filing requirements during fiscal year 2018 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 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 2018 and 2017.

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)(2)	Total ($)
Anja Krammer	2018	310,000	72,917	835,168	9,000	1,227,085
President and Director	2017	250,000	60,000	362,137	9,000	681,137
Kin F. Chan, PhD	2018	270,000	36,250	341,777	—	648,027
Executive Vice President of Research and Technology	2017	225,000	25,000	161,163	—	411,163
Greg Kitchener	2018	237,000	19,875	258,961	—	515,836
Executive Vice President and Chief Financial Officer	2017	225,000	60,000(3)	139,729	—	424,729

(1) Amounts represent the aggregate fair value amount computed as of the grant date of each award during fiscal year 2018 in accordance with Financial Accounting Standards Board ("***FASB***") Accounting Standards Codification ("***ASC***") 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, 2018.

(2) The amounts represent reimbursements for self-sourced health care insurance premiums.

(3) Mr. Kitchener joined us in August 2015 and received bonuses following the successful completion of equity financing transactions as detailed in his offer letter.

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 or her commencement of employment with us. These offers of employment were each subject to execution of our standard confidential information and invention assignment agreement.

Anja Krammer's Employment Agreement

On April 20, 2017, we entered into an employment agreement with Ms. Krammer, pursuant to which Ms. Krammer is employed as our President. Ms. Krammer's employment agreement provides for a base salary of $310,000 per year and a bonus based on criteria and terms and conditions as may be established by our board of directors or our Compensation Committee in its sole discretion. Ms. Krammer is eligible to participate in our employee benefit plans and paid vacation in accordance with our vacation policy on the same basis as other executive employees. Ms. Krammer is eligible to receive future grants of our equity awards, in all cases as determined by, and subject to the approval of, our Compensation Committee.

In the event of Ms. Krammer's termination of employment (a) by us (i) on account of Ms. Krammer's death, (ii) on account of Ms. Krammer's disability, (iii) for Cause (as defined in the Krammer Employment Agreement) or (b) by Ms. Krammer without Good Reason (as defined in the Krammer Employment Agreement), we are obligated to pay Ms. Krammer (1) any unpaid salary through the date of termination; (2) reimbursement for any unreimbursed expenses incurred through the date of termination; and (3) all other payments, benefits or fringe benefits to which Ms. Krammer is entitled upon a termination of employment under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program (collectively, the "Accrued Amounts").

In the event of Ms. Krammer's termination of employment by us without Cause (and other than termination by us on account of Ms. Krammer's disability or death), and provided that Ms. Krammer delivers a signed Release (as defined in the Krammer Employment Agreement) and satisfies all conditions to make the Release effective, Ms. Krammer will be entitled to receive (1) the Accrued Amounts, (2) a lump sum cash payment in an amount equal to nine months of Ms. Krammer's then current annual base salary, (3) reimbursement of premiums paid for continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("Cobra") until the earlier of (a) nine months and (b) the date that Ms. Krammer is covered under the health plan of another employer, and (4) acceleration of vesting with respect to outstanding time-based equity awards which would have become vested as of the nine month anniversary of Ms. Krammer's Termination Date (as defined in the Krammer Employment Agreement).

In the event of Ms. Krammer's termination by us without Cause (and other than termination by us on account of Ms. Krammer's disability or death) or Ms. Krammer's resignation for Good Reason, in each case within the period beginning one month prior to the effective date of a Corporate Transaction (as defined in the Krammer Employment Agreement) and ending on the twelve month anniversary of the effective date of such Corporate Transaction, and provided that Ms. Krammer delivers a signed Release and satisfies all conditions to make the Release effective, Ms. Krammer will be entitled to receive (1) the Accrued Amounts, (2) a lump sum cash payment in an amount equal to twenty-four months of Ms. Krammer's then current base salary, (3) reimbursement of premiums paid for Cobra until the earlier of (a) eighteen months and (b) the date that Ms. Krammer is covered under the health plan of another employer, and (4) full acceleration of all outstanding time-based equity awards.

Greg Kitchener's Employment Agreement

On August 10, 2015, we entered into an Employment Agreement with Mr. Kitchener, pursuant to which Mr. Kitchener is employed as Executive Vice President and Chief Financial Officer.

Mr. Kitchener's employment agreement provides for a base salary of $237,000 per year and an annual bonus if performance targets are met, which determination will be made at the discretion of the board of directors.

If we terminate Mr. Kitchener's employment without cause (as defined in his employment agreement) or if Mr. Kitchener resigns for good reason (as defined in his employment agreement) within 12 months of a change in control (as defined in his employment agreement) and he delivers a customary release of claims, he would be entitled to: (i) an amount equal to twelve (12) months of his then current base salary; (ii) a continuation of company-paid health insurance benefits applicable to him as of the change of control (or provision of benefits equivalent thereto) for 18 months; and (iii) 100% acceleration of his then unvested options or other equity awards and, subject to Section 409A of the Code, restricted stock units, performance-based restricted stock units and long-term incentives.

Kin Chan's Employment Agreement

On February 17, 2014, we entered into an Employment Agreement with Dr. Chan, pursuant to which Dr. Chan is employed as Executive Vice President of Research and Technology.

Dr. Chan's employment agreement provides for a base salary of $270,000 per year or such higher rate as the Company's board of directors may determine from time to time, and an annual bonus if performance targets are met, which determination will be made at the discretion of the board of directors.

If we terminate Dr. Chan's employment or Dr. Chan resigns for good reason (as defined in his employment agreement) within 12 months of a change in control (as defined in his employment agreement) and he delivers a customary separation agreement and release of claims, he would be entitled to: (i) an amount equal to twenty four (24) months of his then current base salary; (ii) continuation of company-paid health insurance benefits applicable to him as of the change or control (or provision of benefits equivalent thereto) for 18 months; and (iii) 100% acceleration of his then unvested options or other equity awards and, subject to Section 409A of the Code, restricted stock units, performance-based restricted stock units and long-term incentives.

Outstanding Equity Awards

The following table includes information as of January 31, 2018 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
Anja Krammer	39,375(1)	65,625	—	0.65	7/1/2026
	360,000(2)	—	—	0.62	7/21/2026
	108,334(3)	291,666	—	0.42	12/8/2026
	—(4)	1,060,000	—	0.74	4/18/2027
	26,112(5)	913,888	—	0.10	12/20/2027
	—(6)	1,960,000	—	0.11	1/8/2028
Kin F. Chan, PhD	20,625(1)	34,375	—	0.65	7/1/2026
	170,000(2)	—	—	0.62	7/21/2026
	40,625(3)	109,375	—	0.42	12/8/2026
	—(4)	435,000	—	0.74	4/18/2027
	25,000(5)	875,000	—	0.10	12/20/2027
	11,500(5)	402,500	—	0.20	12/20/2027
Greg Kitchener	141,979(7)	93,021	—	1.67	8/10/2025
	20,625(1)	34,375	—	0.65	7/1/2026
	41,250(8)	68,750	—	0.62	7/21/2026
	47,396(3)	127,604	—	0.42	12/8/2026
	—(4)	290,000	—	0.74	4/18/2027
	25,000(5)	875,000	—	0.10	12/20/2027
	11,500(5)	402,500	—	0.20	12/20/2027

(1) The stock option was granted on July 1, 2016, 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 on the last day of each full calendar month thereafter.

