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CONSOLIDATED FINANCIAL STATEMENTS

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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, 2016

or

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

For the transition period from to

Commission File No. 001-37411

BioPharmX Corporation

(Exact name of registrant as specified in its charter)

Delaware	**59-3843182**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1098 Hamilton Court, Menlo Park, California	**94025**
(Address of principal executive offices)	(Zip Code)

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

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

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 o

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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company ☒

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

As of July 31, 2015, 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 $31.8 million, based upon the closing price of the Registrant's common stock as reported on the NYSE MKT on July 31, 2015. 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 1, 2016, there were outstanding 28,817,017 shares of the registrant's common stock, $0.001 par value.

Documents incorporated by reference: Certain sections of the registrant's definitive Proxy Statement for the 2016 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Rule 14A not later than 120 days after end of the fiscal year covered by this Form 10-K are incorporated by reference into Part III of this Form 10-K.

BioPharmX Corporation
Form 10-K

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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 women's health and dermatology. 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, 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 molecular iodine (I_2) and antibiotics.

Our management team has experience in formulation development, intellectual property generation, clinical trial execution, regulatory strategy definition and licensing and direct to consumer product commercialization. Our business model is to outsource our manufacturing and at times commercialization activities in order to maintain our focus on technology sourcing, acquisitions and strategic partner development to create new products to address unmet needs in well-defined global markets. Our current portfolio of product candidates targets significant market opportunities and includes two clinical stage product candidates: (1) BPX01, a topical antibiotic for the treatment of acne based on a unique formulation of minocycline and (2) BPX03, a molecular iodine (I_2) tablet for the treatment of benign breast pain associated with fibrocystic breast condition, or FBC, and cyclic mastalgia. The molecular iodine project includes an OTC dietary supplement version, or VI_2OLET, for the alleviation of symptoms of FBC, as well as a prescription drug version for the treatment of moderate to severe, periodic breast pain associated with FBC and cyclic mastalgia.

Since inception, we have devoted substantially all of our efforts to developing 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 and are expanding into retail pharmacies, specialty pharmacy and grocery chain outlet stores throughout the United States. We continue to pursue additional channel distribution expansion for VI_2OLET to provide even broader access to consumers. We are exploring commercial growth opportunities, which may include strategic partnerships with women's health companies. To date, we have generated a de minimis amount of revenue from product sales while we focus on building market awareness for our product. We are not dependent on sales to any one customer. We have financed our operations primarily through the sale of equity and convertible debt securities. In June 2015, we raised net proceeds of $7.8 million through the sale of our common stock and concurrently completed an uplisting to the NYSE MKT. In December 2015 we raised net proceeds of $5.5 million in a private offering of our common stock and, in April 2016, we raised net proceeds of approximately $3.6 million from the issuance of common stock and warrants to purchase common stock in a public offering.

Share Exchange

On January 23, 2014, we (then operating as Thompson Designs, Inc.), BioPharmX, Inc. and the stockholders of BioPharmX, Inc., who collectively owned 100% of BioPharmX, Inc., entered into and consummated transactions pursuant to a share exchange agreement, such transaction referred to as the

Share Exchange, whereby we issued to the stockholders of BioPharmX, Inc. an aggregate of 7,025,000 shares of our common stock, in exchange for 100% of the shares of BioPharmX, Inc. held by such stockholders. The shares of our common stock received by the stockholders of BioPharmX, Inc. in the Share Exchange constituted approximately 77.8% of our then issued and outstanding common stock, after giving effect to the issuance of shares pursuant to the share exchange agreement. As a result of the Share Exchange, BioPharmX, Inc. became our wholly-owned subsidiary. For accounting purposes, the Share Exchange was treated as a reverse acquisition, with BioPharmX, Inc. as the acquirer and us as the acquired party, and as a result the historical financial statements prior to the Share Exchange included in this Annual Report on Form 10-K are the historical financial statements of BioPharmX, Inc. On March 3, 2014, we changed our name to BioPharmX Corporation. On May 16, 2014, we reincorporated from Nevada to Delaware.

Product and Product Candidates

We have developed our product portfolio using our proprietary drug delivery technologies including innovative delivery mechanisms for molecular iodine and antibiotics. We currently have one marketed product, VI_2OLET, and two clinical-stage product candidates, BPX01 and BPX03. The following table presents a summary of our marketed products and clinical-stage product candidates (years are in calendar years):

Product/ Product Candidates	Delivery Mechanism	Platform Technology/ Application	Product Type	Anticipated Study Initiation
VI_2OLET	Oral	Molecular iodine (I_2) for the alleviation of symptoms of FBC	OTC Dietary Supplement	Post market non-IND study 2016
BPX03	Oral	Molecular iodine (I_2) for treatment of moderate to severe periodic breast pain associated with FBC and cyclic mastalgia	Prescription Drug	Phase 3 ready 2017
BPX01	Topical	Topical antibiotic for treatment of acne	Prescription Drug	Phase 2a and 2b 2016

VI_2OLET Iodine

Our first commercial product, VI_2OLET, is a patented OTC molecular iodine dietary supplement that addresses cyclic breast discomfort and is clinically demonstrated 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 patented molecular iodine formula is delivered to breast tissue and is intended to reduce the breast cell build-up that results in breast discomfort. We launched VI_2OLET in December 2014 in online stores and are expanding into retail pharmacies, specialty pharmacy and grocery chain outlet stores throughout the United States.

BPX03

In addition to VI_2OLET, we are also developing BPX03, 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 are exploring commercial growth opportunities for the expansion of VI_2OLET, which may include strategic partnerships with women's health companies. To distribute BPX03 globally, products such as ours may require a prescription due to regulatory requirements. We

are currently in the process of conducting a clinical study (using VI_2OLET) under Health Canada and institutional review board, or IRB, oversight to provide additional insight on how to design a Phase 3 safety and efficacy study. We are planning to commence our first Phase 3 clinical trial for BPX03 to support FDA and foreign regulatory requirements upon completion of the non- investigational new drug application, or non-IND, study meeting with the FDA, and submission of our IND for BPX03. We expect to complete the non-IND study in calendar 2016, which would allow us to commence a Phase 3 clinical study in calendar 2017. We would seek approval only in those countries where we plan to market the prescription product. Should we decide to pursue prescription drug approval in the United States, we would submit a full 505(b)(1) New Drug Application, or NDA.

BPX01

We are developing BPX01, a hydrophilic, topical antibiotic for the treatment of acne. BPX01 is a novel formulation and utilizes a transepidermal delivery mechanism for minocycline that we believe has the potential to kill P. acnes bacteria without the systemic side effects of orally-administered antibiotics. BPX01 contains an active pharmaceutical ingredient that is well known, and is expected to also possess anti-inflammatory properties, which reduce swelling and redness. We have completed a 4-week animal toxicity study to support our first Phase 2a clinical study, and we are currently conducting a 13-week animal toxicity study to support the planned 12-week Phase 2b clinical study. An IND to initiate the first Phase 2a clinical trial of BPX01 was submitted to the FDA in January 2016, and we received a letter from the FDA in March 2016 stating that the study may proceed. We intend to immediately commence the Phase 2a clinical study. We are also preparing to conduct a bridging safety study using oral minocycline as the comparator and a Phase 2b dose-finding clinical study for BPX01. We intend to pursue regulatory approval under Section 505(b)(2) of the FDC Act, or Section 505(b)(2). We believe the Section 505(b)(2) regulatory pathway, which permits us to rely in part on the FDA's prior findings of safety and/or efficacy for an approved drug product, may reduce the product development risk and could reduce the time and resources we spend during development of BPX01. We believe our design approach for transepidermal delivery may also be utilized with other APIs.

BPX02

We are developing BPX02, an injectable utilizing biologic materials for aesthetic dermatology applications. This research stage product candidate is currently under internal development with preclinical testing expected to begin in late calendar year 2016. We will likely pursue regulatory approval 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, or PHSA, for approval of BLAs. However, the application process and requirements for approval of BLAs are very similar to those for NDAs.

Target Markets

We believe that the industry dynamics in the areas of dermatology and women's health represent significant opportunities for innovative new products to emerge as attractive solutions for unmet needs in multi-billion dollar therapeutic categories. In particular, we believe that both the dermatology and women's health markets are large specialty markets with significant global patient demand, and we believe that our focus on these markets coupled with our proprietary platform technologies should enable us to develop and commercialize attractive products within these categories. We have one commercially marketed product, VI_2OLET, which targets the specific indication of periodic breast pain associated with fibrocystic breast condition, or FBC, and cyclic mastalgia. We are building our product portfolio to include a topical acne drug for the treatment of moderate to severe acne.

Strategy and Competitive Strengths

We believe that the combination of our proprietary platform technologies and the expertise of our team in the areas of product development and commercialization, for both OTC and prescription products, are the core elements driving our company. The key elements of our corporate strategy and the competitive advantages we believe these elements provide us include the following:

- patented platform technologies;
- potentially shorter time to market for product introductions;
- bifurcated market penetration;
- opportunistic commercialization;
- efficient advancement of early-stage product candidates into late- stage development;
- strategic partnerships, joint development and licensing; and
- continued development of committed, experienced employees and relationships with members of the women's health and 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 a strong 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. In addition to an aggressive licensing strategy, we have several pending patent applications related to our novel iodine-based technologies for women's health and topical compositions for dermatological conditions. We have both United States provisional and utility patent applications pending. We also have pending international patent applications, which were filed according to the Patent Cooperation Treaty and which enable us to apply for patent protection for the described inventions in key individual countries in the future.

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. The licensed patents have expiration dates between 2017 and 2029.

Trademarks

We have applied for trademark protection for several trademarks in the United States. The United States Patent and Trademark Office has registered several of our trademarks: "VIOLET," "VI_2OLET," "BIOPHARMX," and "GET IT OFF YOUR CHEST." We have received a Notice of Allowance from the United States Patent and Trademark Office for our applications for other trademarks. A trademark application for the VI_2OLET logo has been accepted by the examiner and published for opposition.

We have also applied for trademark protection in two markets outside the United States. In the European Union, we have a pending trademark application for "BIOPHARMX" and a registered trademark for "VI_2OLET." In China, we have pending trademark applications for five trademarks, which include BIOPHARMX, VIOLET IODINE and the VI_2OLET logo.

Strategic Alliances and Partnerships

As part of our business strategy, we augment our internal development efforts by establishing strategic partnerships and/or alliances with third parties that have technologies, patents or other know-how that we believe will be additive to our internal efforts in the areas of women's health and dermatology.

Iogen

We have executed collaboration and licensing agreements with Iogen, a biotechnology company with iodine-based solutions and associated intellectual property. Our molecular iodine OTC dietary supplement, VI_2OLET, and the development of our molecular iodine prescription product, BPX03, build upon this licensed technology and its associated intellectual property. Under the terms of the agreement, we received an exclusive, worldwide, perpetual, irrevocable license to Iogen's patented technology relating to an oral iodine tablet. In consideration of the license granted under the agreement, we agreed to pay to Iogen a non-refundable license issue fee of $150,000, which we paid in full, and 30% of net profit associated with direct commercialization of an OTC iodine tablet product or 30% of net royalties received from any sub- licensee. For other products developed and commercialized using licensed technology and associated intellectual property covered by this agreement, including a prescription iodine tablet, we agreed to pay to Iogen a royalty of 3% of net sales for the first 12 months of commercialization and 2% of net sales thereafter.

NuTech

We have executed a collaboration and supply agreement with NuTech Medical, Inc., or NuTech, a biologics company specializing in the spinal and orthopedics markets. This agreement describes the collaboration between NuTech and us to develop products in the field of dermatology. Products and intellectual property developed under this agreement are exclusively owned by us and licensed to NuTech for use in indications outside of dermatology. In exchange for an exclusive license to NuTech's intellectual property in the field of dermatology, we will pay to NuTech a royalty of 3% of net sales on products sold in the field of dermatology. In exchange for granting NuTech an exclusive license to our intellectual property and intellectual property developed in collaboration with NuTech in indications outside of dermatology, we will receive from NuTech a royalty of 3% of net sales on products they sell.

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, 2016 and December 31, 2014 were approximately $5.7 million and $2.5 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 in place a commercial supply agreement with UPM Pharmaceuticals, or UPM, to manufacture and package our VI_2OLET tablets. UPM provides high-quality 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. Our joint development agreement with NuTech specifies that NuTech will supply materials for certain of our dermatological products.

Marketing, Sales & Distribution

Our team has experience in the commercialization of consumer products within channels such as drug stores, grocery stores, wholesalers, department stores, mass merchants and specialty retailers. We have experience in branding and launching products in the United States, Europe and Asia, our team has a deep understanding of channel strategies that include branded, private label and licensed product strategies.

VI_2OLET is sold through online stores, drug stores, grocery stores and specialty pharmaceutical retail chains throughout the United States. Our product launch for VI_2OLET is supported by a marketing program, including in-store merchandising, a digital strategy focused on education and activation, public relations events and traditional media to drive awareness and a physician and pharmacist sampling and trial program.

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

FBC and Cyclic Mastalgia

Our competitors, typically large pharmaceutical companies, vary from product to product. 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 and, if approved, BPX03, are innovative products that provide new treatment options 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 methylanthine 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.

The following figure presents a typical treatment algorithm for FBC given the current/limited options available to physicians.

Fibrocystic Breast Condition Treatment Algorithm
Phase 4 Administration of Hormone Based Treatments Danocrine Tamoxifen Bromocriptine
Phase 3 Prescription Treatment Analgesics
Phase 2 Nutritional Supplement Administration Evening primrose oil (gamma-linolenic acid)
Phase 1 Dietary Changes Low fat diet Abstention from caffeine and methylanthine

Symptom severity increases

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.

Acne

While the acne market has a number of competitive products, BPX01 is being developed to combine the most successful oral antibiotic drug for the treatment of moderate-severe acne (minocycline) 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, Bayer Healthcare, Galderma S.A., Pfizer, Pharmacia, Teva and Valeant. Additionally, there are several prescription acne products that exist in topical form such as antimicrobials, retinoids, or some combination of the two. These topical solutions are marketed by companies such as Allergan, Galderma S.A., GlaxoSmithKline, Mylan 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 combination of IPL and radiofrequency devices, elos, by Syneron. 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.

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.

Dietary supplements are also regulated by various governmental agencies for the states and localities in which product are sold. 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, or NAD, of the Council of Better Business Bureaus 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 U.S. 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 U.S. 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 a draft guidance document in July 2011 that clarifies when the FDA believes a dietary ingredient is an NDI, when a manufacturer or distributor must submit an NDI premarket notification 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 is extremely broad and seems to imply that virtually every new dietary supplement requires a premarket notification. Although the industry and Congress have objected to and questioned the FDA's interpretations of law set forth in the draft guidance, and the FDA has committed to issuing a new version of the draft guidance, it is unclear when the FDA will issue the new draft guidance and whether the FDA will make

significant changes to the draft guidance. 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 U.S. that are imported for sale into the U.S. 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.

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 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 U.S. 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 the NAD and states Attorney Generals, 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, 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 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 investigational new drug 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 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 rare 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.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2,374,000 for fiscal year 2016, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding $114,000 per product and $585,000 per establishment for fiscal year 2016. These fees are typically increased annually.

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

typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMPs is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

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

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

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

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new

indication being studied has been approved. 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, pre-clinical 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 is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

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

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 US 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. Only one biosimilar and no interchangeable products have been approved under the BPCIA to date. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation and 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 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 non-clinical 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 European Union, 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, which will be no earlier than May 28, 2016.

The new Regulation (EU) No 536/2014 aims to simplify and streamline the approval of clinical trial in the European Union. 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.
- 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 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 European Union, 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 Authorisations 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.

- 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 Paediatric 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 European Union 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, or MAH, 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 European Union, 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 European Union. 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 European Union, 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.

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 European Union, 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 European Union 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 considerably 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.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. 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, 2016, we had 30 employees, all of whom were full time. We had 10 employees in research and development. We had 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 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. While VI_2OLET has been on the market since December 2014 in online stores and drug, grocery and retail chains throughout the United States, we have never been profitable and, as of January 31, 2016, we had an accumulated deficit of $26.2 million and incurred net losses of $15.6 million and $7.8 million in the years ended January 31, 2016 and December 31, 2014, 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.

Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates, in particular BPX01 and BPX03.

Our portfolio of product candidates includes two clinical-stage drug product candidates, BPX01, a topical antibiotic for the treatment of acne, and BPX03, a molecular iodine tablet for the treatment of moderate to severe, periodic breast pain associated with FBC and cyclic mastalgia. The success of our business, including our ability to finance our company and generate revenues in the future, will primarily depend on the successful development, regulatory approval and commercialization of these clinical-stage 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;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to (i) manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, (ii) remain in good standing with regulatory agencies and (iii) develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMPs;
- a continued acceptable safety profile during clinical development and subsequent to approval of our product candidates or any future product candidates, if any;
- our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries or territories, whether alone or in collaboration with others;
- acceptance by physicians and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;

- our ability to avoid third-party patent interference or intellectual property infringement claims; and

- our ability to in-license or acquire additional product candidates or commercial-stage products that we believe 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.

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 its report on our consolidated financial statements for the year ended January 31, 2016, for the one month ended January 31, 2015 and for the year ended December 31, 2014 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, 2016 and December 31, 2014 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.

