Flex Pharma, Inc.
Form 10-K
March 24, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)

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

For the Fiscal Year Ended December 31, 2014
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 Number: 001-36812

FLEX PHARMA, INC.
(Exact name of Registrant as specified in its charter)

Delaware	2834	46-5087339
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

800 Boylston Street, 24th Floor
Boston, MA 02199
(617) 874-1821
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Christoph Westphal, M.D., Ph.D.
President and Chief Executive Officer
Flex Pharma, Inc.
800 Boylston Street, 24th Floor
Boston, MA 02199
(617) 874-1821
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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

Title of Class	Name of Each Exchange on Which Registered
Common Stock, $ 0.0001 par value	NASDAQ Global Market

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 ý

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

Indicate by check mark 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 the filing requirements for the past 90 days. Yes o No ý

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 o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of the 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. ý

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

Large Accelerated Filer o	Accelerated Filer o	Non-accelerated Filer ý (Do not check if a smaller reporting company)	Smaller Reporting Company o

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

The registrant completed the initial public offering of its common stock, par value $0.0001 per share, on February 3, 2015. There was no public market for the registrant's common stock as of June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter.

As of March 20, 2015, there were 17,933,664 shares of common stock outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical studies and trials;
- our ability to obtain and maintain regulatory approval of our drug product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved drug product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete clinical development and file a new drug application for drug product candidates;
- our plans to launch a consumer brand and our cornerstone product;
- our plans to develop and commercialize consumer products and our drug product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our consumer products and our drug product candidates, and our ability to serve those markets;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the rate and degree of market acceptance of our consumer products and our drug product candidates;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are, or become, available;
- the loss of key scientific or management personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for our consumer product and drug product candidates.

Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in Part I, Item 1A. "Risk Factors" below and for the reasons described elsewhere in this Annual Report on Form 10-K. Any forward-looking statement in this Annual Report on Form 10-K reflects our current view with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and the markets for certain drugs and consumer products, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

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Except where the context otherwise requires, in this Annual Report on Form 10-K, "we," "us," "our" and the "Company" refer to Flex Pharma, Inc. and, where appropriate, its consolidated subsidiary.

PART I

Item 1. BUSINESS

Overview

We are a biotechnology company that is developing innovative and proprietary treatments for exercise-associated muscle cramps, nocturnal leg cramps and spasms associated with severe neuromuscular conditions. Our founders' novel insights regarding neuromuscular physiology form the basis of our development efforts. We believe that activation of certain receptors in primary sensory neurons reduces the repetitive firing, or hyperexcitability, of alpha-motor neurons, thereby preventing or reducing the frequency and intensity of muscle cramps and spasms. We also believe that we are the only company developing products based on this mechanism of muscle cramp inhibition. We have conducted three randomized, blinded, placebo-controlled cross-over studies of our proprietary treatment, which have shown a statistically significant reduction in the intensity of muscle cramps induced in healthy normal volunteers. We intend to initially focus our drug development efforts on developing a product to treat nocturnal leg cramps. There is no drug product currently available in the United States that has been approved to treat nocturnal leg cramps. We estimate, based on independent third-party survey results, that approximately four million U.S. adults over the age of 65 suffer from nocturnal leg cramps on a daily basis. In the second quarter of 2015, we expect at least one individual to complete treatment in our first human proof-of-concept study of our proprietary treatment in individuals suffering from nocturnal leg cramps.

A muscle cramp is a sudden, painful contraction of a muscle that can last several minutes and, in many instances, results in soreness lasting several days. Spasticity is an abnormal, involuntary tightness of muscles including uncontrolled movement, muscle stiffness, difficulty straightening joints, reduced mobility, limb weakness, shaking and pain. We believe that muscle cramps and spasms result from the hyperexcitability of alpha-motor neurons. Our proprietary treatment, which forms the basis of both our drug product and consumer product development efforts, activates the transient receptor potential, or TRP, cation channel receptors in primary sensory neurons in the spinal cord, which enhances overall inhibitory tone in motor neurons throughout the body. In doing so, we believe our proprietary treatment reduces alpha-motor neuron hyperexcitability, thereby preventing muscle cramps and spasms. We believe the results from the studies of our proprietary treatment in healthy normal volunteers have validated our approach of using TRP activators to relieve muscle cramps and spasms. We protect our technology through a combination of patents, trade secrets and proprietary know-how, and we intend to seek marketing exclusivity for any approved drug products.

Nocturnal leg cramps are muscle cramps that occur during sleep and can cause distress, interrupted sleep, reduced quality of life and interference with activities of daily living. The prevalence of nocturnal leg cramps is widespread and increases with age. We believe our primary target patient population will include individuals that suffer from nocturnal leg cramps daily or weekly and, based on independent third-party survey results, estimate that approximately four million U.S. adults over the age of 65 suffer from nocturnal leg cramps on a daily basis. Nocturnal leg cramps also affect people younger than 65 and we believe there is an opportunity to serve this patient population as well. Stretching and systemic treatments, including dietary supplements, vasodilators and calcium channel blockers, have shown some limited benefit in treating nocturnal leg cramps but these treatments lack durable evidence of clinical efficacy. In the second quarter of 2015, we expect at least one individual to complete treatment in our first human proof-of-concept study of our proprietary treatment for individuals with nocturnal leg cramps. The protocol for this proof-of-concept study in the United States was accepted by an institutional review board, or IRB. We have also submitted a protocol to a local ethics committee in each of the United Kingdom and Australia for an additional proof-of-concept study of individuals with nocturnal leg cramps.

We may also initiate human proof-of-concept studies of our proprietary treatment in patients outside the United States that suffer from spasms associated with severe neuromuscular conditions and other conditions where patients

experience abnormal muscle contractions, including multiple sclerosis, cervical dystonia and spinal cord injury, or SCI. According to the National Institute of Neurological Disorders and Stroke, between 250,000 and 350,000 people in the United States suffer from multiple sclerosis, or MS, approximately 84% of whom experience spasticity. According to the National Spasmodic Torticollis Association, cervical dystonia affects approximately

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90,000 people in the United States and we estimate, based on industry sources, that spasticity following spinal cord injury, affects at least 150,000 people in the United States.

We are also developing a consumer brand with products based on the same mechanism of action as our proprietary treatment. Our consumer brand and products will be targeted towards athletes experiencing exercise-associated muscle cramps, or EAMCs. EAMCs are painful, spasmodic and involuntary contractions of skeletal muscle that occur during or following exercise in individuals with no underlying metabolic, neurological or endocrine pathology. EAMCs can be experienced by individuals participating in any sport but are particularly prevalent in athletes engaging in high-intensity activities, such as running, cycling and triathlons. There are a number of well-known sports drinks and other consumer products used to prevent EAMCs. However, we do not believe any of these products have been proven to be clinically effective in preventing EAMCs. We have commenced formulation and commercialization efforts of our consumer brand and cornerstone consumer product to address this attractive market, and we anticipate launching our cornerstone product in the first half of 2016. While our consumer product and any eventual drug product we may develop may contain the same active ingredients, we believe the TRP activators in our consumer product will not be purified and will be at lower amounts than the TRP activators in any future drug product.

To date, we have developed our proprietary treatment as a dietary supplement. This has allowed us initially to test our proprietary treatment in humans for the prevention and treatment of muscle cramps without first filing an investigational new drug application, or IND, with the U.S. Food and Drug Administration, or the FDA. We are studying TRP activators at different drug dosage levels, across alternative delivery systems and using different single agent and combination formulations in order to identify the most potent product candidate to bring to drug clinical trials. We intend to initiate a clinical trial with one of our drug product candidates, all of which are currently in the pre-clinical phase of development, if the results of one or more of our human proof-of-concept studies are favorable. Prior to initiating this drug clinical trial, we will submit one or more INDs with the FDA and intend to discuss with the FDA our intent to initiate a Phase 2 registration-directed clinical trial for a drug product candidate intended to treat nocturnal leg cramps.

The development path for our potential drug product candidates and consumer product is described in the following table.

Consumer Product Development Plans

Target Market	Current Development Status	Future Development Plans
Exercise-associated muscle cramps, or EAMCs	• Formulation and launch efforts underway	• Launch our consumer brand and cornerstone product in the first half of 2016

Pre-Clinical Drug Product Candidates Development Plans

Target Indications	Current Development Status
Nocturnal leg cramps	• At least one individual expected to complete treatment in our first human proof-of-concept, or POC, study of our proprietary treatment as a dietary supplement in the second quarter of 2015
MS spasticity, cervical dystonia and/or SCI spasticity	• Evaluating initiation of one or more POC studies of our proprietary treatment for one or more future drug indications

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Our Leadership Team and Scientific Advisors

Our company is led by our scientific co-founders, Roderick MacKinnon, M.D. and Bruce Bean, Ph.D., and our President, Chief Executive Officer and Chairman, Christoph Westphal, M.D., Ph.D. Dr. MacKinnon, a member of the National Academy of Sciences and of our Board of Directors, was awarded the Nobel Prize in Chemistry in 2003 for his work on ion channel activation, the foundation of our approach to preventing muscle cramping. Dr. Bean is a member of the National Academy of Sciences and the Robert Winthrop Professor of Neurobiology at Harvard Medical School, where he oversees a leading research laboratory studying the biophysics of sodium, calcium and potassium ion signaling in relation to pain processing. Dr. Westphal has co-founded and served as the Chief Executive Officer of several biotechnology companies, including Alnylam Pharmaceuticals, Inc., Acceleron Pharma Inc., Sirtris Pharmaceuticals, Inc., Momenta Pharmaceuticals, Inc. and Verastem, Inc. Dr. Westphal also co-founded Alnara Pharmaceuticals, Inc., OvaScience, Inc. and Concert Pharmaceuticals, Inc.

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Our management team also includes:

Jennifer Cermak, Ph.D., Vice President of Research and Development	Research and development experience in new product development, candidate selection and first-in-man through Phase 4 global clinical trials, serving as a member of Sirtris Pharmaceuticals' executive management team and in leadership positions at Pfizer, GlaxoSmithKline and United Therapeutics
Robert Hadfield, General Counsel	Broad experience advising companies on securities law compliance, corporate governance matters and mergers and acquisitions as an attorney at Cooley LLP and as a financial analyst at SG Cowen
Marina Hahn, President, Consumer	Extensive experience developing and building consumer brands, including serving as Chief Marketing Officer of Spirits Marque One LLC, makers of SVEDKA vodka, and a division of Constellation Brands
John McCabe, Vice President of Finance	Over 20 years of experience leading global finance, accounting and administrative operations, including positions at ARIAD Pharmaceuticals, Charles River Associates and Biogen Idec
Thomas Wessel, M.D., Ph.D, Chief Medical Officer	Board certified neurologist with extensive drug development experience, including serving as the medical lead for three products approved in United States: Razadyne®, Lunesta® and Ampyra®. Prior leadership roles at Johnson & Johnson, Sepracor, Inc. and Acorda Therapeutics, Inc.
Elizabeth Woo, Senior Vice President of Investor Relations and Corporate Communications	Over 20 years of experience in investor relations, biotechnology and pharmaceuticals, previously serving as Vice President of Investor Relations for Biogen Idec and as an investor relations consultant to Ironwood Pharmaceuticals and Cubist Pharmaceuticals

Our team is supported by our scientific advisory board comprised of leading academic and industry scientists:

Roderick MacKinnon, M.D., Scientific Co-Founder and Chair and Member of our Board of Directors	Investigator at Howard Hughes Medical Institute and the John D. Rockefeller Jr. Professor, Laboratory of Molecular Neurobiology and Biophysics at the Rockefeller University, member of the National Academy of Sciences
Bruce Bean, Ph.D., Scientific Co-Founder and Chair	Robert Winthrop Professor of Neurobiology at Harvard Medical School and member of the National Academy of Sciences
David Julius, Ph.D.	Professor and Chair, Department of Physiology, University of California, San Francisco. Member of the National Academy of Sciences and the Institute of Medicine.