(2) The stock option was granted on July 21, 2016, and the shares subject to this option vest one-half on the grant date and 1/12 of the remaining shares vest on the last day of each full calendar month thereafter.

(3) The stock option was granted on December 8, 2016, 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 on the last day of each full calendar month thereafter.

(4) The stock option was granted on April 18, 2017, 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 on the last day of each full calendar month thereafter.

(5) The stock option was granted on December 20, 2017, and the shares subject to this option vest 1/36 of the shares on the last day of each full calendar month.

(6) The stock option was granted on January 8, 2018, and the shares subject to this option vest 1/36 of the shares on the last day of each full calendar month.

(7) The stock option was granted on August 10, 2015, 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 on the last day of each full calendar month thereafter.

(8) The stock option was granted on July 21, 2016, 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 on the last day of each full calendar month thereafter.

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 2018, 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 2018. Ms. Krammer, our President, received no compensation for her service as a member of our board of directors during fiscal year 2018, and is not included in this table. The compensation received by Ms. Krammer as an employee of the Company is presented in “Summary Compensation Table”.

Director Compensation Fiscal Year 2018

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Michael Hubbard	113,500	160,767	274,267
Stephen Morlock	82,000	160,767	242,767
C. Gregory Vontz(2)	53,667	114,230	167,897

(1) Amounts listed under the “Option Awards” column represent the aggregate fair value amount computed as of the grant date of each option and award during fiscal year 2018 in accordance with ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 7 to our consolidated financial statements contained in our annual report on Form 10-K for the year ended January 31, 2018 as filed with the SEC. Our directors will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options. For information regarding the number of stock options held by each non-employee director as of January 31, 2018, see the column “Number of Securities Underlying Stock Options Held as of January 31, 2018” in the table below.

(2) Mr. Vontz resigned from the Company’s board of directors effective November 30, 2017.

Each person who served as a non-employee member of our board of directors during fiscal year 2018 held the following aggregate number of shares of our common stock subject to outstanding stock options as of January 31, 2018:

Name	Number of Securities Underlying Stock Options Held as of January 31, 2018
Michael Hubbard	1,200,000
Stephen Morlock	1,180,000
C. Gregory Vontz	203,751

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. From February 2016 to June 2016, our non-employee directors were compensated as follows:

- $5,000 on a quarterly basis for service as the chair of our Audit Committee;
- $5,000 on a quarterly basis for service as the chair of our Compensation Committee; and
- $5,000 on a quarterly basis for service as the chair of our Nominating and Corporate Governance Committee.

From July 2016 to January 2018, our non-employee directors were compensated as follows:

- $40,000 annual retainer;
- $35,000 for service as the chair of the board (a one-time, supplemental retainer fee of $20,000 was paid to the Mr. Hubbard for his service as chair of the board in fiscal year 2017);
- $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 to purchase 65,000 shares of 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 to purchase 200,000 shares of 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 2018 were Mr. Hubbard, Mr. Morlock and Mr. Vontz. No member of our Compensation Committee in fiscal year 2018 was at any time during fiscal year 2018 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 2018.

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 March 31, 2018 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 191,518,731 shares of common stock outstanding as of March 31, 2018. 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 March 31, 2018 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, 1505 Adams Drive, Suite D, Menlo Park, California 94025.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Shares of Common Stock**	**%**
Directors and Named Executive Officers:		
Anja Krammer(1)	3,685,209	1.9%
Greg Kitchener(2)	560,207	*
Kin F. Chan(3)	1,748,646	*
Michael Hubbard (4)	817,917	*
Stephen Morlock (5)	2,904,373	1.5%
All executive officers and directors as a group (5 persons)(6)	9,716,352	4.9%
5% or Greater Stockholders		
Entities Affiliated with Vivo Capital VIII, LLC.(7)	29,626,684	14.5%
Entities Affiliated with Franklin Advisors, Inc.(8)	13,300,865	6.8%

* Represents holdings of less than one percent

(1) Includes options exercisable for 1,185,209 shares of common stock within 60 days of March 31, 2018.

(2) Includes options exercisable for 560,207 shares of common stock within 60 days of March 31, 2018.

(3) Includes options exercisable for 548,646 shares of common stock within 60 days of March 31, 2018.

(4) Includes options exercisable for 817,917 shares of common stock within 60 days of March 31, 2018.

(5) Includes 251,071 shares of common stock held by the Stephen W. Morlock and Karen R. Morlock TIEE UPT dated 04/21/03, of which Mr. Morlock is a co-trustee and co-beneficiary, options exercisable for 797,917 shares of common stock within 60 days of March 31, 2018 and warrants exercisable for 981,429 shares of common stock within 60 days of March 31, 2018.

(6) Includes options exercisable for 3,909,896 shares of common stock within 60 days of March 31, 2018 and warrants exercisable for 981,429 shares of common stock within 60 days of March 31, 2018.

(7) Affiliates of Vivo Capital Fund VIII, LLC beneficially own the following securities of the Company: 14,418,159 shares are held by Vivo Capital Fund VIII, L.P., 1,710,356 shares are held by Vivo Capital Surplus Fund VIII, L.P., up to 11,860,005 shares of common stock are issuable upon exercise of warrants held by Vivo Capital Fund VIII, L.P. and up to 1,638,164 shares of common stock are issuable upon exercise of warrants

held by Vivo Capital Surplus Fund VIII, L.P. Vivo Capital VIII, LLC is the general partner of both Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P. The voting members of Vivo Capital VIII, LLC are Frank Kung, Albert Cha, Edgar Engleman, Chen Yu and Shan Fu, none of whom has individual voting or investment power with respect to these shares and each of whom disclaims beneficial ownership of such shares. The address of Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P. is 575 High Street, Suite 201, Palo Alto, CA 94301.

(8) Franklin Advisors, Inc., or FAV, an indirectly wholly owned subsidiary of a publicly traded company, Franklin Resources, Inc., or FRI, may be deemed to be the beneficial owner of these securities for purposes of Rule 13d-3 under the Exchange Act in its capacity as the investment adviser to Franklin Strategic Series—Franklin Biotechnology Discovery Fund and Franklin Templeton Investment Funds—Franklin Biotechnology Discovery Fund pursuant to investment management contracts that grant investment and/or voting power to FAV. When an investment management contract (including a sub-advisory agreement) delegates to FAV investment discretion or voting power over the securities held in the investment advisory accounts that are subject to that agreement, FRI treats FAV as having sole investment discretion or voting authority, as the case may be, unless the agreement specifies otherwise. Accordingly, FAV reports for purposes of Section 13(d) of the Exchange Act that it has sole investment discretion and voting authority over the securities covered by any such investment management agreement, unless otherwise specifically noted. Includes warrants exercisable for 3,551,250 shares of common stock within 60 days of March 31, 2018. The address of FRI is One Franklin Parkway, San Mateo, CA 94403-1906.