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 of approximately $15.6 million and $7.8 million for the years ended January 31, 2016 and December 31, 2014, respectively. At January 31, 2016, we had cash and cash equivalents of $4.0 million and significant liabilities and obligations. Absent additional funding, we believe that our cash will be sufficient to fund our operations only for a relatively short period of time, even including the net proceeds from our public offering in April 2016 and assuming Korea Investment Partners Overseas Expansion Platform Fund ("KIP"), an existing stockholder, purchases 1,081,081 shares of common stock from us at a price of $1.85 per share pursuant to a subscription agreement (the "subscription agreement") dated October 24, 2014 ("KIP private placement"). Pursuant to the subscription agreement, KIP shall purchase shares in the KIP private placement upon the earlier to occur of (i) the company receiving revenues from Violet of $2,000,000 or (ii) receipt by the company of approval to list on any tier of the NYSE or Nasdaq stock market at a market price of at least $3.70 per share. In addition, KIP has previously informed the company of its

intention to complete the KIP private placement even if the company's stock price was not at least $3.70 per share. The development of our business will require substantial additional capital in the future to commercialize our VI_2OLET product and 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 private sales of our equity or debt securities, in addition to a public offering, to fund our operations. We currently have no credit facility or committed sources of capital, other than the KIP private placement. If we do not complete the KIP private placement, we will need to obtain additional financing sooner than expected. 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. We are unable to predict when and if the KIP private placement will be closed and funds received.

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.

We have a limited operating history and have yet to recognize more than a de minimis amount of revenue from sales of VI_2OLET 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_2OLET 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.

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 VI_2OLET or our product candidates, if approved, or generate product revenue.

The near-term growth of our product revenues heavily relies on VI_2OLET. We launched our product in December 2014 in online stores and in drug, grocery and retail chains throughout the United States. We have devoted substantial resources to the development of VI_2OLET. The success of our commercialization of VI_2OLET is a key component of our business growth over the next few years. To successfully commercialize VI_2OLET and 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;
- 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 VI_2OLET and 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 VI_2OLET and product candidates, should they receive approval, which may vary significantly;
- potential side effects of VI_2OLET and 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 VI_2OLET and product candidates;
- our ability to establish and maintain an effective sales, marketing and distribution infrastructure;
- market acceptance of VI_2OLET and product candidates, if approved, and our ability to forecast demand for VI_2OLET and those product candidates;
- our ability to receive approval and commercialize VI_2OLET and our product candidates outside of the United States;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- 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.

We rely on a single, qualified supplier to manufacture our products.

Currently, we rely on one third-party manufacturer for our product manufacturing needs. UPM, a division of Gregory Pharmaceutical Holdings, Inc., manufactures solid dose iodine supplement tablets for VI_2OLET. UPM is required by law to comply with the FDA's regulations, including the cGMP regulations for dietary supplements. 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, UPM is contractually obligated to comply with all applicable laws and regulations. However, we cannot guarantee that UPM will so comply. Failure of UPM to maintain compliance with applicable laws and regulations could result in decreased sales of our products, decreased revenues and reputational harm to us and may subject us to sanctions by the FDA, including 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.

Our manufacturing contract is a short-term agreement. We are dependent upon renewing agreements with UPM or finding replacement manufacturers to satisfy our requirements. If we do not renew our agreement with UPM, there can be no assurance that we will be able to find or engage a replacement manufacturer on a timely basis, on acceptable terms, or 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 manufacturer 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 manufacturer 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.

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

As of January 31, 2016, we had NOL carryforwards available to reduce future taxable income, if any, for federal and California state income tax purposes of $19.4 million and $19.4 million, respectively. 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 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

Our only commercialized product, VI_2OLET, is subject to regulation by U.S. regulatory authorities.

Our first and only commercialized product, launched in December 2014, is our women's health dietary supplement distributed under the brand name "VI_2OLET" iodine. The processing, formulation, safety, manufacturing, packaging, labeling, advertising and distribution of VI_2OLET is subject to federal laws and regulation by one or more federal agencies, including the FDA, the Federal Trade Commission, or FTC, the Consumer Product Safety Commission, or 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 the National Advertising Division of the Council of Better Business Bureaus ("NAD"). 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.

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 VIO_2LET may be alleged to be non-compliant with FDA 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 advent 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 VI_2OLET. 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 July 2011, the FDA issued 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.

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 BPX01, BPX02, BPX03 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 such as BPX01 or BPX03, or a new biological product such as BPX02, 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. For example, Phase 2 studies may be conducted in populations that may differ from those in Phase 3 trials and may be conducted using endpoints or measures that differ from those used in later clinical trials. For example, the Phase 2 trial of BPX03 conducted by the prior sponsor used the Lewin pain scale, which was not a validated patient-reported outcome instrument, or PRO, and which the FDA suggested not be used to assess the primary efficacy endpoint in Phase 3 trials. In addition, despite positive results from the Phase 2 trial of BPX03 comparing the 3.0 mg and 6.0 mg doses to the 1.5 mg dose and placebo on the Lewin pain scale, a Phase 3 clinical trial for BPX03, was not completed due to insufficient funds of the prior sponsor and did not meet any of its primary or secondary efficacy endpoints. Accordingly, regardless of the outcome of any Phase 2 trials, our Phase 3 trials may not be successful.

In the case of our topical product candidate, BPX01, 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 is very 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 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 accptable 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 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 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 BPX03 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.

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 BPX01, BPX03 or our early-stage 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 BPX01 and BPX03, 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.

We are currently developing one product candidate, BPX01, for which we intend to seek FDA approval through the Section 505(b)(2) regulatory pathway, and may decide to seek FDA approval for 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 is a topical formulation 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 route of administration and dosage form, however, differs 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, 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 Solodyn, the listed drug we intend to reference in our NDA. There are currently five 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.

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, 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, we intend to use PROs in our planned Phase 3 clinical program for BPX03 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 never conducted a clinical trial or obtained approval of any product candidates, and may be unable to do so successfully.

As a company, we have no 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 recently enacted 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 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 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, 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 dematological and women's health—related issues have received limited or no reimbursement coverage by insurers and, accordingly, coverage for BPX03 and BPX01, 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.

BPX01 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 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. 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 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

Future discovery and preclinical development collaborations may be important to us. If we are unable to 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. 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. 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.

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. We are highly dependent on our management and scientific personnel, including: our Chief Executive Officer, James R. Pekarsky; our President and Secretary, Anja Krammer; our Executive Vice President of Research & Development, 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 the 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 at 1098 Hamilton Court, Menlo Park, California. If this or any future facility were to be damaged, destroyed or otherwise 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 workers 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 women's health and dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not currently own or license issued patents covering all of the recent developments in our technology and we are unsure of the extent to which we will obtain adequate patent protection, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. In particular, due to the extensive prior art relating to antibiotics for topical acne and iodine for breast health and because BPX01 and BPX03 represent forms of such therapies, respectively, the patent protection available for BPX01 and BPX03 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 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 were 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

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 success of, and fluctuations in, the commercial sales of VI_2OLET and any product candidates approved for commercialization in the future;
- the development status of our product candidates, including whether any of our product candidates receive regulatory approval;
- 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;
- our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these 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 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 market 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 MKT, 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 have instituted securities class action litigation following periods of market volatility. If we

were 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. 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 as of December 31, 2014 and January 31, 2016. 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.

Our accounting staff at January 31, 2015 consisted of an accounting manager and an interim controller who was working full-time during quarterly reporting periods. The limited staff did not allow for effective internal control over financial reporting due to the lack of adequate segregation of duties and insufficient secondary review of GAAP related to the accounting for warrants, convertible notes payable and convertible redeemable preferred stock, accounting for stock-based compensation and the recording of liabilities in the appropriate reporting period commensurate with our financial reporting requirements. As a result, adjustments identified as part of the audit process were necessary to completely and accurately present the consolidated financial statements in accordance with GAAP. Consequently, post-closing adjustments during the year ended December 31, 2014 included increases to current liabilities, stockholders' deficit and net loss of approximately $69,000, $286,000 and $334,000, respectively, and a decrease to convertible redeemable preferred stock of approximately $289,000. Post-close entries for the one-month transition period ended January 31, 2015 included decreases to current liabilities and net loss of approximately $261,000 and $117,000, respectively. No post-close entries were recorded for the year ended January 31, 2016.

As of the date hereof, we have not remediated these material weaknesses. Subsequent to January 31, 2015, we have hired a controller, who is a certified public accountant, and a Chief Financial Officer. Both have extensive public company experience. To better manage our internal systems and controls, effective beginning the third fiscal quarter of 2016, we implemented an enterprise resource planning system throughout the company. We are continuing to adopt and implement written policies and procedures for accounting and financial reporting. We plan to hire additional qualified personnel to address inadequate segregation of duties, although the timing of such hires is largely dependent on our securing additional financing to cover such costs. The implementation of these initiatives may not fully address any material weakness or other deficiencies that we may have in our internal control over financial reporting.

Even if we develop effective internal control over financial reporting, such controls may become inadequate due to changes in conditions or the degree of compliance with such policies or procedures may deteriorate, which could result in the discovery of additional material weaknesses and deficiencies. In any event, the process of determining whether our existing internal control over financial reporting is compliant with Section 404 of the Sarbanes-Oxley Act, or Section 404, and sufficiently effective requires the investment of substantial time and resources, including by our Chief Executive Officer and other members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete. In addition, we cannot predict the outcome of this process and whether we will need to implement remedial actions in order to establish effective controls over financial reporting. The determination of whether or not our internal controls are sufficient and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. We may also fail to timely complete our evaluation, testing and any remediation required to comply with Section 404.

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

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

As a newly-listed company on the NYSE MKT, we incurred and will continue to incur significant legal, accounting and other expenses that we did not incur before when trading on the OTCQB Marketplace. For example, we are subject to the rules and regulations required by the NYSE MKT, 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 MKT.

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, including pursuant to our equity incentive plans or otherwise, could result in dilution to the percentage ownership of our stockholders and could cause our stock price to fall.

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, convertible securities or other equity securities

in one or more transactions at prices and in a manner we determine from time to time. If we sell additional common stock, convertible securities or other equity securities, investors in a prior transaction may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. Further, any future sales of our common stock by us or resale of our common stock by our existing stockholders could cause the market price of our common stock to decline. Moreover, we have registered all shares of common stock that we may issue under our equity compensation plan and may issue additional shares upon the exercise of warrants. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

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 45% of our outstanding common stock as of January 31, 2016. 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.

In addition, investment vehicles of Franklin Advisers collectively hold approximately 16% of the aggregate voting power of the Company as of January 31, 2016. Investment vehicles of Franklin Advisers purchased additional common stock and warrants to purchase our common stock in our public offering in April 2016, resulting in their aggregate voting power remaining at approximately 16%. Investment vehicles of Franklin Advisers could acquire up to 25% in the aggregate of the voting power through open-market purchases of our common stock. Franklin Advisers could have considerable influence over matters such as approving a potential acquisition of us. Franklin Adviser's investment 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 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 1098 Hamilton Court, Menlo Park, California 94025, where the we occupy 10,800 sq. ft. of research and development and administration facilities that are nearby to external formulation, clinical and pre-clinical testing facilities. Our lease expires in November 2016. 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 the lease in November 2016.

ITEM 3. LEGAL PROCEEDINGS

We may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. In addition, we may receive letters alleging infringement of patents or other intellectual property rights. We are not a party to any material legal proceedings, nor are we aware of any pending or threatened litigation that 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 MKT under the symbol "BPMX." Prior to June 25, 2015, our common stock was traded on the OTCQB Marketplace 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 MKT or www.otcmarkets.com, as applicable.

	High	Low
Fiscal Year Ended January 31, 2016:		
First Quarter	$ 3.50	$ 2.00
Second Quarter (through June 24)	$ 4.50	$ 2.50
Second Quarter (after June 24)	$ 2.85	$ 1.82
Third Quarter	$ 2.25	$ 0.91
Fourth Quarter	$ 2.75	$ 0.99
One month ended January 31, 2015	$ 3.00	$ 2.75
Fiscal Year Ended December 31, 2014:		
First Quarter	$ 0.15	$ 0.15
Second Quarter	$ 0.15	$ 0.15
Third Quarter	$ 3.00	$ 0.15
Fourth Quarter	$ 3.50	$ 2.01

As of April 1, 2016, there were approximately 101 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.

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 women's health and dermatology. 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 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 taking advantage of the abbreviated regulatory pathway available for reformulated drugs that are bioequivalent to FDA-approved products. Our current platform technologies include innovative delivery mechanisms for molecular iodine and antibiotics.

Since our inception, we have devoted substantially all of our efforts to developing 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 and are expanding into retail pharmacies, specialty pharmacy and grocery chain outlet stores throughout the United States. To-date we have not generated a significant amount of revenue from product sales while we focus on building market awareness for our product. We are not dependent on sales to any one customer. We have financed our operations primarily through the sale of equity and convertible debt securities. In June 2015, we raised net proceeds of $7.8 million through the sale of our common stock and concurrently completed an uplisting to the NYSE MKT. In December 2015 we raised net proceeds of $5.5 million in a private offering of our common stock and, in April 2016, we raised net proceeds of approximately $3.6 million from the issuance of common stock and warrants to purchase common stock in a public offering.

Results of Operations

Change in Fiscal Year End

On March 26, 2015, our board of directors approved a change in our fiscal year end from December 31 to January 31. As a result of this change we previously filed a transition report on Form 10-KT for the one-month transition period ended January 31, 2015. References to any previous fiscal years mean the fiscal years ending on December 31.

Fiscal Years Ended January 31, 2016 and December 31, 2014, Months Ended January 31, 2015 and 2014

Revenue

Year ended January 31, 2016	Year ended December 31, 2014	Change	%	One month ended January 31, 2015	One month ended January 31, 2014 (unaudited)	Change	%
			($ in thousands)				
$ 64	$ —	$ 64	*	$ 1	$ —	$ 1	*

* Not meaningful

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. During 2016, our revenues increased as we expanded into retail pharmacies, specialty pharmacy and grocery chain outlet stores in the United States and increased adoption by consumers.

Cost of Goods Sold

Year ended January 31, 2016	Year ended December 31, 2014	Change	%	One month ended January 31, 2015	One month ended January 31, 2014 (unaudited)	Change	%
			($ in thousands)				
$ 237	$ —	$ 237	*	$ 1	$ —	$ 1	*

* Not meaningful

Cost of goods sold includes direct costs related to the sale of VI_2OLET, our iodine dietary supplement, which began in January 2015, write-downs of excess and obsolete inventories and amortization of our intangible assets. The increase in cost of goods sold of $237,000 for the year ended January 31, 2016 compared to the year ended December 31, 2014 is primarily related to the increase in recognized revenue related to our product, inventory reserves and other manufacturing costs.

Research and Development Expenses

Year ended January 31, 2016	Year ended December 31, 2014	Change	%	One month ended January 31, 2015	One month ended January 31, 2014 (unaudited)	Change	%
			($ in thousands)				
$ 5,702	$ 2,519	$ 3,183	126%	$ 365	$ 103	$ 262	254%

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 increased $3.2 million for the year ended January 31, 2016 compared to the year ended December 31, 2014 primarily due to increased headcount, consulting, preclinical and clinical studies, and regulatory expenses. We increased staffing to help with the logistics, final testing and meeting regulatory standards related to VI_2OLET, as well as for progressing our BPX01 candidate from preclinical formulation to pilot production in preparation for Phase 2a trials.

Research and development expenses associated with our molecular iodine project for the years ended January 31, 2016 and December 31, 2014 were $1.3 million and $0.9 million, respectively. The

increase was primarily due to increased consulting and regulatory expenses. We have commenced an IRB study for our molecular iodine project in preparation for Phase 3 trials.

Research and development expenses for our BPX01 product candidate for the years ended January 31, 2016 and December 31, 2014 were $4.1 million and $1.7 million, respectively. The increase was primarily due to increased consulting and clinical trial costs. We initiated our first Phase 2a clinical trial under an IND application with the FDA in the first quarter of 2017. We expect research and development expenses related to BPX01 to continue to increase period over period, primarily due to the ramping of clinical trial costs.

Research and development expenses increased $262,000 for the one month ended January 31, 2015 compared to 2014. This increase was primarily due to an increase in headcount-related and consulting costs.

Sales and Marketing Expenses

Year ended January 31, 2016	Year ended December 31, 2014	Change	%	One month ended January 31, 2015	2014 (unaudited)	Change	%
			($ in thousands)				
$ 5,109	$ 2,299	$ 2,810	122%	$ 378	$ 73	$ 305	418%

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. Sales and marketing expenses are expensed as incurred.

Sales and marketing expenses increased $2.8 million for the year ended January 31, 2016 compared to the year ended December 31, 2014 primarily due to higher headcount, market research, advertising and stock-based compensation expenses, partially offset by lower consulting expenses. Following the launch of VI_2OLET, we have been focusing on increasing customer awareness of the product through multi-media advertising campaigns and participation in tradeshows, as well as increasing awareness among medical professionals through a national physician sampling and trial progam.

Sales and marketing expenses increased $305,000 for the month ended January 31, 2015 compared to 2014. This increase was primarily due to the ramp up in marketing and sales efforts to launch VI_2OLET, including the hiring of employees and use of outside agencies.