	Discovered the TRPV1 ion channel
Christopher Walsh, Ph.D.	Hamilton Kuhn Professor in the Department of Biological Chemistry and Molecular Pharmacology at Harvard Medical School. Member of the National Academy of Sciences and the Institute of Medicine
Roger Tung, Ph.D.	President and Chief Executive Officer of Concert Pharmaceuticals, Inc., former Vice President of Drug Discovery of Vertex Pharmaceuticals, Inc. and co-inventor of Lexiva® and Agenerase. Oversaw the development Incivek® and Kalydeco®

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Our Strategy

Our strategy is to become a leading biotechnology company focused on treating muscle cramps and spasms associated with severe neuromuscular conditions in areas of significant unmet need. We intend to develop products using TRP activators, leveraging our experienced management team and our relationships with top scientific advisors to expedite our drug and consumer product development efforts. The key elements of our strategy are as follows:

- Rapidly develop and advance our drug product candidates for the treatment of nocturnal leg cramps. We believe the nocturnal leg cramp market represents a significant opportunity that historically has been underserved. There is no drug currently approved in the United States for the treatment of nocturnal leg cramps. In the second quarter of 2015, we expect at least one individual to complete treatment in our first human proof-of-concept study of our proprietary treatment in individuals suffering from nocturnal leg cramps. This proof-of-concept study is being conducted pursuant to the regulatory framework applicable to dietary supplements in the United States. We plan to develop drug product candidates for the treatment of nocturnal leg cramps and, if the results of one or more of our human proof-of-concept studies are favorable, we intend to file an IND with the FDA for one or more of our drug product candidates and initiate a Phase 2 registration-directed clinical trial.
- Expand our drug development efforts into severe neuromuscular conditions of significant unmet need. We believe drug products based on the TRP activators used in our proprietary treatment may relieve spasticity and abnormal muscle contractions affecting individuals suffering from severe neuromuscular conditions. We are currently evaluating the initiation, outside the United States, of human proof-of-concept studies of our proprietary treatment in patients that suffer from multiple sclerosis spasticity, cervical dystonia and spasticity associated with spinal cord injury.
- Develop and launch our consumer brand and products for the prevention of EAMCs. We intend to develop a consumer brand and products specifically formulated to treat athletes suffering from EAMCs. To lead this effort, we have hired Marina Hahn as our President, Consumer, who has extensive experience developing and building consumer brands. In the first half of 2016, we expect to begin selling the cornerstone product of our consumer brand, which will be a liquid marketed to athletes engaging in high-intensity sports where muscle cramping is prevalent. As our brand and target market evolves, we anticipate evaluating product line extension opportunities. The breadth of our consumer products will depend on a variety of factors, including brand positioning, target audience and product formulation alternatives. Additionally, we will consider partnering with established consumer brand companies following our initial launch to accelerate market acceptance of our consumer products.
- Collaborate selectively to augment and accelerate our research, development and commercialization efforts. We may seek third-party collaborators for the development and eventual commercialization of any drug product candidate we develop. In particular, we may enter into third-party arrangements for targeted neuromuscular indications in which our potential collaborator has particular expertise or for which we need access to additional research, development or commercialization resources.
- Pursue the acquisition or in-licensing of product candidates. We may enhance our product pipeline through strategically acquiring or in-licensing pre-clinical or clinical stage product candidates. We believe that our management team and scientific advisory board's expertise in neuronal circuits experience may make us an attractive partner for companies seeking to out-license products or develop product candidates in this area of focus.

Market Opportunity

We are developing products for the treatment of muscle cramps including nocturnal leg cramps, spasms associated with severe neuromuscular conditions and other conditions where patients experience abnormal muscle contractions. A muscle cramp is a sudden and painful contraction of a muscle that may last several minutes and, in many instances, results in soreness lasting several days. Spasticity, which is frequently experienced by patients with severe neuromuscular conditions, such as multiple sclerosis and as the result of SCI, is an abnormal, involuntary tightness of muscles and is characterized by uncontrolled movement, muscle stiffness, difficulty straightening joints, reduced mobility, limb weakness, shaking, intermittent spasms and pain. Dystonias are characterized by sustained or intermittent muscle contractions causing abnormal, often repetitive, movements,

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postures, or both. The treatment of muscle cramps remains challenging because we do not believe there is any product that has been rigorously proven to be effective in treating muscle cramps. Many products intended to treat spasms and dystonias are not available to all patients and are generally limited by unwanted side effects. We believe there is a large and underserved market for effective treatment of muscle cramps and spasms as a result of the limitations of the current standard of care.

Nocturnal Leg Cramps

Background. Nocturnal leg cramps are muscle cramps, usually occurring in the calf during sleep, that cause pain, stress, disability and poor sleep quality in affected individuals resulting in reduced quality of life and interference with activities of daily living. The causes of nocturnal leg cramps remain unknown but are related to various conditions such as inactivity, overexertion, peripheral artery disease, metabolic problems, certain medications and spinal stenosis. The prevalence of nocturnal leg cramps is widespread and increases with age. According to a survey of 233 individuals, 37% of adults over the age of 50 suffered from nocturnal leg cramps. Based on a separate survey of 365 individuals, 50% of adults over the age of 65 suffered from nocturnal leg cramps. We believe our primary target patient population will include individuals that suffer from nocturnal leg cramps daily or weekly and, based on independent third-party survey results, estimate that approximately four million U.S. adults over the age of 65 suffer from nocturnal leg cramps on a daily basis. Nocturnal leg cramps also affect people younger than 65 and we believe there is an opportunity to serve this patient population as well. In the United Kingdom, quinine is prescribed for the treatment of nocturnal leg cramps, in addition to being a treatment for malaria. In 2013, approximately 4.5 million quinine prescriptions were written for patients in the United Kingdom, a country with approximately one-fifth the population of the United States. We believe a majority of these prescriptions were for the treatment of individuals suffering from nocturnal leg cramps.

Limitations of Current Treatment. We do not believe any therapy has been shown to be safe and effective in treating nocturnal leg cramps in well-designed, blinded clinical trials. Stretching and systemic treatments, such as dietary supplements, vasodilators and calcium channel blockers, have shown some benefit in treating nocturnal leg cramps, but we do not believe any medication has shown durable evidence of clinical efficacy. Quinine is prescribed in the United Kingdom for the treatment of nocturnal leg cramps. However, quinine is associated with serious and life-threatening adverse events, including thrombocytopenia, hypersensitivity reactions and QT prolongation. In 1994, the FDA banned the use of over-the-counter quinine for the treatment of leg cramps and reinforced this view for prescription quinine products in 2006. Notwithstanding its ban, the FDA estimated that approximately 206,000 and 51,800 patients continued to be prescribed quinine in 2008 and 2011, respectively, the majority of which were associated with off-label indications relating to leg cramps and muscle pain.

Multiple Sclerosis Spasticity

Background. MS is an autoimmune disease where the nerves of the patient's brain and spinal cord are damaged by the immune system, resulting in a loss of muscle control, sensation and vision. Spasticity is caused by damage to the brain and spinal cord by MS. This imbalance causes hyperactive muscle stretch reflexes, which result in involuntary contractions of the muscle and increased muscle tension. While spasticity can be useful in the earlier stages of MS to assist ambulation, the need to treat spasticity increases as the disease progresses in order to prevent contracture, bed sores and severe pain. According to the National Institute of Neurological Disorders and Stroke, between 250,000 and 350,000 people in the United States suffer from MS and approximately 84% of patients with MS experience spasticity.

Limitations of Current Treatment. Patients suffering from MS spasticity may be treated with muscle relaxants, sedatives and Botox injections, which frequently result in unwanted side effects, including dizziness, drowsiness, dry mouth, fatigue, weakness, diarrhea or constipation and low blood pressure. Further, patient responses to single or combination agents vary and treatments may be incomplete in managing spasticity.

Cervical Dystonia

Background. Also known as spasmodic torticollis, cervical dystonia is a painful and debilitating neurological movement disorder. Cervical dystonia is characterized by sustained or intermittent muscle contractions causing abnormal, often repetitive, movements or postures. The patient's head may turn to the right or left (torticollis), may tilt to one side (laterocollis), or may tilt upwards (retrocollis) or downwards (anterocollis). Patients may also experience

spasmodic jerking of the head. The causes of cervical dystonia are unknown. Cervical dystonia affects approximately three in every 10,000 people, or about 90,000 people in the United States, according to the National Spasmodic Torticollis Association.

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Limitations of Current Treatment. Botox injection is the most commonly used treatment for cervical dystonia and while Botox can provide significant relief, it may result in side effects that include weakness, difficulty swallowing or speaking, flu-like symptoms, pain and bruising. The effectiveness of Botox therapy may be limited by the skill of the injector at isolating muscles and the accessibility of the affected muscle to treatment.

Spasticity as a Result of Spinal Cord Injury

Background. Spasticity commonly occurs following spinal cord injury, or SCI, and results from injury to the upper motor neurons within the central nervous system, or CNS. SCI spasticity may cause pain and fatigue and can impede rehabilitation efforts. There are approximately 273,000 people in the United States with SCI and between 65% and 78% of individuals with chronic spinal cord injury have symptoms of spasticity. Based on these patient populations, we estimate that at least 150,000 people in the United States suffer from SCI spasticity.

Limitations of Current Treatment. Depending on the severity, SCI spasticity is treated with physical therapy, including surface electrical stimulation, surgery or drug therapy, including muscle relaxants, sedatives and Botox injection. These treatments are sometimes unavailable to patients with severe forms of spasticity and patients receiving these treatments may experience side effects that include weakness, sedation, nausea, malaise, dry mouth or dizziness.

Other Potential Indications

We may also pursue the use of our drug product candidates in several other conditions where muscle cramps, spasms or abnormal muscle contractions afflict patients, including amyotrophic lateral sclerosis, spasms due to brain injury such as in stroke or cerebral palsy or trauma, focal dystonias (e.g. blepharospasm), peripheral neuropathy (e.g. diabetic), fibromyalgia, Machado-Joseph disease, hereditary spastic paraplegia, cramp fasciculation syndrome, cramps due to dialysis, spasmodic dysphonia, hypomagnesemia, hypocalcemia, piriformis syndrome, lower lumbar radiculopathy and neuromyotonias (focal).

Exercise-Associated Muscle Cramp

Background. We are also developing a consumer brand with products to prevent exercise-associated muscle cramps, or EAMCs. EAMCs are painful, involuntary contraction of a skeletal muscle that occurs during or following exercise in individuals and result in acute pain, stiffness, bulging or knotting of the muscle and soreness that can last for several days. EAMCs can be experienced by individuals participating in any sport, but EAMCs are particularly prevalent in athletes engaged in high-intensity activities, such as triathlons, marathons and cycling events. Our cornerstone consumer product will be directed towards endurance athletes participating in these types of high-intensity sports.