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, 2017 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.

In April 2017, through a registered direct offering, we issued and sold 1,282,052 shares of common stock and warrants to purchase 641,026 shares of common stock to investment funds managed by Vivo Capital.

In November 2017, through a public offering, we issued and sold 330,000 shares of common stock and warrants to purchase 660,000 shares of common stock to Stephen Morlock, one of our directors.

During fiscal year 2018, we employeed a family member related to Ms. Krammer in the marketing department. For fiscal year 2018, we paid the family member aggregate compensation, including salary and the grant date fair value of stock options, of approximately $224,000.

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 Anja Krammer, 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 2018 and 2017. 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 2018 and 2017 for each of the following categories of services are as follows:

Fees Billed to BioPharmX Corporation	2018	2017
	(in thousands)	
Audit fees(1)	$ 304	$ 331
Audit related fees(2)	—	—
Tax fees(3)	—	—
All other fees(4)	—	—
Total fees	$ 304	$ 331

(1) *"Audit fees"* include fees for professional services rendered in connection with the audit of our annual financial statements, review of our quarterly 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 and is generally subject to a specific budget. 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	Incorporated by Reference				Filed Herewith
		Form	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	
3.1	Certificate of Incorporation	S-8	333-201708	1/26/2015	4.01	
3.2	Bylaws	S-8	333-201708	1/26/2015	4.02	
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	
4.1	Specimen Stock Certificate	S-8	333-201708	1/26/2015	4.03	

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
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	
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	

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
10.1*	Employment Agreement between Anja Krammer and BioPharmx, Inc.	10-K	001-37411	4/21/2017	10.23	
10.2*	Offer letter, dated July 14, 2015, by and between BioPharmX Corporation and Greg Kitchener	10-Q	001-37411	9/14/2015	10.1	
10.3*	Employment Agreement, dated August 10, 2015, by and between BioPharmX Corporation and Greg Kitchener	10-Q	001-37411	9/14/2015	10.2	
10.4*	Notice of Inducement Option Grant and Inducement Stock Option Plan and Agreement, dated August 10, 2015, by and between BioPharmX Corporation and Greg Kitchener	10-Q	001-37411	9/14/2015	10.3	
10.5*	Employment agreement between Kin Chan and Thompson Design, Inc.	10-K	000-54871	3/30/2015	10.4	
10.6	Amended and Restated Collaboration and License Agreement dated March 1, 2013 between BioPharmX, Inc. and Iogen LLC	8-K	000-54871	1/27/2014	10.4	
10.7	Sublease Agreement entered into on December 14, 2016 between BioPharmX, Inc. and Refuge Biotechnologies, Inc.	8-K	001-37411	12/19/2016	10.1	
10.8	First Amendment to the Sublease Agreement between BioPharmX, Inc. and Refuge Biotechnologies, Inc. dated September 25, 2017	10-Q	001-37411	12/12/2017	10.1	
10.9*	2014 Equity Incentive Plan	8-K	000-54871	1/27/2014	10.7	
10.10*	Form of 2014 Equity Incentive Plan award agreement	S-8	333-201708	1/26/2015	4.05	
10.11*	2016 Equity Incentive Plan (as amended)	10-K	001-37411	4/21/2017	10.11	
10.12*	Form of Stock Option Agreement	S-8	333-213627	9/14/2016	4.05	
10.13*	Form of Restricted Stock Unit Award Agreement	S-8	333-213627	9/14/2016	4.06	
10.14*	Form of Stock Bonus Award Agreement	S-8	333-213627	9/14/2016	4.07	
10.15*	Form of Restricted Stock Agreement	S-8	333-213627	9/14/2016	4.08	

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
10.16*	Form of Stock Appreciation Right Award Agreement	S-8	333-213627	9/14/2016	4.09	
10.17	Form of Indemnification Agreement	S-1/A	333-203317	5/14/2015	10.16	
10.18	Commercial Supply Agreement dated effective as of June 25, 2014 between BioPharmX, Inc.and Gregory Pharmaceutical Holdings, Inc.	S-1/A	333-203317	5/14/2015	10.17	
10.19	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	
10.20	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	
10.21	Form of Common Stock Purchase Warrant	8-K	001-37411	9/27/2016	4.1	
10.22	Form of Securities Purchase Agreement	8-K	001-37411	9/27/2016	10.1	
10.23	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	
10.24	Form of Securities Purchase Agreement	8-K	001-37411	4/26/2017	10.1	
10.25	Form of Securities Purchase Agreement	8-K	001-37411	7/24/2017	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

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
32.1	Certification of Chief Executive Officer and Chief Financial 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
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

* Indicates a management contract, 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 Menlo Park, California, on April 26, 2018.

BIOPHARMX CORPORATION

By: /s/ ANJA KRAMMER
Name: Anja Krammer
Title: *President*

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/ ANJA KRAMMER Anja Krammer	President and Director (Principal Executive Officer)	April 26, 2018
/s/ GREG KITCHENER Greg Kitchener	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 26, 2018
/s/ MICHAEL HUBBARD Michael Hubbard	Director	April 26, 2018
/s/ STEPHEN MORLOCK Stephen Morlock	Director	April 26, 2018

BIOPHARMX CORPORATION
CONSOLIDATED FINANCIAL STATEMENTS
Years ended January 31, 2018 and 2017

CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders 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, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, convertible preferred stock stockholders' equity, and cash flows for each of the two years in the period ended January 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended January 31, 2018, 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.

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.

/s/ BPM LLP

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

San Jose, California
April 26, 2018

BIOPHARMX CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	January 31, 2018	January 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 7,576	$ 6,501
Accounts receivable, net	7	4
Inventories	10	38
Prepaid expenses and other current assets	388	284
Total current assets	7,981	6,827
Property and equipment, net	109	120
Other assets	—	154
Total assets	$ 8,090	$ 7,101
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,376	$ 2,551
Accrued expenses and other current liabilities	1,603	1,176
Total current liabilities	2,979	3,727
Long-term liabilities:		
Warrant liability	39	403
Total liabilities	3,018	4,130
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Series A convertible preferred stock, $0.001 par value; 10,000,000 shares authorized; 0 and 1,515 shares issued and outstanding as of January 31, 2018 and 2017, respectively	—	1,515
Common stock, $0.001 par value; 450,000,000 shares authorized; 160,062,509 and 67,719,577 shares issued and outstanding as of January 31, 2018 and 2017, respectively	160	68
Additional paid-in capital	66,190	46,026
Accumulated deficit	(61,278)	(44,638)
Total stockholders' equity	5,072	2,971
Total liabilities and stockholders' equity	$ 8,090	$ 7,101