General and Administrative Expenses

Year ended January 31, 2016	Year ended December 31, 2014	Change	%	One month ended January 31, 2015	2014 (unaudited)	Change	%
			($ in thousands)				
$ 4,174	$ 2,953	$ 1,221	41%	$ 401	$ 165	$ 236	143%

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 $1.2 million for the year ended January 31, 2016 compared to the year ended December 31, 2014 primarily due to higher headcount, compliance costs of being a new publicly-traded company, and legal and insurance expenses, and was partially offset by lower consulting expenses.

General and administrative expenses increased $236,000 for the month ended January 31, 2015 compared to 2014. This increase was primarily due to the cost of the Share Exchange and overhead related to being a publicly-traded company.

Other Income (Expense), net

Year ended January 31, 2016	Year ended December 31, 2014	Change	%
	($ in thousands)		
$ (436)	$ 40	$ 476	*

* Not meaningful

For the year ended January 31, 2016, other income and expenses primarily included an expense related to the modification of warrants and other miscellaneous items. There were no other income and expenses recorded for the months ended January 31, 2015 and 2014.

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, 2016	One month ended January 31, 2015	Year ended December 31, 2014
Net cash used in operating activities	$ (12,614)	$ (844)	$ (6,001)
Net cash used in investing activities	(38)	—	(263)
Net cash provided by financing activities	15,386	38	8,372
Net increase (decrease) in cash and cash equivalents	$ 2,734	$ (806)	$ 2,108

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

	As of January 31, 2016	As of January 31, 2015
Current assets	$ 4,431	$ 1,705
Current liabilities	2,797	1,557
Working capital	$ 1,634	$ 148

As of January 31, 2016, we had cash and cash equivalents of $4.0 million and working capital of $1.6 million. In June 2015, we completed a public offering of common stock, which generated net proceeds of $7.8 million. We also issued an unsecured convertible note with a principal amount of $0.5 million, which was automatically converted into common stock upon our uplisting to the NYSE MKT. In December 2015 we raised net proceeds of $5.5 million in a private offering of our common stock and, in April 2016, we raised net proceeds of approximately $3.6 million from the issuance of common stock and warrants to purchase common stock in a public offering.

During the year ended December 31, 2014, we raised net proceeds of $7.3 million upon the completion of the private placement of shares of Series A preferred stock and warrants to purchase common stock. The private placement was consummated in a series of closings that occurred between April 2014 and November 2014.

In addition, KIP has previously informed the company of its intention to complete the KIP private placement even if the company's stock price was not at least $3.70 per share. As of May 2, 2016, the KIP private placement has not closed, and we are unable to predict if or when the private placement will close.

Our primary capital requirements are to fund working capital, including the development of our products, 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, 2016 was $12.6 million, which primarily resulted from a net loss of $15.6 million, partially offset by non-cash expense of $1.7 million and changes in operating assets and liabilities of $1.2 million. Changes in operating assets and liabilities were primarily attributable to purchases of inventory and timing of payments to vendors.

Net cash used for operating activities for the month ended January 31, 2015 was $844,000, which was primarily due to a net loss of $1.1 million, partially offset by changes in operating assets and liabilities of $199,000 and stock-based compensation of $99,000.

Net cash used for operating activities for the year ended December 31, 2014 was $6.0 million, which was primarily due to a net loss of $7.8 million, partially offset by changes in operating assets and liabilities of $413,000, non-cash interest expense of $76,000, warrants issued for $99,000 and stock-based compensation of $1.2 million. Changes in operating assets and liabilities were primarily attributable to purchases of inventory and timing of payments to vendors.

Net cash used for investing activities for the year ended January 31, 2016 was $38,000, which was for the purchase of property and equipment. No cash was used in investing activities during the month of January 31, 2015. Net cash used for investing activities for the year ended December 31, 2014 was $263,000, which was primarily for the acquisition of intellectual property and purchase of property and equipment.

Net cash provided by financing activities for the year ended January 31, 2016 was $15.4 million, which was due to $7.8 million of net proceeds from the sale of common stock in our public offering, $5.5 million of net proceeds from the sale of common stock in a private placement, $1.6 million from the exercise of stock options and warrants and $0.5 million from the issuance of a convertible note. Net cash provided by financing activities for the month ended January 31, 2015 was $38,000, which included proceeds from the exercise of stock options. Net cash provided by financing activities for the year ended December 31, 2014 was $8.4 million, which was primarily due to net proceeds of $7.3 million from issuing Series A preferred stock, $1.0 million from issuing convertible notes payable and $0.1 million from the exercise of stock options.

Subsequent Events

In April 2016, we raised net proceeds of approximately $3.6 million, after expenses of approximately $0.7 million, excluding any proceeds for warrant exercises, from the issuance of 3,600,000 shares of common stock and 1,952,000 warrants to purchase common stock in an equity offering under shelf registration statement.

Going Concern

As reflected in the accompanying financial statements, the financial statements have been prepared assuming we will continue as a going concern. We have a limited operating history and our prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the industry. Our ability to generate income in the short-run will depend greatly on the rate of adoption and ability to establish a sustainable market for VI_2OLET. We plan to continue our research and development efforts for our products, which will require significant funding. If revenues fall short of expectations or research and development efforts require higher than anticipated capital, then there may be a negative impact on the financial viability of the Company.

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 offerings and the issuance

of convertible notes, Series A convertible redeemable preferred stock and warrants. In June 2015, we raised net proceeds of $7.8 million in a public offering of our common stock. In December 2015, we raised net proceeds of $5.5 million in a private offering of our common stock and, in April 2016, we raised net proceeds of approximately $3.6 million, from an issuance of common stock and warrants to purchase common stock in a public offering.

We plan to increase working capital by managing our cash flows and expenses, securing financing and increasing revenue. We continue to pursue additional channel distribution expansion for VI_2OLET to provide even 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 $100 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. Failure to generate sufficient cash flows from operations, raise additional capital 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.

As shown in the accompanying consolidated financial statements, we have incurred a net loss available to common stockholders of $16.0 million during the year ended January 31, 2016, and had an accumulated deficit of $26.2 million as of January 31, 2016. As of January 31, 2016, we had working capital of approximately $1.6 million. While we believe we have a plan to fund ongoing operations, there is no assurance that our plan will be successfully implemented.

Recent Accounting Pronouncements

In July 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-11, Inventory (Topic 330), Simplifying the Measurement of Inventory, which applies to all inventory except that which is measured using last-in, first-out (LIFO) or the retail inventory method. Inventory measured using first-in, first-out (FIFO) or average cost is included in the new amendment. The amendment will take effect for public business entities for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. We are in process of evaluating the impact of adoption on our consolidated financial statements.

In August 2015, FASB issued Accounting Standards Update No. 2015-14, Revenue from Contracts with Customers (ASU No. 2014-09). This update defers the effective dates of ASU No. 2014-09 (originally issued in June 2014) for public business entities by one year, or until annual reporting periods beginning after December 15, 2017, including interim reporting periods within the reporting period. ASU No. 2014-09 gives entities a single comprehensive model to use in reporting information about the amount and timing of revenue resulting from contracts to provide goods or services to customers. The proposed ASU, which would apply to any entity that enters into contracts to provide goods or services, would supersede the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance throughout the Industry Topics of the Codification. Additionally, the update would supersede some cost guidance included in Subtopic 605-35, Revenue Recognition—Construction-Type and Production-Type Contracts. The update removes inconsistencies and weaknesses in revenue requirements and provides a more robust framework for addressing revenue issues and more useful information to users of financial statements through improved disclosure

requirements. In addition, the update improves comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. We are continuing to review the provisions of this ASU to determine if there will be any impact on our results of operations, cash flows or financial condition.

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 August 2014, FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40). This ASU provides guidance to determine when and how to disclose going-concern uncertainties in the financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date that the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. This standard is effective for annual periods ending after December 15, 2016. We are evaluating the impact of the adoption of this ASU on our consolidated financial statements.

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

Our significant accounting policies are summarized in Note 1 of our audited consolidated financial statements. While all these significant accounting policies impact our financial condition and results of operations, we view certain of these 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 and such differences may be material to the financial statements. Our management believes that given current facts and circumstances, it is unlikely that applying any other reasonable judgments or estimate methodologies would have 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

VI_2OLET is a new product in the dietary supplement field. 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, calculability 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 excess and obsolete inventory when appropriate.

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 fiscal years ended January 31, 2016 and 2015 and December 31, 2014, 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, 2016. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer 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 Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Based upon that evaluation, our Chief Executive Officer 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, 2016 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, 2016, 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.

In fiscal year 2016, we hired a controller, who is a certified public accountant, and a Chief Financial Officer. Both have extensive public company experience. To better manage our internal systems and controls, effective beginning the third quarter of fiscal year 2016, we implemented an enterprise resource planning system throughout the Company.

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, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information regarding our directors and corporate governance will be presented in our definitive proxy statement for our 2016 Annual Meeting of Stockholders to be held on or about June 15, 2016, which information is incorporated into this report by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information required to be provided in response to this item will be presented in our definitive proxy statement for our 2016 Annual Meeting of Stockholders to be held on or about June 15, 2016, which information is incorporated into this report by reference.

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

Information required to be provided in response to this item will be presented in our definitive proxy statement for our 2016 Annual Meeting of Stockholders to be held on or about June 15, 2016, which information is incorporated into this report by reference.

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

Information required to be provided in response to this item will be presented in our definitive proxy statement for our 2016 Annual Meeting of Stockholders to be held on or about June 15, 2016, which information is incorporated into this report by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required to be provided in response to this item will be presented in our definitive proxy statement for our 2016 Annual Meeting of Stockholders to be held on or about June 15, 2016, which information is incorporated into this report by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Financial Statements and Schedules

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 and schedules are filed as part of this Annual Report on Form 10-K.

(b) Exhibits

See the Exhibit Index immediately following the signature page of this Annual Report on Form 10-K.

BIOPHARMX CORPORATION
CONSOLIDATED FINANCIAL STATEMENTS
Year ended January 31, 2016, month ended January 31, 2015 and year ended December 31, 2014

CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
BioPharmX Corporation

We have audited the accompanying consolidated balance sheets of BioPharmX Corporation and its subsidiary (the "Company") as of January 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, convertible redeemable preferred stock and stockholders' equity (deficit), and cash flows for the year ended January 31, 2016, the one-month period ended January 31, 2015, and the year ended December 31, 2014. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of BioPharmX Corporation and its subsidiary as of January 31, 2016 and 2015, and the results of their operations and their cash flows for the year ended January 31, 2016, the one-month period ended January 31, 2015 and the year ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America.

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.

/s/ Burr Pilger Mayer, Inc.

San Jose, California
May 2, 2016

BIOPHARMX CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	January 31, 2016	January 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,039	$ 1,305
Accounts receivable, net	7	1
Inventories	100	160
Prepaid expenses and other current assets	285	239
Total current assets	4,431	1,705
Property and equipment, net	216	234
Intangible assets, net	119	149
Other assets	50	50
Restricted cash	35	35
Total assets	$ 4,851	$ 2,173
LIABILITIES, CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,777	$ 1,152
Accrued liabilities and other current liabilities	795	187
Related party payables	225	218
Total current liabilities	2,797	1,557
Commitments and contingencies (Note 5)		
Series A convertible redeemable preferred stock, $0.001 par value; 10,000,000 shares authorized; none issued and outstanding as of January 31, 2016 and 4,207,987 issue and outstanding as of January 31, 2015 (liquidation preference of $8.0 million as of January 31, 2015)	—	6,823
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 90,000,000 shares authorized; 25,208,684 and 11,415,416 shares issued and outstanding as of January 31, 2016 and 2015, respectively	25	11
Additional paid-in capital	28,261	4,416
Accumulated deficit	(26,232)	(10,634)
Total stockholders' equity (deficit)	2,054	(6,207)
Total liabilities, convertible redeemable preferred stock and stockholders' equity (deficit)	$ 4,851	$ 2,173

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, 2016	One month ended January 31, 2015	Year ended December 31, 2014
Revenues, net	$ 64	$ 1	$ —
Cost of goods sold	237	1	—
Gross deficit	(173)	—	—
Operating expenses:			
Research and development	5,702	365	2,519
Sales and marketing	5,109	378	2,299
General and administrative	4,174	401	2,953
Total operating expenses	14,985	1,144	7,771
Loss from operations	(15,158)	(1,144)	(7,771)
Other income (expense), net	(436)	—	40
Interest expense	—	—	(76)
Loss before income taxes	(15,594)	(1,144)	(7,807)
Provision for income taxes	4	—	—
Net and comprehensive loss	(15,598)	(1,144)	(7,807)
Accretion on Series A convertible redeemable preferred stock	(202)	(43)	(163)
Deemed dividend on Series A convertible redeemable preferred stock	(201)	(50)	(159)
Net loss available to common stockholders	$ (16,001)	$ (1,237)	$ (8,129)
Basic and diluted net loss available to common stockholders per share	$ (0.89)	$ (0.11)	$ (0.80)
Shares used in computing basic and diluted net loss per share	17,950,000	11,408,000	10,217,000

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

BIOPHARMX CORPORATION

CONSOLIDATED STATEMENTS OF CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands, except share data)

	Series A Convertible Redeemable Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2014	—	$ —	7,025,000	$ 7	$ 306	$ (1,683)	$ (1,370)
Thompson Designs, Inc. common stock assumed in conjunction with Share Exchange	—	—	2,000,000	2	(2)	—	—
Issuance of convertible notes payable with beneficial conversion feature	—	—	—	—	204	—	204
Issuance of common stock due to exercise of options and release of awards		—	824,310	1	98	—	99
Issuance of warrants to non-employees		—			204	—	204
Conversion of convertible notes payable to common stock	—	—	1,526,001	1	1,846	—	1,847
Stock-based compensation	—	—	—	—	1,193	—	1,193
Issuance of preferred stock, related warrants and common stock	4,207,987	6,408			845	—	845
Interest on preferred stock		159			(159)	—	(159)
Accretion of stock issuance costs		163			(163)		(163)
Net and comprehensive loss	—	—	—	—	—	(7,807)	(7,807)
Balance at December 31, 2014	4,207,987	6,730	11,375,311	11	4,372	(9,490)	(5,107)
Stock-based compensation	—	—	—	—	99	—	99
Issuance of common stock due to exercise of options and release of awards		—	40,105	—	38	—	38
Interest on preferred stock		50	—	—	(50)	—	(50)
Accretion of stock issuance costs		43	—	—	(43)		(43)
Net and comprehensive loss	—	—	—	—	—	(1,144)	(1,144)
Balance at January 31, 2015	4,207,987	6,823	11,415,416	11	4,416	(10,634)	(6,207)
Issuance of common stock, net of expenses of $2,500	(4,207,987)	(7,226)	12,508,395	12	20,530	—	20,542
Issuance of common stock due to exercise of options	—	—	666,157	1	82	—	83
Issuance of common stock due to exercise of warrants		—	618,716	1	1,486	—	1,487
Expense related to the modification of warrants		—	—		436	—	436
Issuance of convertible notes payable	—	—	—	—	500	—	500
Stock-based compensation	—	—	—	—	1,214	—	1,214
Interest on preferred stock		201			(201)	—	(201)

Accretion of stock issuance costs		202			(202)		(202)
Net and comprehensive loss	—	—	—	—	—	(15,598)	(15,598)
Balance at January 31, 2016	—	—	25,208,684	$ 25	$ 28,261	$ (26,232)	$ 2,054

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, 2016	One month ended January 31, 2015	Year ended December 31, 2014
Cash flows from operating activities:			
Net loss	$ (15,598)	$ (1,144)	$ (7,807)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	1,214	99	1,193
Expense related to modification of warrants	436	—	—
Depreciation expense	56	1	25
Amortization expense	30	1	—
Warrants issued for services provided	—	—	99
Noncash interest expense	—	—	76
Changes in assets and liabilities:			
Accounts receivable	(6)	1	(2)
Inventories	60	(22)	(138)
Prepaid expenses and other assets	(46)	30	(133)
Accounts payable	625	666	257
Accrued expenses and other liabilities	608	(495)	355
Related party payables	7	19	74
Net cash used in operating activities	(12,614)	(844)	(6,001)
Cash flows from investing activities:			
Change in restricted cash	—	—	(35)
Purchases of property and equipment	(38)	—	(228)
Net cash used in investing activities	(38)	—	(263)
Cash flows from financing activities:			
Proceeds from the issuance of common stock, net of $2,500 issuance costs	13,316	—	—
Proceeds from exercises of stock options	83	38	99
Proceeds from exercises of common stock warrants	1,487	—	—
Net proceeds from issuance of convertible redeemable preferred stock and common stock warrants	—	—	7,253
Proceeds from issuance of convertible notes payable	500	—	1,020
Net cash provided by financing activities	15,386	38	8,372
Net increase (decrease) in cash and cash equivalents	2,734	(806)	2,108
Cash and cash equivalents at beginning of year	1,305	2,111	3
Cash and cash equivalents at end of year	$ 4,039	$ 1,305	$ 2,111
Non-cash investing and financing activities:			
Conversion of preferred stock to common stock	$ 7,226	$ —	$ —
Conversion of convertible notes payable to common stock	$ —	$ —	$ 1,847
Fair value of beneficial conversion feature issued in connection with convertible notes payable	$ —	$ —	$ 204
Issuance of common stock warrants in connection with convertible notes payable	$ —	$ —	$ 105
Supplemental disclosures:			
Income taxes paid	$ 4	$ —	$ —

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 women's health and dermatology. The Company's 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 suboptimal. The Company's strategy is designed to bring new products to market by identifying optimal delivery mechanisms and/or alternative applications for FDA-approved active pharmaceutical ingredients, or APIs, while in appropriate circumstances, reducing the time, cost and risk typically associated with new product development by repurposing drugs with demonstrated safety profiles, taking advantage of the regulatory approval pathway under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act available for repurposed/reformulated drugs. The Company believes the 505(b)(2) regulatory pathway may reduce drug development risk and could reduce the time and resources it spends during development.