Limitations of Current Products. There are a number of well-known sports drinks and other consumer products that are intended to treat electrolyte abnormalities and dehydration. However, we do not believe clinical studies have proven that these factors, in isolation, cause EAMCs. Scientists recently began hypothesizing that altered neuromuscular control, as a result of muscle fatigue, causes EAMCs. Our cornerstone product will include TRP activators that reduce alpha-motor neuron hyperexcitability caused by muscle fatigue, thereby preventing muscle cramps. We believe endurance athletes participating in high-intensity sports want a product that has been shown to be clinically effective and that may provide a competitive advantage.

Our Scientific Approach

Recent research has shown that muscle cramping is caused by the uncontrolled and repetitive firing of alpha-motor neurons in the spinal cord, resulting in maintained contraction of the muscle. We believe that by reducing this firing of the alpha-motor neurons that control muscle contraction, muscle cramping can be reduced or prevented.

Motor neurons respond to inputs from complex circuits in the spinal cord that both (A) reduce neuronal and muscle activity, known as "inhibitory" input, and (B) increase neuronal and muscle activity, known as "excitatory" input. Our approach exploits a general principle of neural circuits: that strong excitatory input from one source in the body enhances overall inhibitory tone in the spinal cord and thereby reduces neuronal response to other excitation throughout the body.

The activation of ion channels forms the basis of our scientific approach and members of our scientific advisory board are leaders in this field. Our co-founder, Roderick MacKinnon, M.D., was awarded the Nobel Prize in 2003 for his work determining the structure of ion channels and showing the mechanism by which they select for particular ions

(Doyle, et al., The Structure of the Potassium Channel: Molecular Basis of K+ Conduction and Selectivity, April 1998, Science). David Julius, Ph.D., a member of our scientific advisory board, first described the TRP vanilloid-1,

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or TRPV1, receptor and illustrated the importance this ion channel played in diverse physiological functions (Caterina, et al., The capsaicin receptor: a heat-activated ion channel in the pain pathway, October 1997, Nature). In particular, the TRPV1 ion channel acts as a receptor that reacts to multiple sensory inputs. TRPV1 is activated by heat, low pH and a variety of molecules, including gingerols and capsaicinoids, which are responsible for the heat sensation from chili peppers and other "spicy" foods.

The TRP subfamily A, member 1, or TRPA1, ion channel is a channel in the cell membrane that can be activated by a wide variety of stimuli, including cold temperature and a variety of pungent chemical agents such as ginger, cinnamon and mustard oil. TRPA1 ion channels are expressed mainly in primary sensory neurons associated with slow-conducting C-fibers and carry signals directly to the spinal cord.

Our proprietary treatment stimulates primary sensory neurons in the mouth, esophagus and stomach by activating TRPV1 and TRPA1 ion channels. These sensory neurons project both directly and indirectly to the spinal cord, and we believe that their activation enhances the overall inhibitory tone in spinal cord circuits, which reduces repetitive firing of the alpha-motor neurons throughout the body and thereby prevents or reduces the frequency and intensity of muscle cramps and spasms. Muscle contractions associated with dystonia and spasticity are also believed to result from abnormal repetitive firing of alpha-motor neurons.

Our proprietary treatment contains three active ingredients that the FDA has deemed to be generally recognized as safe, or GRAS, when used in ingested food: (1) ginger extract, an activator of both TRPV1 and TRPA1 ion channels, (2) cinnamon extract, an activator of TRPA1 ion channels, and (3) capsicum, an activator of TRPV1 ion channels. Our proprietary treatment stimulates TRP channels located in the mouth, esophagus and stomach, activating receptors in the gastrointestinal tract. We believe that the effects of the TRP activators in our proprietary treatment directly interact with TRPA1 and TRPV1 ion channels in a topical and local fashion to yield strong, centrally-acting excitatory inputs from peripheral sensory neurons. The signals activated in the TRPA1 and TRPV1 ion channels are channeled directly to the spinal cord, creating an inhibitory effect from the central nervous system on alpha-motor neurons throughout the body, thereby reducing neuron excitation and muscle cramps. Moreover, we believe that the physical properties of the TRP activators largely limit their action to sensory neurons in the mouth, esophagus and stomach, with minimal concentrations reaching the bloodstream and, consequently, fewer potential systemic side-effects.

Clinical Development

Clinical Studies

In 2014, we completed three randomized, blinded, placebo-controlled cross-over studies, which we refer to as Flex-001, Flex-002 and Flex-003, of our proprietary treatment in a total of 37 healthy normal volunteers.

In each study, our proprietary treatment showed statistical significance in reducing muscle cramps as compared to vehicle control, with good safety and tolerability, which supports our belief that TRP activation can dampen the repetitive firing of alpha-motor neurons to prevent or reduce muscle cramps.

We have studied the effectiveness of our proprietary treatment in preventing electrically induced muscle cramps in healthy normal volunteer studies without submitting an IND to the FDA. Previous studies have shown a correlation between electrically induced cramping and individual susceptibility to naturally occurring cramping. As a result, we believe that the use of our electrically induced muscle cramping technique is an effective tool for understanding the pathogenesis and treatment of naturally occurring muscle cramping. Our proprietary treatment demonstrated statistical significance in reducing the intensity of electrically induced muscle cramps in each of our three studies and we believe that our proprietary treatment has the potential to prevent naturally occurring muscle cramping such as nocturnal leg cramps and EAMCs.

Testing Procedures and Clinical Study Design

In each study, we induced muscle cramping in the flexor hallucis brevis muscle, (a small muscle on the bottom of the hallux (big toe), using electrical stimulation and then measured the duration and intensity of the subject's cramp using electromyography, or EMG. EMG is a technique used for evaluating and recording the electrical activity produced by skeletal muscles and produces a record called an electromyogram. During our clinical studies, a stimulating electrode was placed on the sole of the foot over the abductor hallucis muscle and recording sensors were attached to the flexor hallucis brevis muscle (see Figure 1). The subject's abductor hallucis muscle and medial plantar nerve were stimulated, which induced a muscle cramp. We then measured muscle cramp intensity and duration using EMG

recording sensors.

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Figure 1

To measure a subject's muscle cramp, we calculated the area under the curve, or AUC, produced by the electromyogram as depicted in Figure 2. Muscle cramp intensity and duration vary by subject, so each study began by inducing a cramp in each subject in order to create a "baseline AUC." This baseline AUC was later compared to the AUC after the subject received either our proprietary treatment or a vehicle control without active ingredients. The time at which the subject receives our proprietary treatment or vehicle control is referred to as timepoint zero. We then attempted to induce muscle cramps using electrical stimulation at various times following timepoint zero. At each timepoint, we measured the subject's cramp intensity and duration using the EMG recording sensors and then compared each AUC against the baseline AUC. We believe that if a subject's AUC at the subsequent timepoints was smaller than the subject's baseline AUC, then our proprietary treatment successfully prevented or reduced the intensity of the subject's muscle cramp.

Figure 2

Each of these studies was conducted in the United States at a third party clinical research organization specializing in early clinical research services and under the oversight of an institutional review board. None of these studies were IND-enabling studies, as they were conducted under the FDA's dietary supplement regulatory framework. Participants were recruited by the clinical research organization and included healthy, adult males or females, 19-65 years of age, without any clinically significant medical history, physical examination findings or laboratory profiles. In each study the subjects were pre-screened for overall general health based on the study protocol's inclusion and exclusion criteria. To be included in the study, each subject must have had a toe cramp successfully induced.

On the first testing day of Flex-001 and Flex-002, the subjects were familiarized with the testing protocol, including the cramp stimulation technique. In subsequent testing days in Flex-001 and Flex-002, subjects received vehicle control without active ingredients or a 50 mL single administration of the original version of our proprietary treatment, and the effect of each test article in preventing cramps was assessed over an eight-hour period during each day. In Flex-003, all subjects received our proprietary treatment on the first day of testing and received vehicle control on subsequent days of testing, and on each day the effect of each test article in preventing cramps was

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assessed. Subjects "crossed-over" from our proprietary treatment to the vehicle control between testing days, or vice versa. As a result, each subject received both our proprietary treatment or vehicle control depending on the testing day. In this way, each subject served as his or her own control.

Results of Clinical Studies

In each study, our proprietary treatment demonstrated statistical significance in reducing muscle cramps. No participants in the studies reported any serious adverse events and our proprietary treatment was well tolerated.

Figure 3

In Flex-001, we tested six subjects at the 15 minute and one, two, six and eight hour timepoints and found our proprietary treatment demonstrated a statistically significant overall treatment effect in reducing muscle cramps in comparison to vehicle control (analysis of variance, or ANOVA, $p<0.0001$). Figure 3 depicts the time-course of cramp reduction observed during Flex-001 and displays a decrease of the baseline-adjusted AUC of our proprietary treatment compared to vehicle control.

Figure 4

In Flex-002, we tested 16 subjects at the 15 minute and one, two, four, six and eight hour timepoints and found our proprietary treatment demonstrated a statistically significant overall treatment effect in reducing muscle cramps in comparison to vehicle control (ANOVA, $p<0.0001$). Figure 4 depicts the time-course of cramp reduction observed during Flex-002 and displays a decrease of the baseline-adjusted AUC of our proprietary treatment compared to vehicle control.

Figure 5

In Flex-003, we tested 15 subjects at the 15 minute and one, two and four hour timepoints and found our proprietary treatment demonstrated a statistically significant overall treatment effect in reducing muscle cramps in comparison to vehicle control (ANOVA, $p=0.0286$). Figure 5 depicts the time-course of cramp reduction observed during Flex-003 and displays a decrease of the baseline-adjusted AUC of our proprietary treatment compared to vehicle control.

In each of our three studies, our proprietary treatment demonstrated a statistically significant overall treatment effect in reducing muscle cramps in comparison to vehicle control. Further, when the data from Flex-001, Flex-002 and Flex-003 are aggregated, our proprietary treatment showed a statistically significant overall treatment effect in the 37 normal healthy volunteers (ANOVA, $p<0.0001$). In smaller clinical studies, such as Flex-001, Flex-002 and Flex-003, statistical significance is often difficult to achieve because, in general, a large effect in the subjects is required. We

believe the level of significance achieved in our studies supports our contention that our proprietary

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treatment reduces the intensity of muscle cramps. However, the results of studies with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of subjects. As a result, there may be less certainty that our proprietary treatment would achieve a statistically significant effect in any future clinical studies.

Figure 6 below depicts the reduction in subjects' muscle cramps at various timepoints following administration of our proprietary treatment or vehicle control in all three studies combined and Figure 7 below depicts the aggregate reduction in subjects' muscle cramps across all timepoints when data from all three studies are combined. The aggregate data reflected in Figures 6 and 7 do not include data at the four hour timepoint for Flex-001 and at the six and eight hour timepoints for Flex-003 because, under the study protocols, data was not collected from subjects at these timepoints.

Figure 6

Figure 7

Product Development

Our proprietary treatment forms the basis of both our drug product and consumer product development efforts. To date, we have developed our proprietary treatment as a dietary supplement for the treatment and prevention of muscle cramps. By developing our proprietary treatment as a dietary supplement, we have been able to conduct our completed clinical studies without filing an IND with the FDA. In addition, we do not believe our proof-of-concept study in individuals suffering from nocturnal leg cramps will require that we file an IND with the FDA.

We are also studying the TRP activators contained in our proprietary treatment to develop prescription drugs that treat nocturnal leg cramps, spasms associated with severe neuromuscular conditions and other conditions where patients experience abnormal muscle contractions. We will be required to file an IND with the FDA prior to testing any drug product candidate in any disease indication in the United States.