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,	
	2018	2017
Revenues, net	$ 73	$ 100
Cost of goods sold	250	516
Gross margin	(177)	(416)
Operating expenses:		
Research and development	9,140	10,158
Sales and marketing	2,415	3,198
General and administrative	5,144	4,654
Total operating expenses	16,699	18,010
Loss from operations	(16,876)	(18,426)
Change in fair value of warrant liability	364	163
Other expense, net	(126)	(141)
Loss before provision for income taxes	(16,638)	(18,404)
Provision for income taxes	2	2
Net loss and comprehensive loss	$ (16,640)	$ (18,406)
Deemed dividend on Series A convertible preferred stock	—	(126)
Net loss available to common stockholders	$ (16,640)	$ (18,532)
Basic and diluted net loss per share	$ (0.19)	$ (0.52)
Shares used in computing basic and diluted net loss per share	85,900,000	35,806,000

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

BIOPHARMX CORPORATION

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

(in thousands, except share data)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance as of February 1, 2016	—	$ —	25,208,684	$ 25	$ 28,261	$ (26,232)	$ 2,054
Issuance of common and preferred stock, net of expenses of $3,138	1,515	1,389	40,453,182	40	15,283	—	16,712
Issuance of common stock due to exercise of options	—	—	131,000	1	40	—	41
Conversion of convertible notes payable to common stock	—	—	1,926,711	2	1,643	—	1,645
Stock-based compensation expense	—	—	—	—	1,491	—	1,491
Deemed dividend for preferred stock	—	126	—	—	(126)	—	—
Fair value of warrants issued	—	—	—	—	(566)	—	(566)
Net and comprehensive loss	—	—	—	—	—	(18,406)	(18,406)
Balance as of January 31, 2017	1,515	1,515	67,719,577	68	46,026	(44,638)	2,971
Issuance of common stock, net of expenses of $1,907	—	—	57,185,258	57	15,992	—	16,049
Issuance of common stock due to exercise of options	—	—	40,000	—	10	—	10
Issuance of common stock due to exercise of warrants	—	—	30,789,103	31	613	—	644
Conversion of Series A convertible preferred stock to common stock	(1,515)	(1,515)	4,328,571	4	1,511	—	—
Stock-based compensation expense	—	—	—	—	1,887	—	1,887
Fair value of modification of warrants	—	—	—	—	151	—	151
Net and comprehensive loss	—	—	—	—	—	(16,640)	(16,640)
Balance as of January 31, 2018	—	$ —	160,062,509	$ 160	$ 66,190	$ (61,278)	$ 5,072

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, 2018	2017
Cash flows from operating activities:		
Net loss	$ (16,640)	$ (18,406)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,887	1,491
Expense related to modification of warrants	151	—
Depreciation expense	52	141
Amortization expense	—	119
Non-cash interest expense	—	145
Change in fair value of warrant liability	(364)	(163)
Changes in assets and liabilities:		
Accounts receivable	(3)	3
Inventories	28	62
Prepaid expenses and other assets	50	(68)
Accounts payable	(1,175)	774
Accrued expenses and other liabilities	427	156
Net cash used in operating activities	(15,587)	(15,746)
Cash flows from investing activities:		
Purchases of property and equipment	(41)	(45)
Net cash used in investing activities	(41)	(45)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, preferred stock and warrants, net of issuance costs	16,049	16,712
Proceeds from exercises of common stock warrants	644	—
Proceeds from exercises of stock options	10	41
Proceeds from issuance of convertible notes	—	1,500
Net cash provided by financing activities	16,703	18,253
Net decrease in cash and cash equivalents	1,075	2,462
Cash and cash equivalents at beginning of period	6,501	4,039
Cash and cash equivalents at end of period	$ 7,576	$ 6,501
Non-cash investing and financing activities:		
Conversion of Series A convertible preferred stock to common stock	$ 1,515	$ —
Conversion of convertible notes payable and accrued interest to common stock	$ —	$ 1,645
Fair value of beneficial conversion feature issued in connection with convertible notes	$ —	$ 88
Deemed dividend on Series A convertible preferred stock	$ —	$ 126
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 utilizing its proprietary drug delivery technologies to develop and commercialize novel prescription and over-the-counter, or OTC, products that address large markets in dermatology and women's health. The Company's objective is to develop products that treat health or age-related conditions that (1) are not presently being addressed or treated at all or (2) are currently treated with drug therapies or drug delivery approaches that are suboptimal. The Company's strategy is designed to bring new products to market by identifying optimal delivery mechanisms and/or alternative applications for United States Food and Drug Administration (FDA) approved active pharmaceutical ingredients and biological materials, while, in appropriate circumstances, reducing the time, cost and risk typically associated with new product development by repurposing drugs 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. The Company believes these approaches may reduce drug development risk and could reduce the time and resources it spends during development. Its current platform technologies include innovative delivery mechanisms for antibiotics, biologic materials and molecular iodine (I_2).

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 commercially launched its breast health supplement in December 2014, although to-date the Company has not generated significant revenue from product sales. The Company is not dependent on sales to any one customer. The Company has financed its operations primarily through the sale of equity and convertible notes.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). The accompanying financial statements include the accounts of BioPharmX and its wholly-owned subsidiary. All intercompany transactions have been eliminated in consolidation.

Use of Estimates

The preparation of 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 financial statements and reported amounts of revenues and expenses recognized during the reported period. Actual results could differ from those estimates.

Reclassification

Certain prior year amounts have been reclassified to conform to the current year presentation. Related party payables have been included in accrued liabilities and other current liabilities in the consolidated statement of cash flows. The amounts for the prior periods have been reclassified to be consistent with the current year presentation and have no impact on previously reported total assets, total stockholders' equity or net loss.

Accounts Receivable

Accounts receivable is recorded net of cash discounts for prompt payment and return allowances. There was no allowance for doubtful accounts receivable recorded at either January 31, 2018 or 2017.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the standard cost method which approximates actual cost on a first-in, first-out basis. The Company regularly reviews inventory quantities in consideration of actual loss experiences, projected future demand and remaining shelf life to record a provision for inventory, which may have become obsolete or are in excess of anticipated demand or net realizable value. If future demand or market conditions for the products are less favorable than forecasted, the Company may be required to record additional write-downs, which would negatively affect its results of operations in the period when the write-downs were recorded.

The Company must order components for its products and build inventory in advance of product shipments. The Company has a purchase commitment relating to the manufacturing of VI_2OLET finished product (iodine supplement tablets) and is non-cancelable as detailed in Note 5. The Company assesses its purchase commitment based on demand forecasts and establishes a liability for quantities deemed in excess of these forecasts.