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 at the end of 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 debt securities. In June 2015, the Company raised $7.8 million through the sale of its common stock in a public offering and concurrently completed an uplisting to the NYSE MKT. In December 2015 we raised net proceeds of $5.5 million in a private offering of our common stock and, in April 2016, we raised net proceeds of approximately $3.6 million from an issuance of common stock and warrants to purchase common stock in a public offering.

Share Exchange

On January 23, 2014, the Company (then operating as Thompson Designs, Inc.), BioPharmX, Inc. and stockholders of BioPharmX, Inc., who collectively owned 100% of BioPharmX, Inc., entered into and consummated transactions pursuant to a share exchange agreement, such transaction referred to as the Share Exchange, whereby the Company issued to the stockholders of BioPharmX, Inc. an aggregate of 7,025,000 shares of its common stock, in exchange for 100% of the shares of BioPharmX, Inc. held by stockholders. The shares of the Company's common stock received by the stockholders of BioPharmX, Inc. in the Share Exchange constituted approximately 77.8% of its then issued and outstanding common stock, after giving effect to the issuance of shares pursuant to the share exchange agreement. As a result of the Share Exchange, BioPharmX, Inc. became the Company's wholly-owned subsidiary. For accounting purposes, the Share Exchange was treated as a reverse acquisition with BioPharmX, Inc. as the acquirer and the Company as the acquired party, and as a result the historical financial statements prior to the Share Exchange included in this Annual Report on Form 10-K are the historical financial statements of BioPharmX, Inc. On March 3, 2014, the Company changed its name to BioPharmX Corporation. On May 16, 2014, the Company reincorporated from Nevada to Delaware.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Change in Fiscal Year End

On March 26, 2015, the board of directors of the Company approved a change in its fiscal year end from December 31 to January 31.

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. Deferred rent, accrued payroll and deferred revenue have been included in accrued liabilities and other current liabilities. 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' deficit or net loss.

Fair Value Measurements

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

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

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

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

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

As of January 31, 2016, the Company held $3.6 million 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.

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, 2016 or 2015.

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. The Company regularly reviews inventory quantities in consideration of actual loss experiences, projected future demand and remaining shelf life to record a provision for excess and obsolete inventory when appropriate.

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 and related party payables approximate fair value due to their short maturities.

Property and Equipment

Property, plant 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 detailed in Note 5. Amortization of the intangible assets commenced in January 2015 with the first recognition of revenue related to VI_2OLET and is being taken on a straight-line basis over 5 years.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 has not identified any such impairment losses to date.

Restricted Cash

The Company has restricted cash in the amount of $35,000 held in a money market account to secure the credit line of the Company's credit cards.

Revenue Recognition

VI_2OLET is a new product in the dietary supplement field. 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, calculability of the resulting receivable is reasonably assured, there are no customer acceptance requirements and we do 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 ("CROs"), consulting, materials, supplies, and facilities and other overhead allocations.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $1.2 million for year ended January 31, 2016, $90,000 for the one month ended January 31, 2015 and $68,000 for the year ended December 31, 2014.

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 year ended January 31, 2016, one month ended January 31, 2015 and year ended December 31, 2014, 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. 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.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

As of January 31, 2016, January 31, 2015 and December 31, 2014, 5,741,000, 9,793,000 and 9,713,000 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 July 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-11, Inventory (Topic 330), Simplifying the Measurement of Inventory, which applies to all inventory except that which is measured using last-in, first-out (LIFO) or the retail inventory method. Inventory measured using first-in, first-out (FIFO) or average cost is included in the new amendment. The amendment will take effect for public business entities for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company is in the process of evaluating the impact of adoption on the its consolidated financial statements.

In August 2015, FASB issued Accounting Standards Update No. 2015-14, Revenue from Contracts with Customers (ASU No. 2014-09). This update defers the effective dates of ASU No. 2014-09 (originally issued in June 2014) for public business entities by one year, or until annual reporting periods beginning after December 15, 2017, including interim reporting periods within the reporting period. ASU No. 2014-09 gives entities a single comprehensive model to use in reporting information about the amount and timing of revenue resulting from contracts to provide goods or services to customers. The proposed ASU, which would apply to any entity that enters into contracts to provide goods or services, would supersede the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance throughout the Industry Topics of the Codification. Additionally, the update would supersede some cost guidance included in Subtopic 605-35, Revenue Recognition—Construction-Type and Production-Type Contracts. The update removes inconsistencies and weaknesses in revenue requirements and provides a more robust framework for addressing revenue issues and more useful information to users of financial statements through improved disclosure requirements. In addition, the update improves comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. The Company is continuing to review the provisions of this ASU to determine if there will be any impact on its results of operations, cash flows or financial condition.

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. The Company is in process of evaluating the impact of adoption on its consolidated financial statements.

In August 2014, FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40). This ASU provides guidance to determine when and how to disclose going-concern uncertainties in the financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date that the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

This standard is effective for annual periods ending after December 15, 2016. The Company is evaluating the impact of the adoption of this ASU on its consolidated financial statements.

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 Company has a limited operating history and its prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the industry. The Company's ability to generate income in the short-run will depend greatly on the rate of adoption and ability to establish a sustainable market for VI_2OLET. The Company continues its research and development efforts for its products, which will require significant funding. If revenues fall short of expectations or research and development efforts require higher than anticipated capital, then there may be a negative impact on the financial viability of the Company.

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 in public and private offerings and the issuance of convertible notes, Series A convertible redeemable preferred stock and warrants. In June 2015, the Company raised net proceeds of $7.8 million in a public offering of its common stock. In December 2015, the Company raised net proceeds of $5.5 million in a private offering of its common stock and, in April 2016, raised net proceeds of approximately $3.6 million in a public offering of its common stock. The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern.

The Company plans to increase working capital by managing its cash flows and expenses, securing financing and increasing revenue. The Company continues to pursue additional channel distribution expansion for VI_2OLET to provide even 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. Management of the Company intends to raise additional funds through the issuance of equity securities. The Company has an effective shelf registration statement on file with the SEC to allow it to sell up to approximately $100 million of its 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 the Company sell securities pursuant to the shelf registration statement with a value of more than one-third of the aggregate market value of its common stock held by non-affiliates in any 12-month period, so long as the aggregate market value of its 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 the Company. Failure to generate sufficient cash flows from operations, raise additional capital 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.

As shown in the accompanying consolidated financial statements, the Company incurred a net loss available to common stockholders of $16.0 million during the year ended January 31, 2016, and had an accumulated deficit of $26.2 million as of January 31, 2016. As of January 31, 2016, the Company had

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. GOING CONCERN (Continued)

working capital of approximately $1.6 million. 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.

3. BALANCE SHEET DETAILS

	January 31, 2016	January 31, 2015
	(in thousands)	
Inventories:		
Work in process	$ 18	$ 61
Finished goods	28	64
Channel inventory	54	35
	$ 100	$ 160

	January 31, 2016	January 31, 2015
	(in thousands)	
Property and equipment, net:		
Furniture	$ 21	$ 18
Laboratory equipment	27	26
Computer and equipment	112	78
Software	144	144
	304	266
Less: accumulated depreciation	(88)	(32)
	$ 216	$ 234

Depreciation expense for the year ended January 31, 2016, one month ended January 31, 2015 and year ended December 31, 2014 was $56,000, $1,000 and $25,000, respectively.

Intangible assets, net:

Intangible assets were as follows (dollar amounts in thousands):

	As of January 31, 2016			
	Estimated Useful Life	Gross Value	Accumulated Amortization	Net Value
Intangible assets	5 years	$ 150	$ (31)	$ 119

	As of January 31, 2015			
	Estimated Useful Life	Gross Value	Accumulated Amortization	Net Value
Intangible assets	5 years	$ 150	$ (1)	$ 149

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. BALANCE SHEET DETAILS (Continued)

Amortization expense for the year ended January 31, 2016 and one month ended January 31, 2015 was $30,000 and $1,000, respectively. No amortization expense was recorded for the year ended December 31, 2014. Amortization is recorded in cost of goods sold.

As of January 31, 2016, the estimated aggregate future amortization expense in future years is as follows (in thousands):

Years ending January 31:	
2017	$ 30
2018	30
2019	30
2020	29
Total	$ 119

	January 31,	
	2016	2015
	(in thousands)	
Accrued liabilities:		
Payroll	$ 209	$ 128
Research and development	160	—
Legal	125	—
Marketing	74	—
Deferred rent	26	49
Deferred revenue	19	6
Other	182	4
	$ 795	$ 187

4. RELATED PARTY PAYABLES

Since inception, the founding executives of the Company have made advances to cover short-term operating expenses. Additionally, since the beginning of 2014 a portion of their compensation has been deferred and is included in this balance. These advances and deferred compensation are non-interest bearing and have periodically been repaid to these executives. Related party payables as of January 31, 2016 and 2015 were $225,000 and $218,000, respectively.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. COMMITMENTS AND CONTINGENCIES

Commitments

The following table summarizes the Company's commitments as of January 31, 2016 (in thousands):

	Total	2017	2018	2019	2020	2021
Operating lease	$ 246	$ 246	$ —	$ —	$ —	$ —
Purchase commitment	1,473	421	263	263	263	263
Total	$ 1,719	$ 667	$ 263	$ 263	$ 263	$ 263

On August 23, 2013, the Company signed a lease for 10,800 square feet of office and laboratory space in Menlo Park, California. The lease expires in November 2016. Rent expense for the year ended January 31, 2016, one month ended January 31, 2015 and year ended December 31, 2014 was $357,000, $26,000 and $310,000, respectively. The purchase commitment relates to the manufacturing of VI_2OLET and is non-cancelable.

Legal Proceedings

The Company is not currently a party to any legal proceedings. The Company is not aware of any pending legal proceeding to which any of its officers, directors, or any beneficial holders of 5% or more of its voting securities are adverse to the Company or have a material interest adverse to the Company.

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,

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. COMMITMENTS AND CONTINGENCIES (Continued)

fully paid-up, non-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 non-exclusive license to the IP.
- Pay 30% of net profit associated with direct commercialization of an OTC product or 30% of net royalties received from any sub-licensee.
- Pay 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.
- Pay 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.
- Pay 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.
- Pay 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. As of January 31, 2016 and 2015, the balance, net of amortization, was $119,000 and $149,000, respectively. No royalties have been paid as of January 31, 2016.

6. CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

Common Stock

As described in Note 1, on January 23, 2014, the Company issued 7,025,000 shares of its common stock to BioPharmX, Inc. stockholders.

The Company issued convertible notes payable ("Notes") from September 2012 through March 2014. Under the terms of the Notes, on April 11, 2014, the Notes automatically converted into 1,526,001 shares of common stock upon the Company's sale of Series A Preferred Stock.

In June 2015, the Company uplisted to the NYSE MKT and simultaneously completed a public offering (the "Offering") in which it issued 3,636,384 shares of common stock resulting in net proceeds of $7.8 million. Pursuant to the subscription agreement dated October 24, 2014, KIP, an existing stockholder, shall purchase shares in the KIP private placement upon the earlier to occur of (i) the Company receiving revenues from Violet of $2,000,000 or (ii) receipt by the Company of approval to list on any tier of the NYSE or Nasdaq stock market at a market price of at least $3.70 per share. In addition, KIP has previously informed the Company of its intention to complete the KIP private placement even if the Company's stock price was not at least $3.70 per share. As of May 2, 2016, this private placement has not closed, and the Company is unable to predict if or when the private placement will close. As consideration for Ping Wang's service as a director of the Company, 290,000

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (Continued)

shares of the Company's common stock were issued, of which 96,667 vested immediately and 193,333 shares of the common stock will vest immediately upon completion of the $2.0 million purchase.

In June 2015, the Company issued a 6% unsecured convertible note in the principal amount of $500,000 to an investor. Under the terms of the convertible note, 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 vehicles of Franklin Advisers. For a period of 5 years, Franklin Advisers have the right to purchase up to an aggregate of 20% of the securities offered by the Company in any subsequent private placement.

Series A Preferred Stock

The Company entered into subscription agreements for the private placement of shares of its Series A preferred stock and warrants with 47 accredited investors during 2014 whereby the Company sold an aggregate of 4,207,987 shares of Series A preferred stock at a per share price of $1.85 for gross proceeds of $7.5 million and issued to the investors for no additional consideration warrants to purchase in the aggregate 2,042,589 shares of common stock, with an exercise price of $3.70 per share. The allocated fair value of the warrants related to these subscription agreements was determined to be $845,000 and was recorded as additional paid-in capital. The fair value was computed using the Black-Scholes pricing model with the following assumptions: dividend rate of 0%, risk-free rate of 1.6% to 4.0%, contractual term of 5 years and expected volatility of 88.8%. In connection with the uplisting to the NYSE MKT, the Series A preferred stock, including accrued and unpaid interest, converted into 4,319,426 shares of common stock.

In March and April 2015, the Company amended certain of the warrants issued in connection with the Series A preferred 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, 2016, 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 the 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 4 to 5 years and expected volatility of 85.9%. As of January 31, 2016, of the warrants issued in connection with the Series A preferred stock financing, warrants to purchase 1,661,055 shares of common stock remain outstanding.

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.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (Continued)

Warrants

In addition to the warrants issued in conjunction with the subscription agreements, the Company issued warrants on May 15, 2014, to a service provider for 316,395 shares of common stock at an exercise price of $2.035 per share, which were valued at $99,000 and expensed. As of January 31, 2016, all were outstanding. On May 14, 2014, the Company also issued warrants valued at $105,000 for 343,559 shares of common stock at an exercise price of $1.85 per share to a qualified investor as a part of his convertible loan package. These warrants expire five years after the date of issuance. These warrants are immediately exercisable, and in June 2015, a portion of the warrants were exercised for 54,054 shares of common stock. As of January 31, 2016, warrants exercisable for 289,505 shares of common stock remain outstanding.

In connection with the Offering, 109,091 warrants were issued to the underwriters at the public offering price of $2.75. These warrants expire five years after the date of issuance. As of January 31, 2016, all were outstanding.

Equity Incentive Plan

On January 23, 2014, the Company adopted the 2014 Equity Incentive Plan, or the 2014 Plan, which permits the Company to grant stock options to directors, officers or employees of the Company or others to purchase shares of common stock of the Company through awards of incentive and nonqualified stock options, restricted stock awards and stock appreciation rights. Stock options previously issued under BioPharmX, Inc.'s 2011 Equity Incentive Plan were substituted with stock options issued under the 2014 Plan. Stock options generally vest in two to four years and expire ten years from the date of grant.

The total number of shares originally reserved and available for grant and issuance pursuant to the 2014 Plan was 2,700,000. Shares issued under the 2014 Plan are drawn from authorized and unissued shares or shares now held or subsequently acquired by the Company. On November 7, 2014, the Company increased the stock reserve available to the 2014 Plan for stock awards from 2,700,000 shares to 4,500,000 shares.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (Continued)

The following table summarizes the Company's stock option activities under the 2014 Plan:

	Available for Grant	Shares	Weighted Average Exercise Prices	Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Balance at January 1, 2013	1,550,000	1,150,000	$ 0.06		
Granted	(1,456,000)	1,456,000	0.40		
Balance at December 31, 2013	94,000	2,606,000	$ 0.25		
Additional shares authorized	1,800,000	—	—		
Granted	(891,000)	891,000	1.85		
Exercised	—	(727,643)	0.14		
Cancelled	160,000	(160,000)	0.37		
Balance at December 31, 2014	1,163,000	2,609,357	$ 0.82	8.52	$ 5,686
Granted	(130,000)	130,000	2.75		
Exercised	—	(40,105)	0.95		
Cancelled	10,000	(10,000)	1.85		
Balance at January 31, 2015	1,043,000	2,689,252	$ 0.91	8.58	$ 5,625
Granted	(1,274,000)	1,274,000	2.25		
Exercised	—	(676,769)	0.12		
Cancelled	581,875	(581,875)	1.59		
Balance at January 31, 2016	350,875	2,704,608	$ 1.59	8.37	$ 1,343
Vested and exercisable		1,059,709	$ 1.13	7.34	$ 794
Vested and expected to vest		2,467,713	$ 1.55	8.29	$ 1,287

Inducement Grants

The Company has also awarded inducement options to purchase common stock to new employees outside of the 2014 Plan as material inducements to the acceptance of employment with the Company as permitted under Section 711(a) of the NYSE MKT 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

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (Continued)

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 at January 31, 2015	—	—	—	—
Granted	660,000	$ 1.44		
Balance at January 31, 2016	660,000	$ 1.44	9.72	$ 227
Vested and exercisable	—	$ —	—	$ —
Vested and expected to vest	529,212	$ 1.44	9.72	$ 182

The following table summarizes significant ranges of outstanding and exercisable options as of January 31, 2016:

	Options Outstanding			Options Vested and Exercisable	
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Prices	Number Vested and Exercisable	Weighted Average Exercise Prices
$0.25 - $1.00	882,108	7.48	$ 0.41	570,340	$ 0.41
$1.01 - $1.67	1,264,000	9.74	$ 1.49	51,664	$ 1.48
$1.68 - $3.00	988,500	8.09	$ 2.28	437,705	$ 2.02
$3.01 - $3.25	230,000	9.33	$ 3.25	—	—
	3,364,608	8.63	$ 1.56	1,059,709	$ 1.13

The total intrinsic value of stock options exercised during the year ended January 31, 2016, the month ended January 31, 2015 and year ended December 31, 2014 was $1.4 million, $82,000 and $676,000, respectively. The weighted average grant date fair values of the stock options granted during the year ended January 31, 2016, the month ended January 31, 2015 and year ended December 31, 2014 was $1.44, $1.92 and $1.10, respectively.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. STOCK-BASED COMPENSATION

The following table summarizes the stock-based compensation expenses included in the Company's Statement of Operations and Comprehensive Loss for the periods ended (in thousands):

	Year ended January 31, 2016	One month ended January 31, 2015	Year ended December 31, 2014
Research and development	$ 256	$ 27	228
Sales and marketing	443	40	147
General and administrative	515	32	818
Total	$ 1,214	$ 99	$ 1,193

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, 2016, total compensation costs related to unvested, but not yet recognized, stock-based awards was $2.7 million, net of estimated forfeitures. This cost will be amortized on a straight-line basis over a weighted average remaining period of 3.02 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, 2016	One month ended January 31, 2015	Year ended December 31, 2014
Expected volatility	81.3% - 82.6%	82.1%	82.2%
Expected term in years	6.0	6.0	6.0
Risk-free interest rate	1.57% - 2.26%	1.56%	1.74%
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 the common shares of selected public companies in the biotechnology sector due to its limited trading history.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. STOCK-BASED COMPENSATION (Continued)

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.