We are also modifying our proprietary treatment's characteristics to specifically formulate our consumer product for the athletic market to prevent EAMCs, which we believe will be marketed as a dietary supplement.

The following table summarizes the development path for our proprietary treatment.

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Consumer Product Development Plans

Target Market	Current Development Status	Future Development Plans
Exercise-associated muscle cramps or EAMCs	• Formulation and launch efforts underway	• Launch our consumer brand and cornerstone product in the first half of 2016

Pre-Clinical Drug Product Candidates Development Plans

Target Indications	Current Development Status
Nocturnal leg cramps	• At least one individual expected to complete treatment in our first human proof-of-concept, or POC, study of our proprietary treatment as a dietary supplement in the second quarter of 2015
MS spasticity, cervical dystonia and/or SCI spasticity	• Evaluating initiation of one or more POC studies of our proprietary treatment for one or more future drug indications

Proof-of-Concept Studies

In the second quarter of 2015, we expect at least one individual to complete treatment in our first human proof-of-concept study of our proprietary treatment for individuals with nocturnal leg cramps. In this randomized, blinded, placebo-controlled, cross-over design study, we will compare our proprietary treatment to a vehicle control in individuals suffering from nocturnal leg cramps. The protocol for our first proof-of-concept study in the United States was accepted by an IRB. In addition, we have submitted a protocol to a local ethics committee in each of the United Kingdom and Australia and may initiate an additional study in one or both of these countries. If regulatory approval is obtained, we believe we can effectively conduct our proof-of-concept clinical study in each of these countries.

Each individual tested in our nocturnal leg cramp study will be tested over a six-week period. Unlike our completed studies of healthy, normal volunteers, our proof-of-concept nocturnal leg cramp study will include male or female subjects over the age of 50 who report having nocturnal leg cramps at least four nights per week in each of the four weeks prior to screening. The first two weeks of the study will be a run-in period where the subjects receive a vehicle control to help reduce potential placebo effects. Only subjects that do not respond to placebo, as determined by a physician's assessment, will continue in the study. Following this run-in period, subjects will be randomly assigned to a two-week treatment period and a two-week placebo period. In the two-week treatment period, subjects will self-administer 50 mL of the original version of our proprietary treatment each day and, in the two-week placebo period, subjects will self-administer 50 mL of a vehicle control without active ingredients each day. Because subjects "cross-over" between treatment and placebo, each subject will act as his or her own control.

We anticipate our proof-of-concept study will include multiple alternate primary objectives, including assessing the effect of our proprietary treatment (a) on the frequency of nocturnal leg cramps as measured by number of cramps per night; (b) on the frequency of nocturnal leg cramps as measured by number of cramps; (c) on the pain/intensity of nocturnal leg cramps as measured by the visual analog scale; (d) on the clinical global impression scale; (e) on measures of quality of life; and (f) on measures of the Insomnia Severity Index. We estimate that approximately 48 eligible subjects will enter the cross-over periods in order to achieve 40 subjects completing the study. We believe our nocturnal leg cramps study will take approximately 12 to 15 months to complete.

We may also initiate human proof-of-concept studies outside the United States to evaluate the efficacy and tolerability of our proprietary treatment compared to vehicle control in patients suffering from multiple sclerosis spasticity, cervical dystonia and SCI spasticity. Preparation of the regulatory submissions for a study of multiple sclerosis spasticity is ongoing and, if initiated, it is expected to take between 12 and 20 months to complete depending on recruitment and treatment timelines. When deciding which other indications to pursue, we will consider multiple factors, including the regulatory pathway for initiating trials, ease of patient recruitment and likely efficacy of our proprietary treatment in these indications.

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Drug Discovery Development Pathway

We have multiple avenues for developing drug products using our novel insight of muscle cramp inhibition and the TRP activators in our proprietary treatment. Developing drug products in advance of clinical trials requires significant effort and, while our planned proof-of-concept studies will not be assessing a drug product candidate, we expect to devote the majority of our future research efforts and financial resources to identifying a lead drug product candidate. In particular, we plan to study purified TRP activators using different single agent and combination formulations at different dosage levels and across alternative delivery systems in order to identify the most promising drug product candidate to study in drug clinical trials.

We believe any drug product candidate we develop based on our proprietary treatment will consist of purified TRP activator molecules. To date, we have not developed a drug product candidate that includes a single purified TRP activator molecule that has shown a statistically significant effect in reducing muscle cramps. We intend to analyze the single molecule components in each of the TRP activators in our proprietary treatment to identify the most appropriate single TRP activator molecule, or combination of multiple TRP activator molecules, to bring to drug clinical trials. We will also need to determine the most appropriate dosage level for any drug product candidate. We expect that our drug product candidates will include one or more TRP activators at higher dosage levels than any consumer products we commercialize.

Our proprietary treatment stimulates TRP channels located in the mouth, esophagus and stomach, activating receptors in the gastrointestinal tract. We intend to explore alternative delivery mechanisms for our drug product candidates, including pill formulations, in order to determine those areas of the gastrointestinal tract that require activation in order to produce a treatment effect.

Before testing any drug product candidate in a clinical trial that would form the basis for FDA approval of a drug product candidate, we will need to conduct non-clinical testing, also referred to as pre-clinical testing. Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug candidate. Once we have completed the pre-clinical studies, we will be able to submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, among other things, to the FDA as part of an IND.

Regulatory Pathway

Because the TRP activators in our proprietary treatment are GRAS ingredients, and the FDA has indicated that a dietary supplement may appropriately be marketed for the treatment of nocturnal leg cramps, we believe we may be able to expedite the timeline to bring a treatment to market by conducting clinical studies of the product for this proposed indication without first filing an IND. We have already completed testing for our proprietary treatment in three clinical studies of healthy normal volunteers and in the second quarter of 2015, we expect at least one individual to complete treatment in our first human proof-of-concept study of our proprietary treatment for individuals with nocturnal leg cramps.

The FDA regulates products on the basis of their "intended use" rather than their mechanism of action. As a result, certain uses of our proprietary treatment will be regulated as dietary supplements and certain uses will be regulated as drug products. Treatment or prevention of nocturnal leg muscle cramps is a particular indication that the FDA stated qualifies as a dietary supplement structure/function claim or intended use, although it can also be targeted by drug products. Unlike drug products, a dietary supplement of GRAS ingredients for the treatment of nocturnal leg cramps may be studied in humans in the United States without submitting an IND application with the FDA. In Flex-001, Flex-002 and Flex-003, we tested our proprietary treatment as a dietary supplement to study its efficacy in treating or preventing muscle cramps. Similarly, we will study our proprietary treatment as a dietary supplement in our proof-of-concept studies for nocturnal leg cramps. As a result, we do not believe our completed clinical studies or our proof-of-concept studies in this proposed indication require that we file an IND with the FDA.

If the results of one or more of our proof-of-concept studies in nocturnal leg cramps are favorable, we intend to pursue the development of a drug product candidate for the treatment of nocturnal leg cramps. We will submit an IND application with the FDA for a drug product candidate in advance of commencing a clinical trial of a drug product candidate in the United States. We would also discuss with regulatory authorities our intent to initiate a Phase 2 registration-directed clinical trial for drug product candidates intended to treat nocturnal leg cramps. We refer to this

trial as a registration-directed because it would be designed to serve as the basis for an application seeking regulatory approval of a prescription drug product candidate. All of the TRP activators in our proprietary treatment are GRAS, and capsaicin has been tested in pre-clinical and clinical studies by other companies and, as

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a result, its safety profile is generally understood. We believe this existing body of information may allow us to enter Phase 2 clinical trials for any capsacin-based drug product candidate that we may develop.

Any proof-of-concept clinical studies in patients suffering from MS spasticity, cervical dystonia and SCI spasticity will be conducted outside of the United States. For our drug product candidates treating these conditions, we will pursue Phase 2 clinical trials in the United States after filing an IND if the results from our proof-of-concept studies are favorable.

Consumer Brand and Products

As we continue the development of our drug product candidates, we are also developing a consumer product to prevent EAMCs and expect the launch of our consumer brand with our cornerstone product in the first half of 2016. While our consumer product and any eventual drug product we may develop may contain the same active ingredients, we believe the TRP activators in our consumer product will not be purified and will be at lower amounts than the TRP activators in any future drug product. We do not believe there is any product that has been shown to be clinically effective in preventing EAMCs. Our cornerstone product will include ingredients from our proprietary treatment, specifically formulated to address the consumer market, and will be subject to regulation by the FDA as a dietary supplement, including Good Manufacturing Practices adopted and implemented by the FDA. We believe our consumer product will be regulated as a dietary supplement because we believe that EAMCs are not a disease claim that would subject the product to regulation as a drug. As we optimize taste and other product attributes, we will continue testing our consumer product using our electrically induced cramping technique and in studies with athletes engaged in high-intensity activities. We are also conducting market research to better understand product attributes important to consumers, including whether our products should be all-natural and/or organic.

We believe our initial consumer product will be a liquid targeting athletes engaging in high-intensity activities who experience EAMCs. We believe these athletes are interested in clinically proven products and that these athletes will drive future adoption by casual athletes. As our brand and target market evolves, we anticipate evaluating product line extension opportunities and that the breadth of our consumer products will depend on a variety of factors, including brand positioning, target audience and product formulation alternatives. Ultimately, our goal is to develop several different products, potentially across different product lines, targeted towards both core and casual athletes.

We expect to focus our initial sales and marketing efforts on a limited number of geographic areas with strong endurance sports markets. Our initial efforts have focused on brand strategy and development, product development, target market research and limited production. Our continued efforts will likely include building brand awareness of our cornerstone product among key opinion leaders and core endurance athletes in order to build demand among a wider audience. We expect to begin pre-launch activities in the second quarter of 2015 to educate and begin building demand for our consumer product among our targeted demographic. As part of these efforts, we will conduct studies in athletic settings where athletes provide feedback of their experience with the product.

We anticipate leveraging early adopters to drive product and messaging advocacy and using targeted digital and social media campaigns to initiate and expand product sales. To drive distribution of our consumer products we intend to initially engage specialty retailers, such as cycle stores, and leading gyms and spas. Over time, we may expand to more mainstream distribution channels such as drugstores, vitamin shops and grocery stores.

Intellectual Property

Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates, consumer products, technology and know-how, and to operate without infringing upon the proprietary rights of others. Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries.

Patents and Patent Applications

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Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current and future drug product candidates and consumer products, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, even patent protection may not always afford us with complete protection against competitors who seek to circumvent our patents. Our commercial success will depend in part upon whether we are able to obtain and maintain adequate protection against unauthorized third-party use of our products and technologies. In our efforts to do so, however, there are a number of risks we may face, any of which may hinder our ability to successfully market our potential products. For more information regarding risks related to patents and other intellectual property, see "Risk Factors — Risks Related to Intellectual Property."

We own one pending U.S. utility patent application and one European patent application directed to compositions for preventing, treating or ameliorating muscle cramping. A patent based on these applications, if issued, would have a statutory expiration in the United States in July 2031 and in Europe in July 2031. We also own four U.S. provisional patent applications. Our provisional patent applications are directed at various aspects of our work including influencing neuromuscular activity by stimulating a TRP channel or acid sensing ion channel, or ASIC, in the nerve ending of a sensory neuron.

The provisional patent applications include methods for preventing and treating various muscle-related conditions and disorders and methods of diagnosing and selecting a patient for treatment. The provisional patent applications also include various uses of TRP or ASIC activators, formulations, compositions of chemical matter, and enabling technology such as the electrical stimulation technique for inducing muscle cramps. While we seek broad coverage for our patents, there is always a risk that an alteration to the formulation of our drug product candidates and consumer products may provide sufficient basis for a competitor to avoid infringement claims by us.