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 and other liabilities approximate fair value due to their short maturities.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation and amortization are recognized using the straight-line method. Repairs and maintenance costs are expensed as incurred. Estimated useful lives in years are as follows:

Description	Estimated Useful Life
Furniture	5 - 7
Laboratory equipment	3 - 5
Computer and equipment	3 - 5
Software	5

Intangible Assets

Intangible assets with finite useful lives are amortized over their estimated useful lives. Intangible assets with finite useful lives are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

The intangible assets were acquired in March 2013 in connection with the collaboration and license agreement with Iogen LLC (Iogen) detailed in Note 5. Amortization of the intangible assets commenced in January 2015 with the first recognition of revenue related to VI_2OLET and was being taken on a straight-line basis over 5 years. In the fourth quarter of 2017, the Company determined that the future cash flows expected to be generated by the intangible assets did not exceed their fair value, therefore deemed the intangible assets were fully impaired. The Company recorded an impairment charge of approximately $89,000 in the fourth quarter of 2017, which is included in cost of goods sold in the consolidated statements of operations and comprehensive loss.

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. The Company recorded an impairment loss related to the intangible assets as detailed in Note 5. In the fourth quarter of 2017, the Company determined that the future cash flows expected to be generated from capitalized software costs did not exceed their fair value, therefore deemed the asset was fully impaired. The Company recorded accelerated depreciation of approximately

$73,000 in the fourth quarter of 2017, which is included in depreciation expense in the consolidated statements of operations and comprehensive loss and cash flows.

Convertible Notes

The Company issued convertible notes that had conversion prices which resulted in an embedded beneficial conversion feature. The intrinsic value of the beneficial conversion feature was recorded as a debt discount with the corresponding amount to additional paid-in capital. The debt discount was amortized to interest expense over the life of the convertible notes using the effective interest method.

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 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 the consolidated statements of operations and comprehensive loss.

Revenue Recognition

VI_2OLET is an iodine dietary supplement. Revenue is recognized provided that persuasive evidence of a sales arrangement exists, the price is fixed or determinable, title and risk of loss has transferred, collectibility of the resulting receivable is reasonably assured, there are no customer acceptance requirements and the Company does not have any significant post-shipment obligations. The Company recognizes revenue on a sell-through basis for customer arrangements in which it does not have historical information to estimate product returns, pricing discounts or other concessions upon shipment. For these product shipments, the Company invoices the reseller, records deferred revenue at the gross invoice sales price and classifies the cost basis of the product held by the wholesaler as a component of inventory. Deferred revenue is adjusted for price protection and other revenue reserves. Revenue is recognized when product is sold by the reseller to the end user, on a first-in first-out (FIFO) basis. For customer arrangements in which returns, price discounts and other concessions can be reasonably estimated, revenue is recognized upon shipment and a reserve is recorded for returns, price discounts and other concessions.

Cost of Good Sold

Costs of good sold includes direct costs related to the sale of the Company's iodine dietary supplement, write-downs of excess and obsolete inventories and amortization of intangible assets.

Shipping and Handling Costs

Shipping and handling costs are expensed as incurred and are included in cost of goods sold.

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.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were approximately $29,000 and $335,000 for the years ended January 31, 2018 and 2017, respectively.

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, 2018 and 2017, the Company's comprehensive loss is equal to 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, 2018 and 2017 exclude 193,333 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. The potential dilutive shares of common stock resulting from the assumed exercise of outstanding stock options, warrants, and the assumed conversion of preferred stock are determined under the treasury stock method.

As of January 31, 2018 and 2017, approximately 215,810,000 and 48,762,000, 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 Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-02, *Leases*, which requires entities to recognize assets and liabilities for leases with lease terms greater than twelve months. The new guidance also requires quantitative and qualitative disclosures regarding the amount, timing and uncertainty of cash flows arising from leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is in the process of evaluating the impact of adoption of this standard on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting*, which relates to the accounting for employee share-based payments. This standard provides guidance on simplifying several aspects of the accounting for employee share-based payment transactions, including the income tax consequences, accounting for forfeitures and classification of excess tax benefits on the statement of cash flows. This standard is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company adopted this standard on February 1, 2017, and there was no material impact on the Company's consolidated financial statements.

In May 2014, as part of its ongoing efforts to assist in the convergence of GAAP and International Financial Reporting Standards, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The new guidance sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed in GAAP. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it

expects in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in the prior accounting guidance. The ASU provides alternative methods of initial adoption and is effective for annual and interim periods beginning after December 15, 2017. The FASB has issued several updates to the standard which beginning after December 15, 2017 i) defer the original effective date, while allowing for early adoption (ASU 2015-14); ii) clarify the application of the principal versus agent guidance (ASU 2016-08); iii) clarify the guidance on inconsequential and perfunctory promises and licensing (ASU 2016-10); and clarify the guidance on certain sections of the guidance providing technical corrections and improvements (ASU 2016-10). In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers (Topic 606) Narrow-Scope Improvements and Practical Expedients*, to address certain narrow aspects of the guidance including collectibility criterion, collection of sales taxes from customers, noncash consideration, contract modifications and completed contracts. This issuance does not change the core principle of the guidance in the initial topic issued in May 2014. The Company implemented this new guidance as of February 1, 2018. The Company has completed its evaluation of the impact of this standard and based on this analysis, does not believe adoption of this standard will have a material impact on its consolidated financial statements. The Company is expected to use the modified retrospective method upon adoption.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This amendment gives guidance and reduces diversity in practice with respect to certain types of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is in process of evaluating the impact of this guidance on its consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. This amendment impacts entities that change the terms or conditions of a share-based payment award. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. This amendment should be applied prospectively to an award modified on or after the adoption date. The Company adopted this guidance as of February 1, 2018 for any awards that are modified after that date.

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, 2018, the Company had cash and cash equivalents of $7.6 million and working capital of $5.0 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 convertible notes. The Company incurred a net loss available to common stockholders of $16.6 million and $18.5 million for the years ended January 31, 2018 and 2017, respectively, and had an accumulated deficit of $61.3 million as of January 31, 2018.

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 continues its research and development efforts for its product candidates, which will require significant funding. If the Company is unable to obtain additional financing in the future or research and development efforts require higher than anticipated capital, there may be a negative impact on the financial viability of the Company. The Company plans to increase working capital by managing its cash flows and expenses, entering into a strategic partnership and/or raising additional capital through either private or public equity or debt financing. There can be no assurance that such financing or partnerships will be available or on terms which are favorable to the Company. While management of the Company believes that it has a plan to fund ongoing operations, there is no assurance that its plan will be successfully implemented. Failure to generate sufficient cash flows from operations, raise additional capital through one or more financings, enter into a strategic partnership or reduce certain discretionary spending could have a material adverse effect on the Company’s ability to achieve its intended business

objectives. 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, 2018	2017
	(in thousands)	
Inventories:		
Work in process	$ 5	$ 23
Finished goods	1	8
Channel inventory	4	7
	$ 10	$ 38

	January 31, 2018	2017
	(in thousands)	
Property and equipment, net:		
Furniture	$ 21	$ 21
Laboratory equipment	106	69
Computer and equipment	116	112
	243	202
Less: accumulated depreciation	(134)	(82)
	$ 109	$ 120

Depreciation expense for the year ended January 31, 2018 was approximately $52,000. Depreciation expense for the year ended January 31, 2017 was approximately $141,000, which included approximately $73,000 of accelerated depreciation related to capitalized software costs.