Risk-Free Interest Rate

The Company bases the risk-free interest rate used in the Black-Scholes pricing method 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.

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 year ended January 31, 2016, the month ended January 31, 2015 and the year ended December 31, 2014.

9. INCOME TAXES

No federal income taxes were provided in the year ended January 31, 2016, month ended January 31, 2015 or year ended December 31, 2014 due to the Company's net losses. The provision of income taxes consist of state minimum income taxes.

At January 31, 2016, the Company had available federal net operating loss ("NOL") carry-forwards of approximately $19.4 million which will begin to expire in 2030 and California state NOL carry-forwards of approximately $19.4 million which will begin to expire in 2030. At January 31, 2016 and 2015, the net deferred tax assets of approximately $8.8 million and $3.6 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 $5.2 million, $0.4 million and $2.6 million during the year ended January 31, 2016, the month ended January 31, 2015 and year ended December 31, 2014, 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.

BIOPHARMX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. INCOME TAXES (Continued)

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

	January 31, 2016	January 31, 2015
Deferred tax assets:		
Net operating loss carryforwards	$ 7,727	$ 3,538
Stock-based compensation expense	577	—
Tax credit carryforwards	311	—
Other	216	50
Total deferred tax assets	8,831	3,588
Less: Valuation allowance	(8,831)	(3,588)
Net deferred tax assets	$ —	$ —

A reconciliation of income taxes provided at the federal statutory rate (34%) to the actual income tax provision was as follows (in thousands):

	Year ended January 31, 2016
Income tax benefit computed at U.S. statutory rate	$ (5,302)
State income tax (net of federal benefit)	(838)
Stock-based compensation	200
Warrant valuation	148
Research and development credits	(128)
Change in valuation allowance	5,904
Other	20
Income tax provision	$ 4

As of January 31, 2016 and 2015, the Company did not have any material unrecognized tax benefits. The tax years from 2010 to 2016 remain open for examination by the federal and state authorities.

10. SUBSEQUENT EVENTS

In April 2016, the Company raised net proceeds of approximately $3.6 million, after expenses of approximately $0.7 million, excluding any proceeds from warrant exercises, from the sale of 3,600,000 shares of common stock and 1,952,000 warrants to purchase common stock at an exercise price of $1.20 per share in an equity offering under its shelf registration statement.

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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, State of California, on this 2nd day of May, 2016.

BioPharmX Corporation

By: /s/ JAMES PEKARSKY

Name: James Pekarsky
Title: *Chief Executive Officer and Chairman of the Board of Directors*

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/ JAMES PEKARSKY James Pekarsky	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	May 2, 2016
/s/ ANJA KRAMMER Anja Krammer	President and Director	May 2, 2016
/s/ GREG KITCHENER Greg Kitchener	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	May 2, 2016
/s/ PING WANG Ping Wang	Director	May 2, 2016
/s/ MICHAEL HUBBARD Michael Hubbard	Director	May 2, 2016
/s/ STEPHEN MORLOCK Stephen Morlock	Director	May 2, 2016
/s/ CRAIG BARBAROSH Craig Barbarosh	Director	May 2, 2016

EXHIBIT INDEX

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
2.1	Form of Share Exchange Agreement dated January 23, 2014 by and among Thompson Designs, Inc., BioPharmX, Inc. and BioPharmX, Inc. Stockholders	8-K	000-54871	1/27/2014	2.1	
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	
4.1	Specimen Stock Certificate	S-8	333-201708	1/26/2015	4.03	
4.2	Promissory Note, dated December 21, 2012 between Thompson Designs, Inc. and Kade Thompson	10-K	000-54871	12/31/12	10.1	
4.3	Subscription Agreement, dated October 24, 2014, between the Company and KIP Overseas Expansion Platform Fund (as amended)					X
4.4	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	
4.5	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	
4.6	Standstill 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	

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
4.7	Form of Common Stock Purchase Warrant (issued in connection with April 2016 stock offering)	8-K	011-37411	3/29/2016	4.1	
4.8	Form of Common Stock Purchase Warrant (issued in connection with Series A stock offering)	10-K	000-54871	3/31/2014	Exhibit B to Exhibit 10.11	
4.9	Form of Underwriters' Warrant Agreement (issued in connection with June 2015 stock offering)	S-1/A	333-203317	6/1/2015	4.4	
10.1*	Form of Employment Agreement between James Pekarsky and Thompson Designs, Inc.	8-K	000-54871	1/27/2014	10.2	
10.2*	Form of Employment Agreement between Anja Krammer and Thompson Designs, Inc.	8-K	000-54871	1/27/2014	10.3	
10.3*	Offer letter, dated July 14, 2015, by and between BioPharmX Corporation and Greg Kitchener	10-Q	001-37411	9/14/2015	10.1	
10.4*	Employment Agreement, dated August 10, 2015, by and between BioPharmX Corporation and Greg Kitchener	10-Q	001-37411	9/14/2015	10.2	
10.5*	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	
10.6	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	Collaboration and Supply Agreement dated October 22, 2013 between BioPharmX, Inc. and Nutech Medical, Inc.	8-K	000-54871	1/27/2014	10.5	
10.8	Lease Agreement dated August 23, 2013 between Prologis, L.P. and BioPharmX, Inc.	8-K	000-54871	1/27/2014	10.6	

Exhibit Number	Description of Document	Incorporated by Reference				Filed Herewith
		Form	File No.	Filing Date	Exhibit	
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	Form of Indemnification Agreement	S-1/A	333-203317	5/14/2015	10.16	
10.12	Commercial Supply Agreement	S-1/A	333-203317	5/14/2015	10.17	
10.13	Investor Rights Agreement, dated October 24, 2014, between BioPharmX Corporation, James Pekarsky, Anja Krammer, Kin Chan and KIP Overseas Expansion Platform Fund					X
21.1	Subsidiaries of the Registrant					X
23.1	Consent of Burr Pilger Mayer, Inc., independent registered public accounting firm					X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended					X
32.1	Certification of Chief Executive Officer 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

Exhibit Number	Description of Document	Form	Incorporated by Reference			Filed Herewith
			File No.	Filing Date	Exhibit	
101.PRE	XBRL Taxonomy Presentation Linkbase Document					X

* Indicates a management contract, compensatory plan or arrangement

Exhibit 4.3

BIOPHARMX CORPORATION

SUBSCRIPTION AGREEMENT

As of October 24, 2014

Mr. James Pekarsky
Chief Executive Officer
BioPharmX Corporation
1098 Hamilton Court
Menlo Park, California 94025

1. Subscription.

(a) The undersigned subscriber (the "Subscriber") hereby irrevocably subscribes for and agrees to purchase the number of shares (the "Shares") of the Company's Series A preferred stock, par value $.001 per share ("Series A Preferred Stock"), with the powers, preferences, rights, qualifications, limitations and restrictions as set forth in the certificate of designations in the form of Exhibit A hereto (the "Certificate of Designations"), set forth on the signature page hereto from BioPharmX Corporation, a Delaware corporation (the "Company") for the purchase price of $1.85 per share in connection with the Company's offering of up to $8,000,000 in Series A Preferred Stock together with the right to receive warrants for no additional consideration (the "Offering"), in the form of Exhibit B hereto, granting subscriber the right to purchase a number of shares of common stock, par value $.001 per share, of the Company (the "Common Stock") equal to fifty percent (50%) of the number of shares of Common Stock into which the Shares are convertible (such warrants, the "Warrants;" together with the Series A Preferred Stock, the "Securities"). The Warrants will have an initial exercise price equal to $3.70 per share and shall be exercisable for a three (3) year period. In addition, the Shares and shares issuable upon exercise of the Warrants (the "Warrant Shares") shall have the registration rights as provided in Section 4 hereof. In addition, Subscriber agrees to enter into the Investor Rights Agreement (the "Investor Rights Agreement"), in the form of Exhibit C hereto, granting the Subscriber additional rights from the Company and certain of its shareholders.

This Subscription Agreement and the Investor Rights Agreement (the "Subscription Agreement") together with the Exhibits and Schedules thereto constitute the "Offering Documents."

This subscription is based solely upon the information provided in the Offering Documents and upon the Subscriber's own investigation as to the merits and risks of this investment. The Subscriber shall deliver herewith duly executed copies of the signature pages to the following documents: (i) the Subscription Agreement, and (ii) the Accredited Investor Questionnaire.

The Offering may be consummated at more than one closing to occur on a date as may be determined by the Company. Each such closing is referred to as a "Closing" and the date of each such Closing is referred to as the "Closing Date." A final Closing shall be held by the Company on or before September 30, 2014"), which can be extended up to October 15, 2014 by the Company's board of directors (the "Final Closing Date"). At each Closing with respect to the Shares subscribed for hereby and accepted by the Company, the Company shall deliver to the Subscriber, the stock certificate for the Shares and the Warrants certificate. If the Company does not accept this subscription, in whole or in part, it will promptly refund to the Subscriber, without deduction therefrom, any subscription payment received from the Subscriber for the Shares, the subscription for which was not accepted by the Company.

(b) Subject to the terms and conditions hereinafter set forth, the Subscriber hereby subscribes for and agrees to purchase the number of Shares from the Company set forth on the signature page hereof, and when this Agreement is accepted and executed by the Company, the Company agrees to issue such Shares and Warrants to the Subscriber. The subscription price is payable by wire transfer pursuant to the following wire instructions.

WIRING INSTRUCTIONS

Bank's Name and Address:

Account #:
ABA Routing #:
SWIFT:
Account Title:

2. Subscriber Representations, Warranties and Agreements. The Subscriber hereby acknowledges, represents and warrants as follows (with the understanding that the Company will rely on such representations and warranties in determining, among other matters, the suitability of this investment for the Subscriber in order to comply with federal and state securities laws):

(a) In connection with this subscription, the Subscriber has read this Subscription Agreement and the other Offering Documents. The Subscriber acknowledges that this Subscription Agreement is not intended to set forth all of the information which might be deemed pertinent by an investor who is considering an investment in the Securities. It being the responsibility of Subscriber (i) to determine what additional information he desires to obtain in evaluating this investment and (ii) to obtain such information from the Company.

(b) THIS OFFERING IS LIMITED TO PERSONS WHO ARE "ACCREDITED INVESTORS," AS THAT TERM IS DEFINED IN REGULATION D UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND

WHO HAVE THE FINANCIAL MEANS AND THE BUSINESS, FINANCIAL AND INVESTMENT EXPERIENCE AND ACUMEN TO CONDUCT AN INVESTIGATION AS TO, AND TO EVALUATE, THE MERITS AND RISKS OF THIS INVESTMENT. THE SUBSCRIBER HEREBY REPRESENTS THAT HE HAS READ, IS FAMILIAR WITH AND UNDERSTANDS RULE 501 OF REGULATION D UNDER THE ACT. THE SUBSCRIBER IS AN "ACCREDITED INVESTOR" AS DEFINED IN RULE 501(A) OF REGULATION D.

(c) The Subscriber has had full access to all the information which the Subscriber (or the Subscriber's advisor) considers necessary or appropriate to make an informed decision with respect to the Subscriber's investment in the Securities. The Subscriber acknowledges that the Company has made available to the Subscriber and the Subscriber's advisors the opportunity to examine and copy any contract, matter or information which the Subscriber considers relevant or appropriate in connection with this investment and to ask questions and receive answers relating to any such matters including, without limitation, the financial condition, management, employees, business, obligations, corporate books and records, budgets, business plans of and other matters relevant to the Company. To the extent the Subscriber has not sought information regarding any particular matter, the Subscriber represents that he or she had and has no interest in doing so and that such matters are not material to the Subscriber in connection with this investment.

(d) The Subscriber understands that the offering of the Securities has not been registered under the Securities Act, in reliance on an exemption for private offerings provided pursuant to Section 4(2) of the Securities Act and that, as a result, the Securities, as well as the securities issuable upon conversion of the Securities as set forth in the Certificate of Designations and the Warrants certificate and the securities issuable in connection with such securities (collectively, the "Conversion Securities"), will be "restricted securities" as that term is defined in Rule 144 under the Securities Act and, accordingly, under Rule 144 as currently in effect, that the Securities or the Conversion Securities must be held until the latest of (i) at least six (6) months after the investment has been made (or indefinitely if the Subscriber is deemed an "affiliate" within the meaning of such rule), or (ii) January 23, 2015, one year from the closing of the reverse acquisition transaction, unless the Securities or Conversion Securities are subsequently registered under the Securities Act and qualified under any other applicable securities law or exemptions from such registration and qualification are available. The Subscriber understands that except as set forth in Section 4 hereof the Company is under no obligation to register the Securities under the Securities Act or to register or qualify the Securities under any other applicable securities law, or to comply with any other exemption under the Securities Act or any other securities law, and that the Subscriber has no right to require such registration.

(e) The Subscriber is empowered and duly authorized to enter into this Subscription Agreement which constitutes a valid and binding agreement of the Subscriber enforceable against the Subscriber in accordance with its terms; and the person signing this

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Subscription Agreement on behalf of the Subscriber is empowered and duly authorized to do so.

(f) The Subscriber has liquid assets sufficient to assure that the purchase price of the Securities will cause no undue financial difficulties and that, after purchasing the Securities the Subscriber will be able to provide for any foreseeable current needs and possible personal contingencies; the Subscriber is able to bear the risk of illiquidity and the risk of a complete loss of this investment.

(g) The information in any documents delivered by the Subscriber in connection with this subscription, including, but not limited to the Investor Questionnaire, is true, correct and complete in all respects as of the date hereof. The Subscriber agrees promptly to notify the Company in writing of any change in such information after the date hereof.

(h) The offering and sale of the Securities to the Subscriber were not made through any advertisement in printed media of general and regular paid circulation, radio or television or any other form of advertisement, or as part of a general solicitation.

(i) The Subscriber recognizes that an investment in the Securities involves significant risks. The Subscriber has read and understands such risks and that such risks, and others, can result in the loss of the Subscriber's entire investment in the Securities.

3. Representations, Warranties and Covenants of the Company. As a material inducement of the Subscribers to enter into this Subscription Agreement and subscribe for the Securities, the Company represents and warrants to the Subscriber, as of the date hereof, as follows:

(a) Organization and Standing. The Company is a duly organized corporation, validly existing and in good standing under the laws of the State of Delaware, has full power to carry on its business as and where such business is now being conducted and to own, lease and operate the properties and assets now owned or operated by it and is duly qualified to do business and is in good standing in each jurisdiction where the conduct of its business or the ownership of its properties requires such qualification except where the failure to be so qualified would not have a Material Adverse Effect on the Company. "Material Adverse Effect" means any circumstance, change in, or effect on the Company that, individually or in the aggregate with any other similar circumstances, changes in, or effects on, the Company taken as a whole: (i) is, or is reasonably expected to be, materially adverse to the business, operations, assets, liabilities, employee relationships, customer or supplier relationships, prospects, results of operations or the condition (financial or otherwise) of the Company taken as a whole, or (ii) is reasonably expected to adversely affect the ability of the Company to operate or conduct the Company's business in the manner in which it is currently operated or conducted or proposed to be operated or conducted by the Company; provided, however, that none of the following shall be deemed in and of themselves, either alone or in combination, to constitute, and none of the following shall be taken into account in determining whether there has been or will be, a

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Material Adverse Effect: (i) any change, event, state of facts or development generally affecting the general political, economic or business conditions of the United States; (ii) any change, event, state of facts or development generally affecting the medical device industry; (iii) any change, event, state of facts or development arising from or relating to compliance with the terms of this Subscription Agreement; (iv) acts of war (whether or not declared), the commencement, continuation or escalation of a war, acts of armed hostility, sabotage or terrorism or other international or national calamity or any material worsening of such conditions; (v) changes in laws or the U.S. generally accepted accounting principles ("GAAP") after date hereof or interpretation thereof; or (vi) any matter set forth in the Offering Documents or the Schedules or Exhibits thereto.