Trade Secrets, Trademarks and Proprietary Information

Our drug product candidates and consumer products have gone through numerous iterations to optimize the effect of our products, thereby creating trade secrets and proprietary know-how. We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees to execute Proprietary Information, Inventions, Non-Solicitation, and Non-Competition Agreements upon the commencement of their employment. Consultants and other advisors are required to sign consulting agreements. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third-parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, and utilizing our property or relating to our business and conceived or completed during their employment with us, shall be our exclusive property to the extent permitted by law. Further, we require confidentiality agreements from entities that receive our confidential data or materials.

Brand development of our consumer products is currently underway. We intend to apply for trademark protection with the U.S. Patent and Trademark Office and applicable foreign bodies for any brand we develop. Issuance of a federally registered trademark creates a rebuttable presumption of ownership of the mark, but may be subject to challenge by others claiming first use in the mark in some or all of the areas in which it is used. Federally registered trademarks have a perpetual life, as long as they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third-parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We believe that trademarks will be an important element of our ability to successfully market our consumer products.

Manufacturing

We do not currently have our own manufacturing facilities. We intend to continue to use our financial resources to focus on developing our consumer product and drug product candidates, and we do not intend to establish our own manufacturing facilities. We intend to meet our pre-clinical and clinical trial manufacturing requirements by establishing relationships with third-party manufacturers and other service providers to perform these services for us. We will continue using third-party manufacturers and other service providers to meet the manufacturing needs of our consumer products while under development. We do not have any long-term agreements or commitments for these services. In anticipation of the launch of our consumer brand and cornerstone product in the first half of 2016, we expect to establish relationships with third-party manufacturers and other service providers for the commercial

production of our cornerstone product.

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We do not currently have any long-term agreements or commitments from any of our suppliers. In connection with the launch of our consumer brand, our cornerstone product and future products and the initiation of our clinical trials, we expect to enter into long-term supply contracts to ensure the availability of the material ingredients in our consumer products and drug product candidates.

Sales and Marketing

We currently have no marketing, sales or distribution capabilities. In order to commercialize our consumer product and any drug product candidate that is approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third-parties that have sales and marketing experience.

Drug Products

We may elect to establish our own sales force to market and sell a drug product candidate for which we obtain regulatory approval if we expect that the geographic market for the product is limited or that the prescriptions for the product will be written principally by a relatively small number of physicians. If we decide to market and sell any products ourselves, we do not expect to establish direct sales capabilities until shortly before the products are approved for commercial sale.

We plan to seek third-party support from established pharmaceutical and biotechnology companies for those products that would benefit from the promotional support of a large sales and marketing force. In these cases, we might seek to promote our products in collaboration with marketing partners or rely on relationships with one or more companies with large established sales forces and distribution systems.

Consumer Brand and Products

We expect to launch our consumer brand with our cornerstone product in the first half of 2016. We expect to begin pre-launch activities in the second quarter of 2015 to educate and begin building demand for our consumer product among our targeted demographic. Our initial sales and marketing efforts have included brand strategy and development, product development, target market research and limited production. Our continued efforts will likely include building brand awareness of our cornerstone product among key opinion leaders and core endurance athletes. To drive product trial, we expect to use a variety of sales and marketing strategies, including public relations campaigns, product sampling and promotional activities at leading gyms, fitness centers and events such as marathons, triathlons, cycling events and obstacle course races. We anticipate leveraging early adopters to drive product and messaging advocacy and using targeted digital and social media campaigns to initiate and expand product sales. We anticipate using e-commerce strategies to sell online through direct-to-consumer websites and partner sites and we may develop strategic partnerships with fitness and lifestyle brand to expand product awareness and encouraging product trial.

We expect to rely on outsourced sales organizations to distribute our product initially to specialty retailers and leading gyms and spas, expanding over time into mainstream channels, such as drugstores, vitamin shops and grocery stores. We may also have a limited internal sales team targeting specific distribution channels.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any drug product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The key competitive factors affecting the success of our drug product candidates, if approved, are likely to be their efficacy, durability, safety, price and the availability of coverage and reimbursement from government and other third-party payors.

For nocturnal leg cramps, systemic treatments, such as dietary supplements, vasodilators and calcium channel blockers, have shown some benefit, but we do not believe any medication has shown evidence of clinical efficacy. Quinine is taken by some individuals outside the United States but the FDA banned the over-the-counter use of quinine for the treatment of nocturnal leg cramps in 1994 and it is presently available only for the prescription treatment of malaria and its labeling contains a boxed warning against use in treating nocturnal leg cramps.

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For patients suffering from MS spasticity, the current treatments include muscle relaxants, sedatives and Botox injections. Other biotechnology companies are currently developing drug products to treat MS spasticity, including Xenoport, Inc., which is developing a r-Baclofen Prodrug, and GW Pharma, which is developing Sativex.
Botox injection is the most commonly used treatment for cervical dystonia. SCI spasticity is treated with physical therapy, including surface electrical stimulation, surgery or drug therapy, including muscle relaxants, sedatives or Botox injections.
We believe our consumer product for the prevention of EAMCs will compete against traditional beverage companies, sports beverage companies and companies developing dietary supplements. We believe the principal elements of competition in the consumer product industry will be price, brand recognition, distribution channel offerings and the effectiveness of the product. We do not expect any third-party payors to cover and reimburse for our consumer products.

Royalty Agreement

In connection with the transfer of certain intellectual property to us, by the scientific founders of our company and by Christoph Westphal, or collectively the Founders, on March 20, 2014, we entered into a royalty agreement with the Founders. Pursuant to the royalty agreement, we are obligated to pay the Founders a royalty of 2%, in the aggregate, of gross sales of any product sold by us or by any of our licensees for use in the treatment of any neuromuscular disorders, and that uses, incorporates or embodies, or made using any of our intellectual property, including any know-how. The royalty agreement grants the Founders certain audit rights and requires any license or sublicense granted by us be consistent with the terms and conditions of the royalty agreement. Each Founder may assign his rights and obligations under the royalty agreement to a third party upon prior written notice to us and we may not assign our rights and obligations thereunder except in the event of a change in control relating to our company. The term of the royalty agreement is perpetual.

Government Regulation

Government authorities in the United States at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Any drug candidate that we develop must be approved by the FDA before they may be legally marketed in the United States and by the corresponding foreign regulatory agencies before they may be legally marketed in foreign countries. Dietary supplements, while generally not subject to premarket review, still must comply with numerous manufacturing, labeling and other regulations.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices, or GLP, or other applicable regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- approval by an IRB at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's laws and regulations pertaining to the conduct of human clinical studies, collectively referred to as Good

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Clinical Practices, or GCP, and according to the International Conference on Harmonization, or ICH, GCP guidelines, to establish the safety and efficacy of the proposed drug for its intended use;

- submission to the FDA of an NDA for a proposed new drug;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's requirements for current good manufacturing practices, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the non-clinical and clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the non-clinical testing stage, also referred to as pre-clinical testing. Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug candidate. The conduct of the pre-clinical tests must comply with federal regulations and requirements including GLP. The IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, among other things, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

Clinical trials involve the administration of the drug candidate to healthy subjects or patients with the target disease under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's regulations which reflect the ICH GCP requirements. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted only in patients having the specific disease.
- Phase 2. The drug is evaluated in a limited patient population to identify possible adverse events and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases

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and to determine dosage tolerance, optimal dosage and dosing schedule for patients having the specific disease.

Phase 3. The drug is administered to an expanded patient population in adequate and well-controlled clinical trials to generate sufficient data to statistically confirm the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

- Generally, at least two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA. In some cases, the FDA has approved a drug based on the results of a single adequate and well-controlled Phase 3 study of excellent design and which provided highly reliable and statistically strong evidence of important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical grounds.

Post-approval studies, also referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the status of drug development and results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects or patients. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to study subjects.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

FDA Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The application includes all relevant data available from pertinent pre-clinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has 12 months after submission of an NDA in which to complete its initial review of a standard new molecular entity NDA and respond to the applicant, and eight months for a priority review NDA. The FDA does not always meet its PDUFA goal dates for review of standard and priority review NDAs. The review process and the PDUFA goal date may be extended by additional three month review periods whenever the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission at any time during the review cycle.

The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which 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 and under what conditions. The FDA is not bound by the recommendations of an advisory

committee, but it considers such recommendations carefully when making decisions. During the drug approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to

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assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is to be manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with FDA regulations regarding conduct of clinical trials for the product's trials. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information.

The NDA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data, which could delay, limit or prevent regulatory approval. The FDA will issue a "complete response" letter if the agency decides not to approve the NDA. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post approval studies, referred to as Phase 4 testing, which involves clinical trials designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-Approval Requirements

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include, among other things, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), rules for conducting industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

We rely, and expect to continue to rely, on third-parties for the production of clinical and future commercial quantities of our products. Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA. These restrictions may include suspension of a product until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a

consent decree of permanent injunction, which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

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U.S. Marketing Exclusivity

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA. If the new drug is a new chemical entity subject to an NDA, the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or 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, such an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an 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 new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. 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 of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Dietary Supplement Government Regulation

Our consumer product under development will be regulated as a dietary supplement. In addition, treatment or prevention of nocturnal leg muscle cramps are a particular indication that the FDA stated, in a Federal Register notice in 2000 (65 Fed. Reg. 1031), qualifies as a dietary supplement structure/function claim or intended use, although it can also be targeted by drug products. Dietary supplement products are subject to extensive regulation in the United States and abroad with respect to their identity, purity, quality, strength, composition, processing, formulation, safety, manufacturing, packaging, labeling, advertising and distribution. The manufacture, packaging, labeling, holding, sale, and distribution of dietary supplements are also subject to extensive local, state, and foreign government regulation. For example, under the European Union Directive (Directive 2002/46/EC as amended), only dietary supplements listed in Annex II to that directive or which were sold in the European Union before the directive entered into force on July 12, 2001 may be sold in Europe subject to EU restrictions on dosage amounts, forms, label claims and advertising. The Bureau of Customs and Border Patrol, or CBP, a division of the Department of Homeland Security, also regulates shipments containing dietary ingredients, dietary supplements, cosmetics, drugs, biologics, and medical devices and engages in enforcement activity in concert with the FDA to block the import or export of articles deemed adulterated or otherwise unlawful for sale in the United States (imports) or in the non-U.S. country to which articles are addressed. CBP holds on articles or demands for recall can interfere with the timely delivery of products to market and can result in regulatory fines and penalties.

The FDCA has been amended several times affecting provisions that concern dietary ingredients and dietary supplements, including by the Dietary Supplement Health and Education Act of 1994, or DSHEA. DSHEA formally defined what may be sold as a dietary supplement, defined statements of nutritional support and the conditions under which they may lawfully be used, and included provisions that permit the FDA to regulate manufacturing practices and labeling claims peculiar to dietary supplements. "Dietary supplements" are defined as vitamins, minerals, herbs, other botanicals, amino acids and other dietary substances that are used to supplement the diet, as well as concentrates, constituents, extracts, metabolites, or combinations of such dietary ingredients. Generally, under DSHEA, dietary ingredients that were on the market before October 15, 1994 may be used in dietary supplements without notifying the FDA. However, a "new" dietary ingredient (i.e., a dietary ingredient that was not marketed as a dietary supplement in the U.S. before October 15, 1994) must be the subject of a new dietary ingredient notification submitted to the FDA unless the ingredient has been "present in the food supply as an article used for food" without having been "chemically altered." A new dietary ingredient notification must provide the FDA with evidence of a "history of use or other evidence of safety" which establishes that use of the dietary ingredient "will reasonably be expected to be safe." A

new dietary ingredient notification must be submitted to the FDA at least 75 days before the new dietary ingredient can be marketed. There can be no assurance that the FDA will accept evidence purporting to establish the safety of any new dietary ingredients that we may want to market, and the FDA's refusal to accept such evidence could prevent the marketing of such dietary ingredients.