	January 31, 2018	2017
	(in thousands)	
Accrued liabilities:		
Legal	$ 438	$ 55
Research and development	404	327
Payroll	368	412
Purchase commitment liability	215	263
Deferred revenue	8	11
Other	170	108
	$ 1,603	$ 1,176

4. FAIR VALUE MEASURMENTS

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, 2018 and 2017, the Company held $7.1 million and $5.5 million, respectively, in money market funds, which are classified as Level 1 within the fair value hierarchy. No unrealized gains or losses are recorded in connection with these amounts.

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 hierachy (in thousands):

	Warrant Liability
Balance as of January 31, 2016	$ —
Fair value of warrants issued	566
Change in fair value of warrants	(163)
Balance as of January 31, 2017	403
Change in fair value of warrants	(364)
Balance as of January 31, 2018	$ 39

5. COMMITMENTS AND CONTINGENCIES

Commitments

The following table summarizes the Company's commitments as of January 31, 2018 (in thousands):

		Fiscal years ending January 31,		
	Total	2019	2020	2021
Operating lease	$ 534	$ 534	$ —	$ —
Purchase commitment	861	323	269	269
Total	$ 1,395	$ 857	$ 269	$ 269

On December 14, 2016, the Company signed a lease for 12,066 square feet of office and laboratory space in Menlo Park, California. In September 2017, the lease term was extended to December 2018 and the square footage increased to 12,203 square feet. Rent expense for the years ended January 31, 2018 and 2017 was $612,000 was $434,000, respectively.

The purchase commitment relates to the manufacturing of VI_2OLET finished product (iodine supplement tablets) and is non-cancelable. The Company assesses its purchase commitments based on demand forecasts and establishes a liability for quantities deemed in excess of these forecasts. During the year ended January 31, 2018, the Company recorded a charge of approximately $215,000 as its demand forecast indicated such inventory was deemed excess. The Company recently entered into an agreement to distribute VI_2OLET in Mexico and Central America. The Company continues to pursue additional channel distribution expansion for VI_2OLET by way of partnerships and sublicense with women's health and/or consumer companies. The expected increase in demand generated from these partnerships is included in the Company's demand forecast. If the Company is unsuccessful in securing such partnerships or sublicensees, it is possible that a loss contingency related to the excess purchase commitments will be required to record additional write-downs, which would negatively affect its results of operations in the period when the write-downs were recorded.

Legal Proceedings

On September 26, 2017, two purported shareholders filed a lawsuit in the Superior Court for the State of California, San Mateo County, against the Company and James Pekarsky, the Company's former Chief Executive Officer. The lawsuit alleges that certain investments were not exempt from registration under the federal securities laws, alleges a violation of California's Corporations Code and asserts a claim for breach of fiduciary duty. The complaint seeks unspecified rescissionary damages, interest thereon, punitive damages, and other relief. The Company continues to deny the plaintiffs' allegations and believes the claims lack merit.

The Company is not a party to any material legal proceeding that the Company believes is likely to have a material adverse effect on its consolidated financial position or results of operations. From time to time the Company may be subject to legal proceedings and claims in the ordinary course of business. 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 and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, 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.

License Agreement

In March 2013, the Company entered into an amended and restated collaboration and license agreement with Iogen, which provides the Company with a license to certain rights to label, market, and resell the finished inventory and ongoing manufacturing of the Iogen molecular iodine technology for future product formulation development and commercialization. New formulation patents developed by the Company will be solely owned by the Company. The agreement gives the Company a perpetual, fully paid-up, exclusive license to make, have made, use, sell and offer for sale and import products.

Pursuant to the terms of the license, the Company must pay:

- a fee for the exclusive license to the IP.
- 30% of net profit associated with direct commercialization of an OTC product or 30% of net royalties received from any sub-licensee.
- a royalty of 3% of net sales for the first 24 months of commercialization and 2% of net sales thereafter for a prescription iodine tablet developed and commercialized under the license.
- a royalty of 3% of net sales for the first 12 months of commercialization for other products developed and commercialized under the license and 2% of net sales thereafter until expiration of applicable patents covering such products and 1% thereafter.
- a fixed royalty fee for the protection and indemnification of licensed intellectual property rights ("IP rights") for the prescription product developed, marketed and sold from newly developed formulations as long as the patents are valid and cover the prescription product.
- a fixed royalty fee for the protection and indemnification of licensed IP rights for the other products utilizing the molecular iodine technology developed, marketed and sold from newly developed formulations as long as the patents are valid and cover the prescription product.

The Company capitalized as intangible assets, the amount of $150,000 related to this agreement. In the fourth quarter of 2017, the Company determined that the future cash flows expected to be generated from the intangible assets did not exceed their fair value, therefore deemed the assets were fully impaired. The Company recorded an impairment charge of approximately $89,000 and is included in amortization expense. No royalties have been paid as of January 31, 2018.

6. CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

Common Stock

In June 2015, the Company uplisted to the NYSE American and simultaneously completed a public offering in which it issued 3,636,384 shares of common stock resulting in net proceeds of $7.8 million. Pursuant to the terms of a convertible note previously issued, immediately prior to the closing of the offering, the principal amount and all accrued and unpaid interest converted into 182,266 shares of common stock.

In December 2015, the Company sold 4,100,000 shares of common stock at a price per share of $1.43 resulting in net proceeds of $5.5 million in a private placement to investment funds managed by Franklin Advisers. For a period of five years, Franklin Advisers has the right to purchase up to an aggregate of 20% of the securities offered by the Company in any subsequent private placement.

In April 2016, the Company issued 3,600,000 shares of common stock at a price per share of $1.195 resulting in net proceeds of $3.6 million and warrants to purchase 1,952,000 shares of common stock in a public offering. These warrants have an exercise price of $1.20 per share and expire on April 1, 2021. As of January 31, 2017, all of these warrants were outstanding.

In August 2016, the Company issued 2,423,077 shares of common stock at a price per share of $0.65 resulting in net proceeds of $1.3 million in a private offering.

In September 2016, the Company issued 1,550,000 shares of common stock at a price per share of $0.60 resulting in net proceeds of $0.8 million and warrants to purchase 1,286,501 shares of common stock in a registered direct offering. These warrants have an exercise price of $0.80 per share and expire in five years. As of January 31, 2017, all of these warrants were outstanding.