(b) Subsidiaries. Except for BiopharmX Inc., a Nevada corporation, as of the date herein, the Company does not own or control any subsidiaries. For purposes of this Agreement, "Subsidiary" means, with respect to any entity at any date, any corporation, limited or general partnership, limited liability company, trust, estate, association, joint venture or other business entity of which more than 50% of (i) the outstanding capital stock having (in the absence of contingencies) ordinary voting power to elect a majority of the board of directors or other managing body of such entity, (ii) in the case of a partnership or limited liability company, the interest in the capital or profits of such partnership or limited liability company or (iii) in the case of a trust, estate, association, joint venture or other entity, the beneficial interest in such trust, estate, association or other entity business is, at the time of determination, owned or controlled directly or indirectly through one or more intermediaries, by such entity.

(c) Authority. The execution, delivery and performance of this Subscription Agreement and the other Offering Documents by the Company and the consummation of the transactions contemplated hereby have been duly authorized by the Board of Directors of the Company. Each of the documents contained in the Offering Documents has been (or upon delivery will be) duly executed by the Company, is or, when delivered in accordance with the terms hereof, will constitute, assuming due authorization, execution and delivery by each of the parties thereto, the valid and binding obligation of the Company enforceable against the Company in accordance with its terms.

(d) No Conflict. The execution, delivery and performance of this Subscription Agreement and the consummation of the transactions contemplated hereby do not (i) violate or conflict with the Company's Certificate of Incorporation, By-laws or other organizational documents, (ii) conflict with or result (with the lapse of time or giving of notice or both) in a material breach or default under any material agreement or instrument to which the Company is a party or by which the Company is otherwise bound, or (iii) violate any order, judgment, law, statute, rule or regulation applicable to the Company, except where such violation, conflict or breach would not have a Material Adverse Effect on the Company. This Subscription Agreement when executed by the Company will be a legal, valid and binding obligation of the Company enforceable in accordance with its terms (except as may be limited by bankruptcy, insolvency, reorganization, moratorium and similar laws and equitable principles relating to or limiting creditors' rights generally).

(e) Authorization. Issuance of the Securities to Subscriber has been duly authorized by all necessary corporate actions of the Company.

(f) Litigation and Other Proceedings. There are no actions, suits, proceedings or investigations pending or, to the knowledge of the Company, threatened against the Company at law or in equity before or by any court or Federal, state, municipal or their governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign which could materially adversely affect the Company. The Company is not subject to any continuing order, writ, injunction or decree of any court or agency against it which would have a material adverse effect on the Company.

(g) Use of Proceeds. The proceeds of this Offering and sale of the Securities, net of payment of placement expenses, will be used by the Company for working capital and general corporate purposes.

(h) Consents/Approvals. No consents, filings (other than Federal and state securities filings relating to the issuance of the Securities pursuant to applicable exemptions from registration, which the Company hereby undertakes to make in a timely fashion), authorizations or other actions of any governmental authority are required to be obtained or made by the Company for the Company's execution, delivery and performance of this Subscription Agreement which have not already been obtained or made or will be made in a timely manner following the initial Closing.

(i) Placement Agents. The Company may engage finders, brokers or placement agents in connection with the transactions contemplated hereby and pay to such brokers fees not to exceed ten (10) percent of the gross proceeds of the Offering and shares of Common Stock representing ten (10) percent of shares of Common Stock sold in the Offering.

(j) Capitalization. A capitalization table illustrating the authorized and outstanding capital stock of the Company as of the date hereof is attached as Schedule 3(j). All of such outstanding shares have been, or upon issuance will be, validly issued, fully paid and non-assessable. As of the date hereof, except as disclosed in Schedule 3(j), and except for Securities issued in the Offering (i) no shares of the Company's capital stock are subject to preemptive rights or any other similar rights or any liens or encumbrances suffered or permitted by the Company, (ii) there are no outstanding debt securities, (iii) there are no outstanding options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its subsidiaries, or contracts, commitments, understandings or arrangements by which the Company or any of its subsidiaries is or may become bound to issue additional shares of capital stock of the Company or any of its subsidiaries or options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its subsidiaries, (iv) except for its obligations under Section 4 of this Agreement, there are no agreements or arrangements under which the

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Company or any of its subsidiaries is obligated to register the sale of any of their securities under the Securities Act, (v) there are no outstanding securities of the Company or any of its subsidiaries which contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any of its subsidiaries is or may become bound to redeem a security of the Company or any of its subsidiaries, and (vi) there are no securities or instruments containing anti-dilution or similar provisions that will be triggered by the issuance or exercise of the Securities as described in this Subscription Agreement. The Company has furnished to the Subscriber true and correct copies of the Company's Certificate of Incorporation, as amended and as in effect on the date hereof (the "Certificate of Incorporation"), and the Company's By-laws, as in effect on the date hereof (the "By-laws"), and the terms of all securities convertible or exchangeable into or exercisable for Common Stock and the material rights of the holders thereof in respect thereto. Schedule 3(j) also lists all outstanding debt of the Company with sufficient detail acceptable to Subscriber.

(k) Intellectual Property Rights. The Company owns or possesses adequate rights or licenses to use all trademarks, trade names, service marks, service mark registrations, service names, patents, patent rights, copyrights, inventions, licenses, approvals, governmental authorizations, trade secrets and rights necessary to conduct its businesses as now conducted. The Company does not have any knowledge of any infringement by the Company of trademark, trade name rights, patents, patent rights, copyrights, inventions, licenses, service names, service marks, service mark registrations, trade secret or other similar rights of others, or of any such development of similar or identical trade secrets or technical information by others and there is no claim, action or proceeding being made or brought against, or to the Company's knowledge, being threatened against, the Company regarding trademarks, trade name rights, patents, patent rights, inventions, copyrights, licenses, service names, service marks, service mark registrations, trade secrets or other infringement.

(l) Disclosure. No representation or warranty by the Company in this Subscription Agreement, the other Offering Documents, nor in any certificate, Schedule or Exhibit delivered or to be delivered pursuant to this Subscription Agreement or the other Offering Documents: contains or will contain any untrue statement of material fact or omits or will omit to state a material fact necessary to make the statements contained herein or therein not misleading. To the knowledge of the Company at the time of the execution of this Subscription Agreement and at each Closing, there is no information concerning the Company which has not heretofore been disclosed to the Subscribers that would have a Material Adverse Effect.

(m) Title. The Company has good and marketable title to all personal property owned by it which is material to the business of the Company, in each case free and clear of all liens, encumbrances and defects.

(n) Tax Status. The Company has made or filed all United States federal and state income and all other tax returns, reports and declarations required by any jurisdiction to which it is

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subject and all such returns, reports and declarations are true, correct and accurate in all material respects. The Company has paid all taxes and other governmental assessments and charges, shown or determined to be due on such returns, reports and declarations, except those being contested in good faith, for which adequate reserves have been established, in accordance with GAAP, and except where the failure to do so would not constitute a Material Adverse Effect on the Company.

(o) Compliance with Laws. The business of the Company has been and is presently being conducted so as to comply with all applicable material federal, state and local governmental laws, rules, regulations and ordinances.

(p) Restrictions on Business Activities. There is no judgment, order, decree, writ or injunction binding upon the Company or any subsidiary or, to the knowledge of the Company or any subsidiary, threatened that has or could prohibit or impair the conduct of their respective businesses as currently conducted or any business practice of the Company or any subsidiary, including the acquisition of property, the provision of services, the hiring of employees or the solicitation of clients, in each case either individually or in the aggregate.

(r) Issuances. The Company's common stock issuable upon conversion of the Shares and exercise of Warrants will be validly issued, fully paid and nonassessable.

(s) USA PATRIOT Act and Money Laundering Laws. The operations of the Company are and have been conducted at all times in compliance with the money laundering requirements of all applicable governmental authorities and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental authority (collectively, the "Money Laundering Laws") and the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (Title III of Pub. L. 107-56 (signed into Law October 26, 2001) (the "USA PATRIOT Act") and no action, suit or proceeding by or before any court or governmental authority or any arbitrator involving any of the Company or any of its Subsidiaries with respect to the Money Laundering Laws or USA PATRIOT Act is pending or, to the best knowledge of the Company, threatened.

(t) For twelve months after the Closing, the Subscribers that have subscribed for at least $500,000 of the Shares shall have the right to purchase on a pro-rata basis up to an aggregate of 50% of the securities offered by the Company in any subsequent offering (the "Follow-On Financing") upon the same terms as offered to all other offerees. The Subscribers shall be given not less than ten days prior written notice (the "Notice of Sale") of any proposed Follow-On Financing and shall have the right during the ten days following receipt of the Notice of Sale to purchase the securities offered in the Follow-On Financing.

(u) Within 12 months after the first Closing, the Company shall increase the number of the directors of the Company to 5, including the current directors, and the Board of Directors

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shall appoint at least one director qualifying as an audit committee financial expert, as defined in Item 407(d)(5)(i) of Regulation S-K, and two directors qualifying as independent directors pursuant to the definition of "independent director" under the Rules of NASDAQ, Marketplace Rule 5605(a)(2).

(v) For sixty (60) days after the date hereof, upon any issuance by the Company or any of its subsidiaries of any security with any term more favorable to the holder of such security or with a term in favor of the holder of such security that was not similarly provided to the Subscriber, the Company shall notify the Subscriber of such additional or more favorable term and such term, at Subscriber's option, shall become a part of the transaction documents with the Subscriber. The types of terms contained in another security that may be more favorable to the holder of such security shall not include any rights to representation on the Company's board of directors.

(W) The Subscribers shall purchase $2,000,000 of the Shares, on basis before Adjustments for Subdivisions, Combinations or Consolidations of Common Stock, at the per share price of $1.85 upon the earlier of the Company receiving revenues for Violet of $2,000,000 (the "Milestone") or upon immediate Qualifying Listing, provided that the Subscribers will have no rights to receive Warrants in connection with the purchase of such Shares. Within fifteen (15) business days after the written notice and verifiable evidence of the Milestone is provided by the Company, the Subscribers shall remit funds to the Company for the $2,000,000 of Shares.

Section 4. Registration Rights.

(a) Registration Rights.

(i) If at any time following the approval of the Common Stock for listing on the NASDAQ or NYSE, (a) there is no effective Registration Statement with respect to shares of Common Stock underlying the Series A Preferred Stock and the Warrant Shares (the "Registrable Shares") and (b) not all of the outstanding Registrable Shares may be sold without registration pursuant to Rule 144 under the Securities Act, then Subscribers that at the time of the written demand (directly or with their affiliates) hold the Registrable Shares representing more than 50% of

the Registrable Shares then outstanding (individually, a "Demanding Holder" and collectively, the "Demanding Holders"), may make a written demand for registration (a "Demand Registration" and the registration statement to be filed pursuant to such Demand Registration, the "Demand Registration Statement") under the Securities Act of the sale of all or part of its Registrable Shares. Any request for a Demand Registration shall specify the number of shares (or other amount) of Registrable Shares proposed to be sold and the intended method(s) of distribution thereof (such written demand, the "Demand Notice"). The Company will notify the Subscribers other than the Demanding Holder of the Demand Registration (each such Holder including Shares of its Registrable Shares in such registration, a "Participating Holder") as soon as practicable, and each such other Holder who wishes to include all or a portion of its

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Registrable Shares of the type that are the subject of the Demand Registration Statement proposed to be filed in such Demand Registration Statement shall so notify the Company within fifteen (15) days after receipt of such notice (the "Demanding Subscribers' Deadline"). The Company shall use its best efforts to file such Demand Registration Statement within forty five (45) days (the "Required Filing Date") after receiving the Demand Notice, and use its best efforts to have the Demand Registration Statement declared effective by the U.S. Securities and Exchange Commission, not later than ninety (90) days after the Required Filing Date.

(ii) The Company will pay all expenses associated with the registration, including, without limitation, filing and printing fees, accounting fees and expenses, costs, if any, associated with clearing the Registrable Securities for sale under applicable state securities laws.

(b) Subscriber Information. Each Subscriber shall (A) furnish to the Company such information regarding itself, the Registrable Securities, other securities of the Company held by it and the intended method of disposition of the Registrable Securities held by it, as shall be reasonably requested by the Company to effect and maintain the effectiveness of the Registration Statement, (B) execute such documents in connection with the Registration Statement as the Company may reasonably request and (C) discontinue disposition of Registrable Securities pursuant to any registration statement upon notice from the Company of (x) the issuance of any stop order or other suspension of effectiveness of the Registration Statement by the Commission, or the suspension of the qualification of any of the Registrable Securities for sale in any jurisdiction by the applicable regulatory authorities or (y) the happening of any eventafter becoming aware of such event, as a result of which the prospectus included in the Registration Statement, as then in effect, includes an untrue statement of a material fact or omission to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading or (z) the failure of the prospectus included in the Registration Statement, as then in effect, to comply with the requirements of the Securities Act until the Subscriber's receipt of a supplemented or amended prospectus or receipt of notice that no supplement or amendment is required.

(c) Indemnification.

(i) In the event any Registrable Securities are included in the Registration Statement under this Section 4, to the extent permitted by law, the Company will indemnify and hold harmless each of the Subscribers (including their officers, directors, members and partners), any underwriter (as defined in the Securities Act) for the Subscribers and each person, if any, who controls such Subscriber or underwriter within the meaning of the Securities Act or the Exchange Act (each a "Subscriber Indemnified Person"), against any losses, claims, damages, or liabilities (joint or several) to which they may become subject under the Securities Act, the Exchange Act or other federal or state law ("Claims"), insofar as such losses, claims, damages, or liabilities (or actions in respect thereof) arise out of or are based upon any of the following

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statements, omissions or violations (collectively a "Violation"): (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto, (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any state securities law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law; and the Company will pay to the Subscriber Indemnified Person, as incurred, any legal or other expenses reasonably incurred by them in connection with investigating or defending any Claim; provided, however, that the indemnity agreement contained in this Section 4 shall not apply to amounts paid in settlement of any such Claim if such settlement is effected without the consent of the Company (which consent shall not be unreasonably withheld or delayed), nor shall the Company be liable to any Subscriber Indemnified Person for any such Claim to the extent that it arises out of or is based upon a Violation which occurs in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by the Subscriber Indemnified Person. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of such Subscriber Indemnified Person and shall survive the transfer of the Registrable Securities by the Subscribers.

(ii) In the event any Registrable Securities are included in the Registration Statement under this Section 4 to the extent permitted by law, each Subscriber shall, severally and not jointly, indemnify, hold harmless and defend, to the same extent and in the same manner as is set forth in Section 4, the Company, each of its directors, each of its officers who signs the registration statement and each Person, if any, who controls the Company within the meaning of the Securities Act or the Securities Exchange Act of 1934, as amended (the "Exchange Act"), (each, a "Company Indemnified Person"), against any Claim, insofar as such Claims arise out of or are based upon any Violation, in each case to the extent, and only to the extent, that such Violation occurs in reliance upon and in strict conformity with written information furnished to the Company by such Subscriber expressly for use in the Registration Statement; and, subject to Section 4, such Subscriber will reimburse any legal or other expenses reasonably incurred by any Company Indemnified Person in connection with investigating or defending any such Claim; provided, however, that the indemnity agreement contained in this Section 4 shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the prior written consent of the indemnifying Subscriber, which consent shall not be unreasonably withheld or delayed. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of such Company Indemnified Person and shall survive the transfer of the Registrable Securities by the Subscribers.

(iii) Promptly after receipt by a Subscriber Indemnified Person or Company Indemnified Person (each, an "Indemnified Person") under this Section 4 of notice of a Claim, such Indemnified Person shall, if a Claim in respect thereof is to be made against any

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indemnifying party under this Section 4, deliver to the indemnifying party a written notice of the commencement thereof, and the indemnifying party shall, by giving written notice to the Indemnified Party within fifteen days after the Indemnified Party has given notice of the Claim, have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume control of the defense thereof with counsel mutually satisfactory to the indemnifying party and the Indemnified Person; provided, however, that an Indemnified Person shall have the right to retain its own counsel with the fees and expenses of not more than one counsel for such Indemnified Person to be paid by the indemnifying party, if, in the reasonable opinion of counsel retained by the indemnifying party, the representation by such counsel of the Subscriber Indemnified Person or Company Indemnified Person and the indemnifying party would be inappropriate due to actual or potential differing interests between such Indemnified Person and any other party represented by such counsel in such proceeding. In the case of any Company Indemnified Person, legal counsel referred to in the proviso of the immediately preceding sentence shall be selected by the holders holding at least a majority in interest of the Registrable Securities included in the registration statement to which the Claim relates. The Indemnified Person shall cooperate fully with the indemnifying party in connection with any negotiation or defense of any such action or Claim by the indemnifying party and shall furnish to the indemnifying party all information reasonably available to the Indemnified Person that relates to such action or Claim. The indemnifying party shall keep the Indemnified Person reasonably apprised at all times as to the status of the defense or any settlement negotiations with respect thereto. No indemnifying party shall be liable for any settlement of any action, claim or proceeding effected without its prior written consent, provided, however, that the indemnifying party shall not unreasonably withhold, delay or condition its consent. No indemnifying party shall, without the prior written consent of the Indemnified Person, consent to entry of any judgment or enter into any settlement or other compromise that does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Person of a full and general release from all liability in respect to such Claim or litigation, and such settlement (a) shall provide for the payment by the Indemnifying Party of money as sole relief for the claimant, (b) shall not include any finding or admission as to fault on the part of the Indemnified Person and (c) shall have no effect on any other claims that may be made against the Indemnified Party.