Increased FDA enforcement could lead the FDA to challenge dietary ingredients already on the market as "illegal" under the FDCA because of the failure to file a new dietary ingredient notification or because the substance may be

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one found to be the subject of an IND for which clinical trials have commenced and been publicized. Although we expect our proprietary treatment to be marketed both as a dietary supplement and a drug product candidate that will eventually be subject to an IND, DSHEA does not restrict marketing of a product as a dietary supplement where the substance is under investigation pursuant to an IND and the product was first marketed as a dietary ingredient or food. The ingredients in our proprietary treatment have a long history of use in food.

The FDA generally prohibits labeling a dietary supplement with any "health claim" (i.e., any statement associating a nutrient with risk-reduction, but not treatment, of a disease or health-related condition), unless the claim is pre-approved by the FDA. The FDA prohibits entirely disease diagnosis, prevention and treatment claims when made for a dietary supplement. However, "statements of nutritional support," including so-called "structure/function claims," are permitted to be included in labeling for dietary supplements without FDA pre-approval. Such statements may describe how a particular dietary ingredient affects the structure, function or general well-being of the body, or the mechanism of action by which a dietary ingredient may affect the structure, function or well-being of the body, but such statements may not state that a dietary supplement will reduce the risk or incidence of a disease unless such claim has been reviewed and approved by the FDA. A company that uses a statement of nutritional support in labeling must possess evidence substantiating that the statement is truthful and not misleading. Such statements must be submitted to the FDA no later than thirty days after first marketing the product with the certification that they possess the necessary evidence and must be accompanied by an FDA mandated label disclaimer that "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease." There can be no assurance, however, that the FDA will not determine that a particular statement of nutritional support that we want to use is an unacceptable disease claim or an unauthorized nutrient-disease relationship claim otherwise permitted with FDA approval as a "health claim." Such a determination might prevent the use of such a claim.

In addition, DSHEA provides that certain "third-party literature," such as a reprint of a peer-reviewed scientific publication linking a particular dietary ingredient with health benefits, may "in connection with the sale of a dietary supplement to consumers" be exempt from labeling regulation. However, the FDA has adopted an "intent to use" doctrine whereby such literature even if exempt from labeling may nonetheless form the basis for an agency determination that the literature in context reveals a company intent to sell a dietary ingredient or dietary supplement as a drug, thereby rendering the supplement an unlawful, unapproved new drug. Because the "intent to use" doctrine is predicated on a subjective assessment of all facts and circumstances associated with the promotion and sale of a dietary supplement, we cannot know whether any particular piece of literature otherwise exempt from labeling will be deemed by the FDA unlawful for use in association with the sale of the dietary ingredient or dietary supplement.

As authorized by the FDCA, the FDA has adopted and implemented Good Manufacturing Practices, or GMPs, specifically for dietary supplements. These GMPs impose extensive process controls on the manufacture, holding, labeling, packaging, and distribution of dietary supplements and the components of dietary supplements. They require that every dietary supplement be made in accordance with a master manufacturing record with all dietary ingredients verified by identity testing before use, that each step in manufacture, holding, labeling, packaging, and distribution be defined with written standard operating procedures, monitored, and documented, and that any deviation in manufacture, holding, labeling, packaging, or distribution be contemporaneously documented, assessed by a quality control expert, and corrected through documented corrective action steps (whether through an intervention that restores the product to the specifications in the master manufacturing record or to document destruction of the non-conforming product). The GMPs are designed to ensure documentation, including testing results that confirm the identity, purity, quality, strength, and composition of finished dietary supplements. In addition, GMPs require a company to make and keep written records of every product complaint that is related to GMPs. The written record of the product complaint must include the following: the name and description of the dietary supplement; the batch, lot, or control number of the dietary supplement, if available; the date the complaint was received and the name, address, or telephone number of the person making the complaint, if available; the nature of the complaint, including, if known, how the product was used; the reply to the complainant, if any; and findings of the company's quality control investigation and follow-up action taken when an investigation is performed. The regulations directly affect all who manufacture the dietary supplements we sell and our distribution of dietary supplements. The FDA may deem any dietary supplement adulterated, whether presenting a risk of illness or injury or not, based on a failure to comply with

any one or more process controls in the GMP regulations. If deemed adulterated, a dietary supplement may not be lawfully sold and may have to be recalled from the market. In recent years, the FDA's main focus has evolved from basic violations, such as failure to set specifications, to more technical violations, such as finished product testing violations. It is possible that the FDA will find one or more of the process controls implemented by our contract manufacturers and, thus, requiring corrective action, requiring

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any one or more of the dietary supplements we sell to be unlawful for sale, or resulting in a judicial order that may impair our ability to market, and sell dietary supplements.

The FDA also requires serious adverse event reporting for all dietary supplements. An "adverse event" is defined by statute to include "any health-related event associated with the use of a dietary supplement that is adverse." While all adverse event complaints received must be recorded in accordance with the GMPs discussed above, only serious adverse events must be reported to FDA. A "serious adverse event" is an adverse event that: results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect; or requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described above. When a manufacturer, packer or distributor whose name appears on the product label of a dietary supplement receives any report of a serious adverse event associated with the use of the dietary supplement in the United States, the company must submit a "serious adverse event report" on MedWatch Form 3500A. The report must be filed within 15 business days of receipt of information regarding the adverse event. All adverse event reports, whether serious or not, must be recorded and kept in company records under the GMP rules. A company must maintain records of each report of any adverse event (both serious and non-serious) for a minimum of six years. These records should include any documents related to the report, including: the company's serious adverse event report to the FDA with attachments; any new medical information about the serious adverse event received; all reports to the FDA of new medical information related to the serious adverse event; and any communications between the company and any other person(s) who provided information related to the adverse event.

The regulation of dietary supplements may increase or become more restrictive in the future. There can be no assurance that, if more stringent statutes are enacted for dietary supplements, or if more stringent regulations are promulgated, we will be able to comply with such statutes or regulations without incurring substantial expense.

The FDA has broad authority to enforce the provisions of the FDCA concerning all of the products it regulates, including powers to issue a public "warning letter" to a company, to quarantine and prohibit the sale of products deemed adulterated or misbranded, to publicize information about illegal products, to request a voluntary recall of illegal products from the market, to request that the Department of Justice initiate a seizure action, an injunction action or a criminal prosecution in U.S. courts, and to seek disgorgement from a federal court of all proceeds received from the sale of products deemed misbranded or adulterated.

The Federal Trade Commission, or FTC, enforces the Federal Trade Commission Act, or FTCA, and related regulations, which govern the advertising associated with the promotion and sale of dietary supplements to prevent misleading or deceptive claims.

In recent years, the FTC has instituted numerous enforcement actions against dietary supplement companies for making false or misleading advertising claims and for failing to adequately substantiate claims made in advertising. These enforcement actions have often resulted in consent decrees and the payment of civil penalties and/or restitution by the companies involved. The FTC also regulates other aspects of consumer purchases including, but not limited to, promotional offers of savings compared policies, telemarketing, continuity plans, and "free" offers.

We are also subject to regulation under various state, local and international laws that include provisions governing, among other things, the formulation, manufacturing, packaging, labeling, advertising and distribution of dietary supplements. California has a law called the "Consumers Legal Remedies Act" (Cal. Civ. Code §§ 1750 et seq) that allows private parties to assert a class action claim for false or deceptive advertising. It is typically asserted in combination with claims for false advertising and unfair competition under the California Business and Professions Code. California law firms specializing in this type of consumer class action claims have recently been targeting dietary supplement makers and sellers of products sold in California, claiming injury based on the products' failure to deliver results as claimed in product labeling and promotion.

The U.S. Postal Inspection Service enforces federal laws governing fraudulent use of the mail. Regulation of certain aspects of the dietary supplement business at the federal level is also governed by the Consumer Product Safety Commission, or CPSC, (e.g., concerning the presence of adulterated substances, such as toxic levels of lead or iron, that render products unsafe for consumption and require a CPSC ordered recall), the Department of Agriculture (e.g., for products that are intended for ingestion as dietary supplements for animals) and the Environmental Protection Agency (e.g., in the methods of disposal used for certain dietary ingredients, such as colloidal silver).

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Government regulations in foreign countries may prevent or delay the introduction, or require the reformulation, of certain of our products. Compliance with such foreign governmental regulations is generally the responsibility of our distributors in those countries. These distributors are independent contractors whom we do not control.

In addition, from time to time in the future, we may become subject to additional laws or regulations administered by the FDA, the FTC, or by other federal, state, local or foreign regulatory authorities, to the repeal of laws or regulations that we generally consider favorable, such as DSHEA, or to more stringent interpretations of current laws or regulations. We are not able to predict the nature of such future laws, regulations, repeals or interpretations, and we cannot predict what effect additional governmental regulation, if and when it occurs, would have on our business in the future. Such developments could, however, require reformulation of certain products to meet new standards, recalls or discontinuance of certain products not able to be reformulated, additional record-keeping requirements, increased documentation of the properties of certain products, additional or different labeling, additional scientific substantiation, additional personnel or other new requirements. Any such developments could have a material adverse effect on our business.

Europe

The European Union, or EU, is responsible for the development of legislation governing foods, nutritional supplements, and medicines sold in Europe. Member States of the EU, or Member States, are authorized to develop local legislation governing these products, provided such legislation is not more restrictive than the legislation promulgated by the EU. Member States are responsible for enforcement of the applicable legislation. In 2002, the EU established a process for Member States to bring this regulating legislation in line with a published directive of the EU, which addressed the labeling and marketing of vitamins and minerals, what nutrients are permitted or not permitted and other packaging requirements. In 2004, the EU established standards for the manufacture and marketing of herbal medicines with the Traditional Herbal Medicinal Products Directive. This requires, among other things, manufacturers of herbal medicinal products to comply with Pharmaceutical Group Standards, and only requires proof of safety, not efficacy.

In 2006, the EU adopted its Commission Directive 2006/37/EC, amending its Directive 2002/46/EC. Under the amended directive, only nutrients listed in Annex II, or approved by subsequent order of the EU, may be lawfully sold in Member States. The EU also regulates labels, labeling, and advertising associated with the promotion and sale of dietary supplements in Europe. These regulations may make it unlawful for us to sell in Europe certain products lawfully labeled and sold in the United States.

In the United Kingdom, the principal governing legislation is the Food Safety Act of 1990 (governing safety of food products) and the Medicines Act of 1968 (governing licensing and sale of medicine). Further guidance is provided by numerous Statutory Instruments addressing the formulation, purity, packaging, advertising and labeling of such products. Medicinal products are regulated and enforced by the Medicines and Healthcare Products Regulatory Agency (MHRA), an agency of the Department of Health. The MHRA determines if an herbal remedy is medicinal by virtue of its "presentation" or "function." Food products are regulated by the Food Standard Agency (FSA), which reports to the Department of Health and to the Department of Environment, Food and Rural Affairs. Vitamin and mineral supplements and soup products with herbal ingredients are generally considered food supplements and are subject to the purview of the FSA. Additional legislative standards have been adopted in the other EU countries, typically similar in scope to the UK. The regulatory scheme in Canada is similar but not identical to that of the United States concerning medicines and healthcare products or material health products and is regulated by Health Canada.