On August 17, 2016, the Company issued a secured convertible promissory note ("Secured Note") in the principal amount of $1.0 million. The Secured Note included a term to maturity of 36 months and an interest rate of 10% per annum. On August 17, 2016, the Company issued an unsecured convertible promissory note ("Unsecured Note") in the principal amount of $0.5 million. The Unsecured Note included a term to maturity of 6 months and an interest rate of 10% per annum. Both the Secured Note and Unsecured Note (together, "Notes") were convertible into the Company's common stock at a conversion price of $0.80 per share. Upon issuance of the Notes, debt discounts of approximately $88,000 resulting from a beneficial conversion feature and debt issuance costs of approximately $16,000 were recorded and expensed to interest expense when converted to common stock. Pursuant to the conversion features included in the Notes, the Notes' principal amount and unpaid accrued interest automatically converted into 1,926,711 shares of common stock immediately prior to the completion of the Company's public offering on November 28, 2016.

In November 2016, the Company issued 31,489,429 shares of common stock at a price per share of $0.35, 1,515 shares of Series A convertible preferred stock ("Preferred Stock") at a price per share of $1,000 and warrants to purchase 31,499,725 shares of common stock in a public offering resulting in net proceeds of $10.6 million. In December 2016, the underwriters exercised their option to purchase an additional 1,390,676 shares of common stock to cover over-allotments resulting in net proceeds of $0.4 million.

In April 2017, the Company issued 6,410,258 shares of common stock at a price per share of $0.78 resulting in net proceeds of $4.4 million and warrants to purchase 3,365,385 shares of common stock at an exercise price of $0.90 in a registered direct offering.

In July 2017, the Company issued 5,500,000 shares of common stock at a price per share of $0.36 resulting in net proceeds of $1.9 million in a registered direct offering.

In November 2017, the Company issued 45,275,000 shares of common stock, pre-funded warrants to purchase 28,225,000 shares of common stock, and accompanying Series A common warrants to purchase 73,500,000 shares of common stock ("Series A Warrants"), and accompanying Series B common warrants to purchase 73,500,000 shares of common stock ("Series B Warrants"), resulting in net proceeds of $9.7 million. Each share of common stock and pre-funded warrant was sold together with a Series A Warrant to purchase one share of common stock and a Series B Warrant to purchase one share of common stock. The public offering price was $0.15 per share of common stock and accompanying Series A Warrant and Series B Warrant and $0.1490 per pre-funded warrant and accompanying Series A

Warrant and Series B Warrant. The pre-funded warrants were issued and sold to purchasers in lieu of shares of common stock that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% (or at the election of the purchaser, 9.99%) of the Company's outstanding Common Stock immediately following the closing of the offering. The pre-funded warrants have a nominal exercise price of $0.001 per share and have been fully exercised. The Series A Warrants have an exercise price of $0.20 per share, are exercisable immediately and expire five years from the date of issuance. The Series B Warrants have an exercise price of $0.25 per share, are exercisable immediately and expire on the earlier of (1) the twenty-first trading day after the Company issues a press release announcing it has entered into a strategic licensing, collaboration, partnership or similar agreement for the commitment to fund its Phase 3 trials for BPX01, and (2) the eighteen month anniversary of issuance.

Series A Convertible Redeemable Preferred Stock

During 2014, the Company entered into subscription agreements for the private placement of 4,207,987 shares of its Series A preferred stock and warrants to purchase 2,042,589 shares of common stock at an exercise price of $3.70 per share. In connection with the uplisting to the NYSE American, the Series A preferred stock, including accrued and unpaid interest, converted into 4,319,426 shares of common stock. The warrant exercise agreements included a provision such that if the public offering price related to the offering was less than $3.125 per share, then immediately prior to the closing of the offering, additional shares of common stock would be issued at no additional consideration to each holder equal to: (i) the product of (A) the difference between $2.50 per share and 80% of the public offering price and (B) such holder's shares of common stock received pursuant to exercise of the amended warrants, divided by (ii) 80% of the public offering price in the offering. Based on a public offering price of $2.75 per share, 77,006 shares of common stock were issued pursuant to this provision.

In March and April 2015, the Company amended certain of the warrants issued in connection with the Series A preferred stock financing to reduce the exercise price of such warrants from $3.70 to $2.50 per share with a corresponding increase in the number of shares of common stock exercisable under the warrants so that the aggregate exercise value of such warrants remained the same. As of January 31, 2018, certain holders had exercised such warrants for an aggregate of 564,662 shares of common stock for an aggregate cash exercise price of $1,411,655. The Company recorded a charge for the incremental fair value of $436,000 in other expense related to the amended warrants in the first quarter of fiscal year 2016. The fair value of these warrants exercised was computed as of the date of modification using the following assumptions: dividend rate of 0%, risk-free rate of 1.6%, contractual term of four to five years and expected volatility of 85.9%. As of January 31, 2018, of the warrants issued in connection with the Series A convertible redeemable preferred stock financing, warrants to purchase 1,661,055 shares of common stock remain outstanding.

As of January 31, 2018 and 2017, there were 10,000,000 shares of Series A convertible preferred stock authorized and none were outstanding. Pursuant to the Certificate of Elimination filed with the Secretary of State of the State of Delaware on March 6, 2018, all shares of Series A convertible preferred stock previously designated were returned to the status of authorized but unissued shares of preferred stock, without designation as to series or rights, preferences, privileges or limitations.

Series A Convertible Preferred Stock

The Preferred Stock issued in November 2016 included warrants to purchase 3,246,429 shares of common stock. The Preferred Stock had a purchase price of $1,000 per share and was convertible into common stock at a conversion rate of $0.35 per share. The Preferred Stock contained a beneficial conversion feature valued at $0.1 million, which was recorded as a deemed dividend at the time of issuance, which is considered to be the earliest time of conversion. As of January 31, 2018, the Preferred Stock had been converted into 4,328,571 shares of common stock.

Warrants

A summary of warrants outstanding as of January 31, 2018 is as follows:

	Total	Price per Share	Expiration Date
Warrants related to January 2014 agreement	289,505	$ 1.85	May 2019
Warrants related to May 2014 agreement	316,395	$2.035	May 2019
Warrants related to April to November 2014 financing	1,661,055	$ 3.70	April 2019 - November 2019
Warrants related to June 2015 financing	109,091	$ 2.75	June 2020
Warrants related to April 2016 financing	1,952,000	$ 1.20	April 2021
Warrants related to September 2016 financing (1)	1,286,501	$ 0.75	September 2021 to March 2022
Warrants related to November 2016 financing	30,406,061	$ 0.35	November 2022 to November 2024
Warrants related to November 2016 financing	895,450	$ 0.44	November 2022
Warrants related to November 2016 financing	198,214	$ 0.33	November 2022
Warrants related to April 2017 financing	801,282	$ 0.90	October 2022
Warrants related to October 2017 financing (2)	3,846,152	$ 0.30	October 2022
Warrants related to November 2017 financing	74,970,000	$ 0.20	November 2022
Warrants related to November 2017 financing	73,500,000	$ 0.25	May 2019

(1) In connection with the sale of common stock in September 2016, warrants to purchase 1,286,501 shares of common stock were issued at an exercise price of $0.75 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 Janaury 31, 2018, the fair value of the warrant liability was approximately $39,000 and was included as a long-term liability.