Following indemnification as provided for hereunder, the indemnifying party shall be subrogated to all rights of the Indemnified Person with respect to all third parties, firms or corporations relating to the matter for which indemnification has been made. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action shall not relieve such indemnifying party of any liability to the Indemnified Person under this Section 4, except to the extent that the indemnifying party is materially prejudiced in its ability to defend such action.

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5. **Legends.** The Subscriber understands and agrees that the Company will cause any necessary legends to be placed upon any instruments(s) evidencing ownership of the Securities, together with any other legend that may be required by federal or state securities laws or deemed necessary or desirable by the Company.

6. **General Provisions.**

(a) Confidentiality. The Subscriber covenants and agrees that it will keep confidential and will not disclose or divulge any confidential or proprietary information that such Subscriber may obtain from the Company pursuant to financial statements, reports, and other materials submitted by the Company to such Subscriber in connection with this offering or as a result of discussions with or inquiry made to the Company, unless such information is known, or until such information becomes known, to the public through no action by the Subscriber; provided, however, that a Subscriber may disclose such information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary in connection with his or her investment in the Company so long as any such professional to whom such information is disclosed is made aware of the Subscriber's obligations hereunder and such professional agrees to be likewise bound as though such professional were a party hereto, (ii) if such information becomes generally available to the public through no fault of the Subscriber, or (iii) if such disclosure is required by applicable law or judicial order.

(b) Successors. The covenants, representations and warranties contained in this Subscription Agreement shall be binding on the Subscriber's and the Company's heirs and legal representatives and shall inure to the benefit of the respective successors and assigns of the Company. The rights and obligations of this Subscription Agreement may not be assigned by any party without the prior written consent of the other party.

(c) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original agreement, but all of which together shall constitute one and the same instrument.

(d) Execution by Facsimile. Execution and delivery of this Agreement by facsimile transmission (including the delivery of documents in Adobe PDF format) shall constitute execution and delivery of this Agreement for all purposes, with the same force and effect as execution and delivery of an original manually signed copy hereof.

(e) Governing Law and Jurisdiction. This Subscription Agreement shall be governed by and construed in accordance with the laws of the State of New York applicable to contracts to be wholly performed within such state and without regard to conflicts of laws provisions. Any legal action or proceeding arising out of or relating to this Subscription Agreement and/or the other Offering Documents may be instituted in the courts of the State of New York sitting in New York County or in the United States of America for the Southern District of New York, and the parties hereto irrevocably submit to the jurisdiction of each such court in any action or proceeding. Subscriber hereby irrevocably waives and agrees

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not to assert, by way of motion, as a defense, or otherwise, in every suit, action or other proceeding arising out of or based on this Subscription Agreement and/or the other Offering Documents and brought in any such court, any claim that Subscriber is not subject personally to the jurisdiction of the above named courts, that Subscriber's property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum or that the venue of the suit, action or proceeding is improper.

(f) (i) Indemnification Generally. The Company, on the one hand, and the Subscriber, on the other hand (for the purpose of this Section 6(f) only, each an "Indemnifying Party"), shall indemnify the other from and against any and all losses, damages, liabilities, claims, charges, actions, proceedings, demands, judgments, settlement costs and expenses of any nature whatsoever (including, without limitation, reasonable attorneys' fees and expenses) resulting from any breach of a representation and warranty, covenant or agreement by the Indemnifying Party and all claims, charges, actions or proceedings incident to or arising out of the foregoing. Notwithstanding any provision herein to the contrary, the

indemnification obligation of any Subscriber shall be limited to the investment amount in the Shares purchased by said Subscriber, except to the extent that such indemnification obligation relates to a breach of Section 2(b).

(ii) Indemnification Procedures. Each person entitled to indemnification under this Section 6 (for the purpose of this Section 6(f) only, an "Indemnified Party") shall give notice as promptly as reasonably practicable to each party required to provide indemnification under this Section 6 of any action commenced against or by it in respect of which indemnity may be sought hereunder, but failure to so notify an Indemnifying Party shall not release such Indemnifying Party from any liability that it may have, otherwise than on account of this indemnity agreement so long as such failure shall not have materially prejudiced the position of the Indemnifying Party. Upon such notification, the Indemnifying Party shall assume the defense of such action if it is a claim brought by a third party, and, if and after such assumption, the Indemnifying Party shall not be entitled to reimbursement of any expenses incurred by it in connection with such action except as described below. In any such action, any Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party unless (i) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the contrary or (ii) the named parties in any such action (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing or conflicting interests between them. The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its written consent (which shall not be unreasonably withheld or delayed by such Indemnifying Party), but if settled with such consent or if there be final judgment for the plaintiff, the Indemnifying Party shall indemnify the Indemnified Party from and against any loss, damage or liability by reason of such settlement or judgment.

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g. Notices. All notices, requests, demands, claims and other communications hereunder shall be in writing and shall be delivered by certified or registered mail (first class postage pre-paid), guaranteed overnight delivery, or facsimile transmission if such transmission is confirmed by delivery by certified or registered mail (first class postage pre-paid) or guaranteed overnight delivery, to the following addresses and facsimile numbers (or to such other addresses or facsimile numbers which such party shall subsequently designate in writing to the other party):

(i) if to the Issuer:

BioPharmX Corporation
1098 Hamilton Court
Menlo Park, California 94025
Attn: Mr. James Pekarsky
Facsimile: (650) 900-4130

(ii) if to the Subscriber to the address set forth next to its name on the signature page hereto.

h. Entire Agreement. This Subscription Agreement (including the Exhibits attached hereto) and other Offering Documents delivered at a Closing pursuant hereto, contain the entire understanding of the parties in respect of its subject matter and supersede all prior agreements and understandings between or among the parties with respect to such subject matter. The Exhibits constitute a part hereof as though set forth in full above.

i. Amendment; Waiver. This Subscription Agreement may not be modified, amended, supplemented, canceled or discharged, except by written instrument executed by the Company and the holders of not less than a majority of the Shares at the time such consent is sought. No failure to exercise, and no delay in exercising, any right, power or privilege under this Subscription Agreement shall operate as a waiver, nor shall any single or partial exercise of any right, power or privilege hereunder preclude the exercise of any other right, power or privilege. No waiver of any breach of any provision shall be deemed to be a waiver of any proceeding or succeeding breach of the same or any other provision, nor shall any waiver be implied from any course of dealing between the parties. No extension of time for performance of any obligations or other acts hereunder or under any other agreement shall be deemed to be an extension of the time for performance of any other obligations or any other acts. The rights and remedies of the parties under this Subscription Agreement are in addition to all other rights and remedies, at law or equity, that they may have against each other.

j. No Impairment. At all times after the date hereof, the Company will not take or permit any action, or cause or permit any subsidiary to take or permit any action that materially impairs or adversely affects the rights of the Subscribers under the this Agreement or any of the other Offering Documents.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the Company has executed this Subscription Agreement as of the date first written above.

BIOPHARMX CORPORATION

By: /s/ James Pekarsky
Name: James Pekarsky
Title: Chief Executive Officer

SIGNATURE PAGE TO SUBSCRIPTION AGREEMENT

INFORMATION IN RESPONSE TO THIS SECTION WILL BE KEPT STRICTLY CONFIDENTIAL

DOLLAR AMOUNT INVESTED: $1,000,000 UPON SIGNING, $2,000,000 UPON MEETING THE MILESTONE IN SECTION 3 (W)

NUMBER OF SHARES: 540,541 UPON SIGNING, 1,081,082 UPON MILESTONE IN SECTION 3 (W)

NUMBER OF WARRANTS: 270,270 UPON SIGNING

NAME IN WHICH SHARES AND WARRANT SHOULD BE ISSUED: KIP OVERSEAS EXPANSION PLATFORM FUND

AMOUNT INVESTED TO BE SENT VIA: o **Check (enclosed)** x **Wire**

Address Information

For individual subscribers this address should be the Subscriber's primary legal residence. For entities other than individual subscribers, please provide address information for the entities primary place of business. Information regarding a joint subscriber should be included in the column at right.

10F ASEM Tower, 517 Yeongdong-daero Legal Address	Legal Address
Gangnam-gu, Seoul, 135-798 Republic of Korea City, State, and Zip Code, Country	City, State, and Zip Code, Country

Alternate Address Information

Subscribers who wish to receive correspondence at an address other than the address listed above should complete the Alternate Address section on the following page.

N/A Tax ID # or Social Security #	Tax ID # or Social Security #
AGREED AND SUBSCRIBED **This day of , 2014**	**AGREED AND SUBSCRIBED** ***SIGNATURE OF JOINT SUBSCRIBER (if any)***
By: /s/ Baek Yer Hyun **Name: BAEK YER HYUN** **Title (if any):**	**This day of , 2014** **By:** _____ **Name:** **Title (if any):**
KIP Overseas Expansion Platform Fund Subscriber Name (Typed or Printed)	_____ **Additional Subscriber Name (Typed or Printed)**

ACCEPTED:

BIOPHARMX CORPORATION

By: /s/ James Pekarsky
Name: James Pekarsky
Title: Chief Executive Officer

Date of Acceptance: 24 Oct. 2014

Alternate Address Information (if applicable)

Alternate Address for Correspondence	Alternate Address for Correspondence
City, State and Zip Code	City, State and Zip Code
Telephone	Telephone
Facsimile	Facsimile
Tax ID # or Social Security #	Tax ID # or Social Security #

CERTIFICATE OF SIGNATORY

(To be completed if the Shares are
being subscribed for by an entity)

I, BAEK YER HYUN, am the CEO of KIP Overseas Expansion Platform Fund (the "Entity").

I certify that I am empowered and duly authorized by the Entity to execute and carry out the terms of the Subscription Agreement and to purchase and hold the Shares, and certify further that the Subscription Agreement has been duly and validly executed on behalf of the Entity and constitutes a legal and binding obligation of the Entity.

IN WITNESS WHEREOF, I have set my hand this 24 day of October 2014.

/s/ Baek Yer Hyun
(Signature)

March 31, 2015

BIOPHARMX CORPORATION

AMENDMENT NO. 1 TO
SUBSCRIPTION AGREEMENT
AND
VOTING RIGHTS AGREEMENT

This AMENDMENT NO. 1 TO SUBSCRIPTION AGREEMENT ("***Subscription Agreement Amendment***") amends that certain Subscription Agreement by and between the Company and Korea Investment Partners Overseas Expansion Fund ("***KIP***") ("***KIP Subscription Agreement***"), and this AMENDMENT NO. 1 TO VOTING RIGHTS AGREEMENT ("***Voting Rights Amendment***" and, together with the Subscription Agreement Amendment, the "***Amendments***") amends that certain Voting Rights Agreement by and between the KIP and each of the Stockholders listed on Schedule I thereto ("***KIP Voting Agreement***"), each dated as of October 24, 2014.

The capitalized terms not otherwise defined herein have the respective meanings given to them in the KIP Subscription Agreement or the KIP Voting Agreement, as applicable.

RECITALS

WHEREAS, the Company wishes to complete a Qualifying Listing (as defined in that certain Investors Rights Agreement, dated as of October 24, 2014, by and among the Company, Senior Management and KIP).

WHEREAS, while the Company entered into subscription agreements in substantially the form of the KIP Subscription Agreement with other purchasers of the Company's Series A Preferred Stock ("***Series A Preferred Stock***"), Section 3(W) of the KIP Subscription Agreement is unique to KIP's subscription agreement and does not appear in the other purchasers' respective subscription agreements.

WHEREAS, although Section 6(i) of the KIP Subscription Agreement states, in part, that any term of the KIP Subscription Agreement may be modified by the holders of not less than a majority of the holders of Series A Preferred Stock at the time such consent is sought, pursuant to ordinary contract law principles, the Company and KIP desire to amend Section 3(W) of the KIP Subscription Agreement to clarify the intent of the parties and provide that KIP will purchase shares of the Company's common stock, $0.001 par value per share ("***Common Stock***"), rather than shares of Series A Preferred Stock upon the completion of a Qualifying Listing, since upon the completion of such Qualifying Listing, all outstanding shares of Series A Preferred Stock will automatically convert into shares of Common Stock.

WHEREAS, Section 6 of the KIP Voting Agreement provides for termination or partial termination of the KIP Voting Agreement "upon both parties [sic] consent or upon SEC requirement for Qualifying Listing," and the Company and KIP desire to amend Section 6 of the KIP Voting Agreement pursuant to Section 7(c) thereof to clarify that the KIP Voting Agreement will immediately terminate upon the occurrence of a Qualifying Listing.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual promises made herein and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto agree as follows:

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1. **Amendment of Section 3(W) of the KIP Subscription Agreement**. Section 3(W) of the KIP Subscription Agreement is hereby amended and restated in its entirety as follows:

The Subscribers shall purchase $2,000,000 of the Shares, before Adjustments for Subdivisions, Combinations or Consolidations of Common Stock, at the per share price of $1.85 upon the earlier of the Company receiving revenues for Violet of $2,000,000 (the "Milestone") or immediately upon a Qualifying Listing, provided that the Subscribers will have no rights to receive Warrants in connection with the purchase of such Shares. Within fifteen (15) business days after the written notice and verifiable evidence of the completion of the Milestone is provided by the Company, the Subscribers shall remit funds to the Company for $2,000,000 of Shares. For purpose of this section only, in the event of a Qualifying Listing, "Shares" shall mean the Common Stock of the Company.

2. **Amendment of Section 6 of the KIP Voting Agreement**. Section 6 of the KIP Voting Agreement is hereby amended and restated in its entirety as follows:

This Agreement and the irrevocable proxies given herein shall terminate upon each parties' consent or upon completion of a Qualifying Listing.

3. Except as expressly modified by these Amendments, all terms of the KIP Subscription Agreement and the KIP Voting Agreement shall remain in full force and effect.

4. These Amendments may be executed in any number of counterparts, each of which when so executed and delivered will be deemed an original and all of which together shall constitute one and the same instrument.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 1 to the KIP Subscription Agreement and this Amendment No. 1 to the KIP Voting Agreement as of the date and year first written above.

COMPANY:

BIOPHARMX CORPORATION

Name: /s/ James Pekarsky

By: James Pekarsky

Title: President and Chief Executive Officer

[SIGNATURE PAGE TO BIOPHARMX CORPORATION AMENDMENT NO. 1 TO KIP SUBSCRIPTION AGREEMENT AND VOTING RIGHTS AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 1 to the KIP Subscription Agreement and this Amendment No. 1 to the KIP Voting Agreement as of the date and year first written above.

INVESTORS:

KOREA INVESTMENT PARTNERS OVERSEAS EXPANSION PLATFORM FUND

By: /s/ Yer-hyun, Baek

Name: Yer-hyun, Baek

Title: CEO of KIP

[SIGNATURE PAGE TO BIOPHARMX CORPORATION AMENDMENT NO. 1 TO KIP SUBSCRIPTION AGREEMENT AND VOTING RIGHTS AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 1 to the KIP Voting Agreement as of the date and year first written above.

STOCKHOLDERS:

/s/ James Pekarsky
James Pekarsky

/s/ Anja Krammer
Anja Krammer

[SIGNATURE PAGE TO BIOPHARMX CORPORATION AMENDMENT NO. 1 TO KIP VOTING RIGHTS AGREEMENT]

Exhibit 10.13

INVESTOR RIGHTS AGREEMENT

THIS INVESTOR RIGHTS AGREEMENT (this "**Agreement**") is made and entered into as of October 24, 2014, by and among (i) (a) BioPharmX Corporation, a Delaware corporation (the "**Company**"), (b) James Pekarsky ("**Pekarsky**"), Anja Krammer ("**Krammer**") and Kin Chan ("**Chan**")(together the "**Senior Management**") and (ii) the subscribers for the Company's Series A Preferred Stock which are parties to the Subscription Agreement (as defined below)(the "**Subscribers**"). Capitalized terms used herein but not otherwise defined herein shall have the respective meanings set forth in the Subscription Agreement (as defined below).

WITNESSETH:

WHEREAS, the Company and the Subscribers have entered into that certain Subscription Agreement dated as of October 24, 2014 (the "**Subscription Agreement**"), pursuant to which the Company has agreed to issue to Subscribers and Subscribers have agreed to purchase from the Company, up to $8,000,000 of Series A Preferred Stock and Warrants;

WHEREAS, in consideration of the Subscribers entering into the Subscription Agreement, the Company has agreed to provide certain rights set forth in this Agreement.