Pharmaceutical Coverage, Pricing and Reimbursement for Drug Products

Significant uncertainty exists as to the coverage and reimbursement status of any drug candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any drug products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government payor programs at the federal and state levels, including Medicare and Medicaid, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of

the FDA-approved drug products for a particular indication. In addition, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

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The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will continue to experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative and regulatory initiatives. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmaco economic studies in order to demonstrate the medical necessity and cost-effectiveness of our drug products, in addition to the costs required to obtain the FDA approvals. If these third-party payors do not consider our drug products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the drug candidates that we are developing and could adversely affect our net revenue and results.

Different pricing and reimbursement schemes exist in other countries. For example, in the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

Healthcare Reform

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, a sweeping law intended to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among other things, the ACA revises the definition of "average manufacturer price" for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare providers and entities, and a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the full effect of the ACA, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes

aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013, and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the

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government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Moreover, the recently enacted Drug Supply Chain Security Act, imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing, which will be phased in over several years beginning in 2015. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

We expect that the ACA, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenue. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. For example, various activities, including but not limited to sales, marketing and scientific/educational grant programs, must comply with the anti-fraud and abuse provisions of the Social Security Act, the federal Anti-Kickback Statute, the federal False Claims Act and similar state laws, each as amended. Failure to comply with such requirements could potentially result in substantial penalties to us. Even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend against enforcement or litigation, in light of the fact that there is significant enforcement interest in pharmaceutical companies in the United States, and some of the applicable laws are quite broad in scope.

The federal Anti-Kickback Statute prohibits any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of co-payments or deductibles, ownership interests and providing anything at less than its fair market value. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection from federal Anti-Kickback Statute liability. The reach of the Anti-Kickback Statute was broadened by the ACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. 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 (discussed below).

Additionally, the federal civil monetary penalties statute imposes fines against any person or entity who, among other things, is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

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The federal false claims laws, including the civil False Claims Act, impose liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the civil False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program. There are many potential bases for liability under the civil False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The civil False Claims Act has been used to assert liability on, for example, the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper promotion of off-label uses (i.e., uses not expressly approved by FDA in a drug's label), and allegations as to misrepresentations with respect to the services rendered. Our business activities relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our future products, and the sale and marketing of our future products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. The cost of defending any such claims, as well as any sanctions imposed, could adversely affect our financial performance.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including healthcare fraud, and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Additionally, many states have adopted laws similar to the federal laws mentioned above, and some of these state laws are broader in scope and may apply to referral of patients for healthcare items or services reimbursed by any third-party payor, not only the Medicare and Medicaid programs.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. For example, HIPAA and its implementing regulations established uniform federal standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included expansion of HIPAA's privacy and security standards under the Health Information Technology for Economic and Clinical Health Act, referred to as HITECH, which became effective on February 17, 2010. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates" — independent contractors or agents of covered entities that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate

family members. Covered manufacturers were required to report these payments for the first reporting period to the Centers for Medicare & Medicaid Services, or the CMS, by June 30, 2014. CMS published certain data reported by covered manufacturers for the first reporting period on September 30, 2014. Compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships.

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Several states have also enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, or register their sales representatives, as well as prohibiting pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and prohibiting certain other sales and marketing practices. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities. Additionally, in order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain.

Many of our current as well as possible future activities are potentially subject to federal and state consumer protection and unfair competition laws. We must also comply with laws that require clinical trial registration and reporting of clinical trial results on the publicly available clinical trial databank maintained by the National Institutes of Health at www.ClinicalTrials.gov. We are subject to various environmental, health and safety regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous substances. From time to time, and in the future, our operations may involve the use of hazardous materials. Because of the breadth of these laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including potentially significant administrative, criminal and civil penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a drug product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, the clinical trial described in that CTA may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with the ICH GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

In the European Economic Area, or EEA (which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations: the Community MA, which is issued by the European Commission through the Centralized Procedure based on the opinion of the Committee for Medicinal Products for Human Use, a body of the European Medicines Agency, or the EMA, and which is valid throughout the entire territory of the EEA; and the National MA, which is issued by the competent authorities of the Member States of the EEA and only authorized marketing in that Member State's national territory and not the EEA as a whole.

The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that

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constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. The National MA is for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member state, or RMS. If the RMS proposes to authorize the product, and the other Member States do not raise objections, the product is granted a national MA in all the Member States where the authorization was sought. Before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. In addition, we may be subject to certain health regulatory laws in the foreign countries in which we conduct business. For instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees

As of March 6, 2015, we had 19 full-time employees and two part-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Research and Development

We incurred $4.0 million of research and development expenses during the period from February 26, 2014 (inception) through December 31, 2014. Our research and development efforts are focused on new product development, including pre-clinical research and clinical studies to develop our proprietary treatment.

Corporate and Other Information

We were incorporated in Delaware in February 2014. Our principal executive offices are located at 800 Boylston Street, 24th Floor, Boston, Massachusetts 02199, and our telephone number is (617) 874-1821. Our corporate website address is www.flex-pharma.com. Information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

We file electronically with the SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make available on our website at www.flex-pharma.com (under "Investors & Media"), free of charge, copies of these reports as soon as reasonably practicable after filing these reports with, or furnishing them to, the SEC.

This Annual Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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Item 1A. Risk Factors

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report as well as our other public filings with the Securities and Exchange Commission.

Risks Related to Our Financial Condition and Need for Additional Capital

We have limited operating history and a history of operating loss. We anticipate that we will continue to incur losses for the foreseeable future.

We are a biotechnology company with limited operating history. Since inception, we have incurred a significant loss. We incurred a net loss of $8,010,860 from February 26, 2014, the date of our inception, to December 31, 2014. Our losses have resulted principally from expenses incurred in research and development of our proprietary treatment and from general and administrative expenses that we have incurred while building our business infrastructure. We expect to incur substantial and increased expenses as we expand our development activities and advance our clinical programs and as we accelerate the development and commercialization of our consumer brand. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company. As a result of the foregoing, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future.

To date, we have financed our operations through private placements of equity securities and the proceeds from our initial public offering completed in February 2015. We have no products approved for commercialization and have never generated any product revenues. The development of biotechnology products is a highly speculative undertaking and involves a substantial degree of risk.

We have never generated any product revenues and may never become profitable.

We have never generated any product revenues and currently do not have any marketed consumer products or drug products approved for marketing. Our ability to generate revenue from drug products and achieve profitability depends on our ability to successfully complete the development of, and obtain the marketing approvals necessary to commercialize, one or more of our drug product candidates. Until, and unless, we receive approval from the FDA and other regulatory authorities overseas for one or more of our drug product candidates, we cannot market or sell our products as drugs and will not have drug product revenues. Any drug product candidate we develop will require significant time and capital before we can apply for approval from the FDA. Further, we do not expect to begin marketing or selling a consumer product until the first half of 2016 and do not expect to generate significant revenue from our consumer products for several years, if ever. Therefore, for the foreseeable future we do not expect to achieve any significant product revenues and will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants, if any, and potentially, future equity or debt offerings.

Even if we succeed in developing and commercializing one or more drug product candidates, all of which are currently in the pre-clinical phase of development, we expect to incur substantial losses for the foreseeable future and may never become profitable. The successful development and commercialization of any drug product candidates will require us to perform a variety of functions, including:

- undertaking pre-clinical development and clinical trials;
- hiring additional personnel;
- formulating and manufacturing products, including stability testing for any drug product candidate;
- obtaining regulatory approval;
- initiating and conducting sales and marketing activities;
- obtaining coverage and adequate reimbursement from third-party payors; and
- implementing additional internal systems and infrastructure.

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Because of the numerous risks and uncertainties with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In cases where we are successful in obtaining regulatory approvals to market one or more of our drug product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such drug products, even if approved. Additionally, if we are not able to generate sufficient revenue from the sale of any approved drug products, we may never become profitable.

The successful development and commercialization of our consumer brand and products will require us to perform a variety of functions, including:

- further developing our consumer product based on the TRP activators in our proprietary treatment;
- developing the brand strategy for our consumer product and, following launch of our consumer products, expanding our product offering and maintaining brand loyalty;
- entering into distribution and other strategic arrangements with third-party retailers and other potential distributors of our products; and
- developing new product lines and extensions.

Even if we are able to develop and commercialize a consumer brand and products, the number of athletes that suffer from EAMCs, or the frequency of EAMCs experienced by athletes, may not be as large as we estimate, and we may not generate significant revenue from sales of our consumer products, and we may never achieve profitability.

We may be unable to develop and commercialize any product candidate, including our consumer brand, and, even if we do, may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

We expect that we will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing pharmaceutical products, including conducting pre-clinical studies and clinical trials, is a time-consuming, expensive and inherently uncertain process that takes years to complete. We expect that our expenses will increase substantially as we commence our proof-of-concept studies of our proprietary treatment for individuals with nocturnal leg cramps, launch and commercialize our consumer brand, our cornerstone product, and future products, commence and complete Phase 2 registration-directed clinical trials of our drug product candidate for individuals with nocturnal leg cramps if results from our proof-of-concept studies are favorable, seek marketing approvals for a drug product candidate, and advance our other product candidates. If we obtain marketing approval for a drug product candidate that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company.

As of December 31, 2014, we had unrestricted cash of $33.9 million. On February 3, 2015 we completed the initial public offering of our common stock and received net proceeds of approximately $79.9 million, after deducting the underwriting discounts and commissions and offering expenses payable by us. These proceeds include amounts received related to the sale of additional shares of our common stock pursuant to to the exercise of an overallotment option granted to the underwriters in connection with the offering. Based upon our current operating plan, we believe our existing cash will enable us to fund our operating expenses and capital requirements until mid-2018. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional drug candidates, increased costs of marketing and selling our consumer products and changes in regulation. Our future funding requirements will depend on many factors, including but not limited to:

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- the timing and size of any future clinical trials and our ability to successfully complete them in a timely manner;
- the number of indications that we pursue for our drug product candidates;
- our ability to obtain approval from the FDA to market our product candidates;
- market acceptance of our consumer products or any drug product candidates, if approved;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- the ability to obtain coverage and adequate reimbursement by third-party payors;
- the cost and timing of marketing authorization or regulatory clearances;
- the cost of goods associated with our consumer products and drug product candidates; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

We expect that our current available funds will not be sufficient to enable us to seek marketing approval for our drug product candidate for individuals with nocturnal leg cramps or our other target indications. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources.

In addition, attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our drug product candidates or consumer brand and products. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our drug product candidates or consumer products;
- seek corporate partners for our drug product candidates or consumer products at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to technologies or drug product candidates or consumer products that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail, or cease, operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. In the event we need to seek additional funds we may raise additional capital through the sale of equity or convertible debt securities. In such an event, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our common shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third-parties, we may have to relinquish valuable rights to our intellectual property or future revenue streams. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have a limited operating history and no history of commercializing pharmaceutical or consumer products, which may make it difficult to evaluate the prospects for our future viability.