(2) On October 23, 2017, the Company entered into agreements with certain of these warrant holders to permit their immediate exercise of 2,564,103 shares of common stock underlying the warrants at an exercise price per share of $0.24. The Company recorded a charge for the incremental fair value of approximately $151,000 in the other expense line item in the condensed 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 2.03%, contractual term of 5 years, expected volatility of 83.9% and a dividend rate of 0%. In addition, these warrant holders were issued new warrants to purchase up to an aggregate of 3,846,152 shares of common stock at an exercise price per share of $0.30.

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 20,000,000 shares to a total of 24,000,000 shares. 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, 2016	350,875	2,704,608	$ 1.59	8.37	$ 1,343
Shares authorized for issuance	4,000,000	—			
Granted	(4,664,054)	4,664,054	0.55		
Exercised	—	(131,000)	0.31		
Canceled prior to and upon termination of the 2014 Plan	587,249	(587,249)	1.76		
Canceled subsequent to termination of the 2014 Plan	—	(184,584)	1.92		
Expired upon termination of the 2014 Plan	(21,691)	—			
Balance as of January 31, 2017	252,379	6,465,829	$ 0.77	8.77	$ 238
Shares authorized for issuance	20,000,000	—			
Granted	(18,553,000)	18,553,000	0.29		
Exercised	—	(40,000)	0.25		
Canceled and returned to the 2016 Plan	185,499	(185,499)	0.65		
Canceled subsequent to termination of the 2014 Plan	—	(68,667)	1.48		
Balance as of January 31, 2018	1,884,878	24,724,663	$ 0.41	9.17	$ 304
Vested and exercisable		4,824,931	$ 0.78	7.47	$ 9
Vested and expected to vest		22,248,572	$ 0.42	9.12	$ 266

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 January 31, 2017 and 2018	660,000	$ 1.44	7.72	$ —
Vested and exercisable	368,541	$ 1.44	7.70	$ —
Vested and expected to vest	634,825	$ 1.44	7.72	$ —

The following table summarizes significant ranges of outstanding and exercisable options as of January 31, 2018:

	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
$0.10 - $0.20	13,408,000	9.90	$ 0.13	390,804	$ 0.13
$0.21 - $0.35	611,441	5.70	$ 0.31	577,066	$ 0.32
$0.36 - $0.65	4,235,751	8.49	$ 0.53	2,072,114	$ 0.55
$0.66 - $1.09	5,539,471	8.73	$ 0.76	993,845	$ 0.83
$1.10 - $1.85	1,490,000	7.11	$ 1.68	1,059,643	$ 1.69
$1.86 - $3.00	100,000	7.25	$ 3.00	100,000	$ 3.00
	25,384,663	9.13	$ 0.44	5,193,472	$ 0.82

The total intrinsic value of stock options exercised during the years ended January 31, 2018 and 2017 was approximately $4,000 and $65,000, respectively. The weighted average grant date fair values of the stock options granted during the years ended January 31, 2018 and 2017 was $0.21 and $0.40, respectively.

7. STOCK-BASED COMPENSATION

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

	Year ended January 31,	
	2018	2017
Research and development	$ 545	$ 398
Sales and marketing	393	346
General and administrative	949	747
Total	$ 1,887	$ 1,491

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, 2018, total compensation costs related to unvested, but not yet recognized, stock-based awards was $4.1 million, net of estimated forfeitures. This cost will be amortized on a straight-line basis over a weighted average remaining period of 2.71 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 for the periods ended:

	Year ended January 31,	
	2018	2017
Expected volatility	83.9% - 96.8%	95.5% - 98.6%
Expected term in years	6.0 - 9.39	5.0 - 6.5
Risk-free interest rate	1.80% - 2.70%	1.12% - 2.03%
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, 2018 and 2017.

9. INCOME TAXES

No federal income taxes were paid during the years ended January 31, 2018 and 2017 due to the Company's net losses. The provision of income taxes consist of state minimum income taxes.

As of January 31, 2018, the Company had available federal net operating loss ("NOL") carry-forwards of approximately $53.5 million which will begin to expire in 2030 and California state NOL carry-forwards of approximately $44.2 million which will begin to expire in 2033. As of January 31, 2018 and 2017, the net deferred tax assets of approximately $16.3 million and $17.3 million, respectively, generated primarily by NOL carry-forwards, have been fully reserved due to the uncertainty surrounding the realization of such benefits. The net valuation allowance increased by approximately $1.0 million and $8.5 million during the years ended January 31, 2018 and 2017, respectively.

Current tax laws impose substantial restrictions on the utilization of net operating loss and credit carry-forwards 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 carry-forwards could be limited. The Company has not conducted a formal net operating loss carryforward analysis.

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

Deferred tax assets:	January 31, 2018	January 31, 2017
Net operating loss carryforwards	$ 14,314	$ 15,618
Stock-based compensation expense	831	908
Tax credit carryforwards	735	576
Other	377	194
Total deferred tax assets	16,257	17,296
Less: valuation allowance	(16,257)	(17,296)
Net deferred tax assets	$ —	$ —

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

	Year ended January 31, 2018	2017
Income tax benefit computed at U.S. statutory rate	$ (5,477)	$ (6,258)
State income tax (net of federal benefit)	(1,150)	(1,196)
Change in federal rate from 34% to 21%	7,662	
Change in valuation allowance	(1,039)	7,342
Research and development credits	(129)	(125)
Other	135	239
Provision for income taxes	$ 2	$ 2

As a result of passage of the Tax Cut and Jobs Act (the "Act") on December 22, 2017, the Company's U.S. deferred tax assets, liabilities, and associated valuation allowance as of January 31, 2018 have been re-measured at the new U.S. federal tax rate of 21%. As of January 31, 2018 and 2017, the Company did not have any material unrecognized tax benefits. The tax years from 2010 to 2018 remain open for examination by the federal and state authorities.

10. SUBSEQUENT EVENTS

The Company received $7.0 million from the exercise of warrants to purchase common stock after January 31, 2018 through the date of this report.

EXHIBIT 21.1

SUBSIDIARY OF BIOPHARMX CORPORATION

As of January 31, 2018, 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. 333-217419, 333-213627 and 333-201708), the Registration Statements on Form S-3 (Nos. 333-220012, 333-213635, 333-212015 and 333-209026) 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 April 26, 2018 relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K.

/s/ BPM LLP

San Jose, California
April 26, 2018

EXHIBIT 31.1

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

I, Anja Krammer, 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: April 26, 2018

/s/ ANJA KRAMMER
Anja Krammer
President (Principal Executive Officer)

EXHIBIT 31.2

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

I, Greg Kitchener, 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: April 26, 2018

/s/ GREG KITCHENER
Greg Kitchener
Chief Financial Officer (Principal Financial Officer and 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, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacities and on the date indicated below, certify 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 their knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); 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: April 26, 2018

/s/ ANJA KRAMMER
Anja Krammer
President (Principal Executive Officer)

/s/ GREG KITCHENER
Greg Kitchener
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.