NOW, THEREFORE, in consideration of the premises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound by this agreement, agree as follows:

1. Representations and Warranties of the Senior Management. Each of the Senior Management, represents and warrants that:

1.1 (i) The Senior Management are beneficial owners, free and clear of all liens, charges or encumbrances of the following numbers of shares of Common Stock (of record or through a brokerage firm or other nominee arrangement), which constitutes 58.8% of the outstanding voting power of the Company's Common Stock:

Pekarsky – 2,500,000 shares;

Krammer – 2,500,000 shares;

Chan – 1,200,000 shares.

1.2 Each member of the Senior Management (each of the foregoing, a "**Warrantor**") has full power and authority to make, enter into and carry out the terms of this Agreement. This Agreement has been duly executed and delivered by each Warrantor and

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constitutes the legal, valid and binding obligations of such Warrantor enforceable against such Warrantor in accordance with its terms.

1.3 The execution and delivery of this Agreement by each Warrantor do not, and the performance of this Agreement by such Warrantor will not: (i) conflict with or violate any law, rule regulation, order, decree or judgment applicable to any Warrantor or by which any Warrantor or any of the properties of any Warrantor is or may be bound or affected, or the certificate of incorporation or by-laws of the Company; (ii) result in or constitute (with or without notice or lapse of time) any breach of or default under any contract to which any Warrantor is a party or by which any Warrantor or any of the affiliates or properties of any Warrantor is or may be bound or affected, or (iii) result in the creation of any encumbrance or restriction on any of the shares of Common Stock in the Company. The execution and delivery of this Agreement by each Warrantor do not, and the performance of this Agreement by each Warrantor will not, require any consent or approval of any person or entity.

2. Covenants and Agreements.

Unless the context requires otherwise, the Company hereby covenants and agrees as follows:

2.1 Periodic Reports and Other Information. As long as each Subscriber that has purchased not less than 500,000 shares of Series A Preferred holds at least 30% (the "**Minimum Holdings**") of its original holdings (a "**Qualified Subscriber**"), the Company shall furnish to such Qualified Subscriber, to the extent not made publicly available and permitted by applicable law and regulations:

(a) Quarterly Reports. Within fifty (50) days after the end of each fiscal quarter of the Company, unaudited consolidated quarterly financial statements for such fiscal quarter, including a balance sheet as of the end of such fiscal quarter, a statement of income and a statement of cash flows of the Company for such fiscal quarter, setting forth in each case in comparative form the figures from the Company's previous fiscal year and for the three, six or nine months then ended, as the case may be, prepared in accordance with generally accepted accounting principles ("**GAAP**") applied on a consistent basis (except as noted) and reviewed by internationally recognized independent certified public accountants, which fairly present the financial condition, results of operations and cash flows of the Company at the date thereof and for the periods covered thereby;

(b) Annual Reports. Within one hundred five (105) days after the end of each fiscal year of the Company, audited consolidated annual financial statements for such fiscal year, including a balance sheet as of the end of such fiscal year, a statement of income and a statement of cash flows of the Company for such year, setting forth in each case in comparative form the figures from the Company's previous fiscal year, if any, prepared in accordance with GAAP applied on a consistent basis (except as noted) and audited by internationally recognized independent certified public accountants, which fairly present the financial condition, results of operations and cash flows of the Company at the date thereof and for the periods covered thereby;

(c) Business Plan and Annual Budget. The Company shall prepare and submit to each Qualified Subscriber and the Company's Board of Directors (the "**Board**") for their approval at least thirty (30) days prior to the beginning of the next financial year or period the annual budget ("**Annual Budget**") of the Company and its subsidiaries on a consolidated basis setting out in reasonable detail the planned annual capital and operating budgets in reasonable detail, projected revenues, a projected financial statement for such fiscal year on a quarterly basis, and promptly after preparation from time to time, any revisions to the forecasts contained therein of the Company and its Subsidiaries and attaching thereto such notes as are necessary, desirable or customary, together with a business plan setting forth in reasonable detail the operating goals of the Company and its Subsidiaries for the following year (the "**Business Plan**").

2.2 Inspection. The Company shall permit each Qualified Subscriber and any authorized representative thereof, to visit and inspect the properties of the Company, including its corporate and financial records, to examine its records and make copies thereof and to discuss its affairs, finances and accounts with its officers, at all such reasonable times and as often as may be reasonably requested upon reasonable notice, provided that such visits and inspections shall not unduly interrupt the daily operation of the Company or its subsidiaries or affiliates. Each Qualified Subscriber and its participating agents and representatives, in exercising rights of inspection hereunder, agree to maintain the confidentiality of all financial and other confidential information of the Company, its subsidiaries and affiliates acquired by them. If requested by the Company, each Qualified Subscriber, in exercising its rights under this Section 2.2 shall execute a confidentiality agreement with the Company in such reasonable form and substance as agreed between each Qualified Subscriber and the Company.

2.3 Qualifying Listing. The Company shall use commercially reasonable efforts to effect a Qualifying Listing (as defined below) on or before the third anniversary of the first issuance of the Series A Preferred. For purposes of this Agreement, a "Qualifying Listing" shall mean the (1) receipt by the Company of approval to list on any tier of the NYSE or NASDAQ which are registered under the Securities Exchange Act of 1934, as amended, as a "national securities exchange," including the NYSE MKT, NASDAQ Global Select Market, NASDAQ Global Market, NASDAQ Capital Market or their successors; (2) at a market price of at least $3.70 per share.

2.4 Accountants. As long as a Qualified Subscriber holds the Minimum Holdings, the Company hereby covenants and agrees that the Company shall retain independent public accountants (the "**Accountants**") of recognized standing and acceptable to the Audit Committee of the Board who shall certify the Company's consolidated financial statements according to GAAP at the end of each fiscal year. The Company shall not terminate the services of the Accountants without the approval of the Audit Committee.

3. Right of Participation in Future Securities Offerings.

3.1 Issuance Notice. Subject to the terms and conditions of this Section and applicable securities laws, and subject to the consent and approval of the Company's underwriter at the time of an offering, if the Company shall effect an underwritten public offering of its securities at the time of a Qualifying Listing each Qualified Subscriber shall have the right to sell through

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such underwriter the following amounts of shares into which the then remaining Series A Preferred is convertible (the "**Conversion Shares**"):

(a) If the public offering price (the "**IPO Price**") is two (2) times the original purchase price of the Conversion Shares (the "**Original Purchase Price**")**,** but less than three (3) times the Conversion Price, the Qualified Subscribers may sell up to 25% of their Conversion Shares;

(b) If the IPO Price is three (3) times the Conversion Price, but less than four (4) times the Original Purchase Price, the Qualified Subscribers may sell up to 15% of their Conversion shares; and

(c) If the IPO Price is four (4) times the Original Purchase Price or more, the Qualified Subscribers may not sell any of their Conversion shares.

4. Tag-Along Right.

4.1 Tag-Along Right. (a) If member of Senior Management is directly or indirectly transferring Common Stock to a third party purchaser that is not a family member or trust (a "**Third Party Purchaser**"), then each Qualified Subscriber shall have the right to sell to such Third Party Purchaser a percentage of its Conversion Shares equal to (i) the percentage of the member of Senior Management's Common Stock being sold times (ii) a fraction, the numerator of which is 1 and the denominator of which is the number of Qualified Subscribers, at a price equal to the price at which the member of Senior Management is selling (the "**Offer Price**").

(b) Each member of Senior Management shall give notice to the Qualified Subscribers of each proposed sale by any of them of Common Stock which gives rise to the rights of the Qualified Subscribers in this Section, at least fifteen (15) business days prior to the proposed consummation of such sale, setting forth the number of shares of Common Stock, the name and address of the proposed Third Party Purchaser, the proposed amount and form of consideration and terms and conditions of payment offered by such Third Party Purchaser, the percentage of shares of Common Stock that each Qualified Subscriber may sell to such Third Party Purchaser, and a representation that such Third Party Purchaser has been informed of the "tag-along" rights provided for in this Section and has agreed to purchase Common Stock in accordance with the terms hereof. The tag-along rights provided by this Section must be exercised by a Qualified Subscriber within fifteen (15) business days following receipt of the notice required by the preceding sentence, by delivery of a written notice to the member of Senior Management indicating the Qualified Subscriber's election to exercise its rights and specifying the number of shares of Common Stock (up to the maximum number of Conversion Shares owned by the Qualified Subscriber to be purchased by such Third Party Purchaser) it elects to sell, *provided* that a Qualified Subscriber may waive its rights under this Section prior to the expiration of such fifteen (15) business day period by giving written notice to the member of Senior Management, with a copy to the Company. The failure of a Qualified Subscriber to respond within such fifteen (15) business day period shall be deemed to be a waiver of the Qualified Subscriber's rights under this Section.

4.2 Exempt Transfers. The tag-along rights set forth in this Section 4 shall not apply to (i) any transfer to a spouse, child, or other dependent or a trust for the benefit of any of the foregoing persons (a "**Permitted Holder**"); *provided* that any such Permitted Holder agrees in writing to be bound by this Agreement in place of the relevant transferor, (ii) the sale in an unsolicited broker's transaction pursuant to Rule 144 under the Securities Act of 1933, as amended, or any successor rule or (iii) the Transfer (as defined below) by a member of Senior Management of no more than 3% of the total

outstanding equity interest in the Company on a fully-diluted basis if, after such Transfer, the members of Senior Management still hold not less than 20% of the total outstanding equity interest in the Company on a fully diluted basis (the "**Exempt Transfers**"). "**Transfer**" shall mean sell, transfer, assign, pledge, hypothecate, dispose of, mortgage, enter into any voting trust or other agreement, option or other arrangement or understanding with respect thereto, whether directly or indirectly and whether voluntarily or involuntarily.

5. Board Representation and Committees.

5.1 Number of Board Members. The Company shall, effective upon Closing and until the termination of this Agreement, take all appropriate actions to fix and maintain a Board of no more than five (5) voting members and the Company shall not change the number of voting members of its Board without the prior written approval of the Qualified Subscribers.

5.2 Qualified Subscriber Nominees. Upon the Qualified Subscriber Election (as defined below), so long as there remains a Qualified Subscriber, the Qualified Subscribers shall be entitled to appoint one (1) voting member of the Company's Board (a "**Qualifying Subscriber Nominee**").

5.3 Board Committees. The Company shall establish Audit and Compensation Committees of the Board and the Qualified Subscriber Nominee shall serve on both committees to the extent permitted by applicable law and exchange listing rules.

5.4 Qualified Subscribe Election. If the Qualifying Subscriber provide written notice to the Company informing the Company of (i) their election (the "**Election**") to be represented on the Board and (ii) the name(s) of the Qualified Subscriber Nominee, then, as soon as practicable after its receipt of such notice from a Qualified Subscriber, but in no event later than five (5) business days after such receipt, the Company shall:

(a) provide notice of the Election to the Company' Board, and

(b) to the extent permissible under applicable law a regulations (including rules of any relevant listing exchange), take all necessary actions so as to permit the Qualified Subscriber Nominee to be duly appointed or elected as a member of the Company's Board as soon as practicable.

5.5 Voting Agreement. The member of Senior Management agree to vote, or cause to be voted, all of the Company's voting share owned by such members of Senior Management (of record or through a brokerage firm or other nominee arrangement), or over which such member of Senior Management has voting control, from time to time and at all times, in

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whatever manner as shall be necessary to ensure that at each annual or special meeting of shareholders at which an election of directors is held or pursuant to any written consent of the shareholders, the Qualified Subscriber Nominees are duly elected to the Board. The members of Senior Management further covenant not to frustrate the purpose of the immediately preceding sentence by any means, including through entering into any agreement or commitment inconsistent with such purpose, including but not limited to any inconsistent pledge, charge, hypothecation, voting agreement, voting trust or other disposition of voting rights of the Common Stock over which the members of Senior Management retain beneficial ownership or the economic benefits and risks attendant thereto.

5.6 Vacancies. Any vacancies created by the resignation, removal or death of a Qualified Subscriber Nominee appointed or elected to the Board shall be filled pursuant to the provisions of this Section.

6. Senior Management Additional Voting Agreement.

6.1 Voting Agreement. At all times that more than 60% of the Series A Preferred issued by the Company under the Subscription Agreement remains outstanding, the members of Senior Management agree to vote, or cause to be voted, all of the Company's voting shares owned by such members of Senior Management (of record or through a brokerage firm or other nominee arrangement), or over which such member of Senior Management has voting control, from time to time and at all times, in favor of any transaction which would result in a sale of more than 50% of the voting stock of the Company or substantially all of its assets, if such transaction is approved in writing by the holders of more than 50% of the then outstanding Series A Preferred. The members of Senior Management further covenant not to frustrate the purpose of the immediately preceding sentence by any means, including through entering into any agreement or commitment inconsistent with such purpose, including but not limited to any inconsistent pledge, charge, hypothecation, voting agreement, voting trust or other disposition of voting rights of the Common Stock over which the members of Senior Management retain beneficial ownership or the economic benefits and risks attendant thereto.

7. Miscellaneous.

7.1 Termination. This Agreement will be terminated at such time that less than 10% of the Series A Preferred (or after conversion shares) originally issued pursuant to the Subscription Agreement remains outstanding.

7.2 Specific Enforcement. Upon a breach by the Company or any member of the Senior Management of this Agreement, the Subscribers shall be entitled to injunctive relief against the Company or such member of the Senior Management if such relief is applicable and available, as a remedy at law would be inadequate and insufficient. Nothing in this Section shall be construed as limiting the Subscribers' remedies in any way.

7.3 Notices. All notices, requests, consents and other communication hereunder shall be in writing and shall be personally delivered or delivered by overnight courier or mailed by first-class registered or certified mail, postage prepaid, return receipt requested, or by facsimile

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transmission. Every notice hereunder shall be deemed to have been duly given or served on the date on which personally delivered, with receipt acknowledged, upon transmission by facsimile and confirmed facsimile receipt, or two (2) days after the same shall have been deposited with a reputable international overnight courier.

(a) If to a Subscriber, at its address as set forth in the Subscription Agreement, or at such other address as may have been furnished to the Company by it in writing.

(b) If to any member of the Senior Management, at the address set forth on Schedule I to this Agreement, or at such other address as may have been furnished to the Company by it in writing.

(c) If to the Company at:

BioPharmX Corporation
1098 Hamilton Court
Menlo Park, California 94025
Attention: James Pekarsky, CEO
Fax: 650-900-4130

with a copy to:

Ofsink, LLC
900 Third Avenue, 5th Floor
New York, New York 10022
Fax: 646-244-9844

7.4 Amendments and Waiver. Unless otherwise specifically stated herein, any term of this Agreement may be amended with the written consent of the party against whom enforcement may be sought and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively). In the case of the Subscribers, a waiver may be effected by written consent of greater than 50% of the then outstanding Series A Preferred. No waivers of or exceptions to any term, condition or provision of this Agreement, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such term, condition or provision.

7.5 Entire Agreement. This Agreement embodies the entire agreement and understanding between the parties hereto and supersedes all prior agreements and understandings relating to the subject matter hereof.

7.6 Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provisions of this Agreement to the extent permitted by law.

7.7 Governing Law. This Agreement shall be governed by an construed in accordance with the laws of the State of New York.

7.8 Successors and Assigns. Except as otherwise provided herein, the terms and conditions of this Agreement shall be binding upon, and inure to the benefit of, the respective representatives, successors and assigns of the parties hereto.

7.9 Counterparts. This Agreement may be executed in a number of counterparts, by facsimile, each of which shall be deemed to be an original as of those whose signature appears thereon, and all of which shall together constitute one and the same instrument. This Agreement shall become binding when one or more of the counterparts hereof, individually or taken together, are signed by all the parties.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned have executed this Investor Rights Agreement as of the day and year written above.

THE COMPANY:

BIOPHARMX CORPORATION

By: /s/ James Pekarsky
Name: James Pekarsky
Title: Chief Executive Officer

SENIOR MANAGEMENT:

/s/ James Pekarsky
James Pekarsky

/s/ Anja Krammer
Anja Krammer

/s/ Kin Chan
Kin Chan

THE SUBSCRIBER:

Accepted and Agreed to:
KIP Overseas Expansion Platform Fund

By: /s/ Baek Yer Hyun

Name: Baek Yer Hyun

Title: Authorized Signatory

EXHIBIT 21.1

SUBSIDIARY OF BIOPHARMX CORPORATION

As of January 31, 2016, BioPharmx Corporation's sole subsidiary was BioPharmx Inc., a Nevada corporation.

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EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-201708) and the Registration Statement on Form S-3 (No. 333-209026) of BioPharmX Corporation of our report dated May 2, 2016 relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K.

/s/ Burr Pilger Mayer, Inc.

San Jose, California
May 2, 2016

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EXHIBIT 31.1

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

I, James Pekarsky, certify that:

1. I have reviewed this annual report of BioPharmX Corporation on Form 10-K for the fiscal year ended January 31, 2016;

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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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 the 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: May 2, 2016

/s/ JAMES PEKARSKY

James Pekarsky
Chief Executive Officer and Chairman of the Board of Directors
(Principal Executive Officer)

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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 of BioPharmX Corporation on Form 10-K for the fiscal year ended January 31, 2016;

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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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 the 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: May 2, 2016

/s/ GREG KITCHENER

Greg Kitchener
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

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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, 2016, 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, certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of 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: May 2, 2016

/s/ JAMES PEKARSKY

James Pekarsky
Chief Executive Officer and Chairman of the Board of Directors (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.

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