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We were formed in February 2014 and, as a result, have no meaningful operations upon which to evaluate our business. Our operations to date have been limited to financing and staffing our company, developing our intellectual property and developing our product candidates. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Risks Related to Clinical Development and Regulatory Approval

We are heavily dependent on the successful development of drug product candidates based on our proprietary treatment, and we cannot be certain that any drug product candidate we develop will enter clinical trials, receive regulatory approval or be successfully commercialized.

We currently have no drug products that are approved for commercial sale and may never successfully develop marketable drug products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to developing drug product candidates and, accordingly, our business depends heavily on the successful development, regulatory approval and subsequent commercialization of the drug product candidates we develop. We expect that our proof-of-concept clinical study of nocturnal leg cramps will be under the regulatory framework applicable to dietary supplements in the United States. We only expect to conduct a drug clinical trial of our drug product candidates for the treatment of nocturnal leg cramps, MS spasticity, cervical dystonia and/or SCI spasticity if the results of our proof-of-concept studies are favorable. There is no guarantee that the results of our proof-of-concept studies will be favorable and that any of our drug product candidates if ultimately developed will enter drug clinical trials.

To date, we have only tested our proprietary treatment as a dietary supplement product candidate in healthy normal volunteers to determine whether our formulation prevents or reduces muscle cramps produced by electrical stimulation. While we understand the physical properties of the TRP activators in our proprietary treatment and their interaction with the primary sensory neurons in the mouth, esophagus, and stomach, we do not know whether it is this interaction that produced the reduction in muscle cramps observed in our three controlled studies performed to date. We are studying the TRP activators of our proprietary treatment and believe the most rapid development path will be to pursue drug product candidates with a single purified TRP activator. However, we do not know which TRP activator is most efficacious in treating or preventing muscle cramps. Further, we have not yet developed a drug product candidate that includes a single purified TRP activator molecule that has shown a statistically significant effect in reducing muscle cramps or spasms. We intend to analyze the single molecule components in each of the TRP activators in our proprietary treatment to identify the most appropriate single TRP activator molecule, or combination of multiple TRP activator molecules, to bring to drug clinical trials. We will also need to determine the most appropriate dosage level and delivery mechanism for any drug product candidate. We expect that our drug product candidates will include one or more TRP activators at higher dosage levels than any consumer products we commercialize. If we are not able to develop drug product candidates that safely and effectively treat nocturnal leg cramps or severe neuromuscular conditions, our future prospects may be limited, which may negatively impact the trading price of our common stock.

Any drug product candidates we develop will require additional clinical development, management of clinical, pre-clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales. Before testing any drug product, we will need to conduct non-clinical testing, also referred to as pre-clinical testing. Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug candidate. Once we have completed the pre-clinical studies, we will be able to submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, among other things, to the FDA as part of an IND. We are not permitted to market any drug product candidate in the United States until it receives regulatory approval from the FDA, or in any foreign countries until it

receives the requisite approval from the regulatory authorities in such countries. We have not previously submitted a new drug application, or NDA, to the FDA or comparable applications to other regulatory authorities, and do not expect to be in a position to do so for the foreseeable future. We cannot be certain that any drug product candidates we develop will be successful in clinical trials or receive regulatory approval. Further, our drug product candidates may not receive regulatory approval even if they are successful in clinical trials, or be successfully commercialized even if

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we receive regulatory approval. If the markets for patients that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our drug product candidates in the United States, the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Because our drug product candidates and consumer product are in early stages of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue.

Our early clinical studies of our proprietary treatment in reducing electrically induced muscle cramps are not necessarily predictive of the results of any proof-of-concept clinical studies we may conduct in nocturnal leg cramps, multiple sclerosis spasticity, cervical dystonia or SCI spasticity. The technique to electrically induce, measure and analyze muscle cramps utilized in connection with our completed studies has not been widely studied, its usefulness in clinical studies has not been validated and the methods of analyzing the results have not been widely agreed upon. For instance, we have noted that subjects experience muscle fatigue from the electrical stimulation, which increases the difficulty of interpreting the results from our clinical studies. As a result, we cannot be certain that our clinical studies performed to date are an accurate predictor of the efficacy of our proprietary treatment in preventing or reducing naturally occurring muscle cramps and spasms. If our proof-of-concept clinical studies do not successfully demonstrate the efficacy of our proprietary treatment, or if we are not successful in developing drug product candidates that replicate the potential efficacy of our proprietary treatment, our ability to develop and commercialize our drug product candidates may be limited.

Our consumer product is still under development and may require significant effort to make it more palatable. If we are not successful in refining the product attributes of our consumer product, we may not be able to derive significant revenue following the launch of our consumer brand.

Because of the small number of subjects in our clinical studies performed to date, the results from our completed clinical studies may be less reliable than results achieved in larger clinical studies.

A study design that is considered appropriate includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. In Flex-001, Flex-002 and Flex-003, we analyzed the effect of our proprietary treatment on reducing electrically induced muscle cramps in 37 healthy normal volunteers. The results of studies with smaller sample sizes, such as Flex-001, Flex-002 and Flex-003, can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of subjects. As a result, there may be less certainty that our proprietary treatment would achieve a statistically significant effect in any future clinical studies. If we conduct any future clinical studies of our proprietary treatment, we may not achieve a statistically significant result or the same level of statistical significance seen in our completed studies.

Clinical development involves an expensive and time-consuming process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

We have completed three clinical studies of our proprietary treatment, and plan to conduct proof-of-concept studies of our proprietary treatment, under the regulatory framework applicable to dietary supplements. The FDA has indicated that products intended for the treatment of nocturnal leg cramps may be marketed as either dietary supplements or drugs. The FDA regulates products on the basis of their intended use, with products claiming to diagnose, cure, mitigate, treat, or prevent disease being regulated as drugs, and dietary supplements being dietary ingredients intended for ingestion which are permitted to be the subject of claims about their effect on the structure or function of the body. To date, we have developed our proprietary treatment as a dietary supplement for the treatment and prevention of muscle cramps. While we intend to develop drug products to treat nocturnal leg cramps, the studies of our proprietary treatment conducted in 2014 were not, and our planned proof-of-concept study for nocturnal leg cramps will not be, conducted pursuant to FDA's regulations governing the clinical testing of drugs. Rather, these studies have been, and

will be, conducted pursuant to the requirements for the clinical testing of dietary supplements.

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We are planning to develop drug product candidates for the treatment of nocturnal leg cramps and spasms associated with severe neuromuscular conditions. However, we have not commenced or completed any clinical trials of these drug product candidates for any of our targeted indications and before we are able to begin clinical trials of drug product candidates in the United States, we will be required to submit an IND to the FDA. An IND requires the submission of manufacturing information, analytical data, the results of nonclinical trials, a proposed clinical trial protocol and other information, and the FDA's primary objective in reviewing an IND is to assure the safety of subjects. We have not completed any toxicology studies of any drug product candidates in assays and animals and there can be no guarantee that our drug product candidates can be safely administered to patients. In contrast, clinical studies of dietary supplements do not require the submission of an IND, although they do require approval of an institutional review board, or IRB, or ethics committee. Therefore, we plan to take advantage of the regulatory framework that permits clinical studies of dietary supplements without an IND for our proof-of-concept studies in individuals with nocturnal leg cramps, and if our proof-of-concept studies are successful, we plan to pursue any future development of our drug product candidates based on our proprietary treatment subject to the IND requirements. The FDA may not agree that studies performed without an IND, even if for GRAS substances in an indication that the FDA has stated is eligible for regulation as a dietary supplement on the basis of its claims, are adequate to support an IND for a disease indication. Further, the FDA may disagree with our strategy to elect to study our proprietary treatment for nocturnal leg cramps in clinical studies as a dietary supplement without an IND.

In the second quarter of 2015, we expect at least one individual to complete treatment in our first human proof-of-concept study of our proprietary treatment for individuals with nocturnal leg cramps. We may also initiate additional proof-of-concept studies of our proprietary treatment for nocturnal leg cramps, multiple sclerosis spasticity, cervical dystonia or SCI spasticity. Our planned proof-of-concept studies and any future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. The FDA may place any IND or clinical trial that we propose on clinical hold, which would require that we resolve any concerns prior to being permitted to initiate or continue clinical development. The protocol for our study in the United States was accepted by an IRB and we have submitted a protocol to a local ethics committee in each of the United Kingdom and Australia. In order to begin our proposed proof-of-concept studies outside the United States, we may also need approval from the applicable regulatory agency in the jurisdiction where the study will take place. If these regulatory authorities do not approve our proof-of-concept studies for any reason, our ability to develop drug products based on our proprietary treatment may be limited.

In addition, human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any clinical trial of our drug product candidates, which may delay the commencement of our drug clinical trials in the United States. The clinical trial process is also time consuming. We estimate that clinical trials of our drug candidates will take several years to complete, and their outcomes are inherently uncertain. Furthermore, failure can occur at any stage of the clinical trial process, and we could encounter problems that cause us to abandon or repeat clinical trials. Drug product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials, and the results of pre-clinical studies and early clinical trials of our drug product candidates therefore may not be predictive of the results of later-stage clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

The commencement and completion of clinical trials may be delayed for a variety of reasons, including:

- failure to obtain regulatory approval to commence a trial;
- failure to obtain independent IRB approval at each trial site;
- addition of new trial sites;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during later-stage clinical trials;
- inability to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among

different CROs and trial sites;

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- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to manufacture sufficient quantities of a drug candidate for use in clinical trials;
- inability to monitor patients adequately during or after treatment, including failure to have patients complete a trial or return for post-treatment follow-up; and
- inability or unwillingness of clinical investigators to follow our clinical protocols.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we will have agreements governing their committed activities, we will have limited influence over their actual performance.

We, the FDA or other regulatory authorities, or the Data Safety Monitoring Board, or DSMB, for a clinical trial or the IRB or ethics committee of an institution in which a clinical trial is being conducted, may suspend or terminate our clinical trials at any time due to a number of factors, including, if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements or our clinical protocol, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of any of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from the candidates may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the development and, in the case of our drug product candidates, the approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug product candidates, our business will be substantially harmed.

Our drug product candidates will require regulatory approval by the FDA and comparable foreign authorities before we can market them. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any drug product candidate, and it is possible that we may never obtain regulatory approval of any drug product candidate that we seek to develop in the future.

Obtaining approval of an NDA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or comparable foreign regulatory authorities may delay, limit or deny approval of our drug product candidates for many reasons, including:

- we may not be able to demonstrate that our drug product candidates are safe and effective as treatments for our targeted indications to the satisfaction of the FDA or comparable foreign regulatory authorities;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval;
- the FDA or comparable foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
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the CRO that we retain to conduct clinical studies and trials may take actions outside of our control that materially adversely impact our clinical studies and trials;

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- the FDA or comparable foreign regulatory authorities may not find the data from pre-clinical and clinical studies sufficient to demonstrate that the clinical and other benefits of our drug product candidates outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our pre-clinical and clinical studies or may require that we conduct additional studies;
- the data collected from clinical trials of our drug product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may not accept data generated at our clinical trial sites;
- if our NDA is reviewed by an advisory committee, the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;
- the FDA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers with which we contract for clinical or commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our drug product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug product candidate. Any of the foregoing scenarios could harm the commercial prospects for our drug product candidates.

Our drug product candidates or consumer products may cause undesirable side effects or have other properties that could impact their market acceptance, or in the case of our drug product candidates, delay or prevent their regulatory approval or limit the scope of any approved label.

Undesirable side effects caused by our drug product candidates could cause us, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval. None of the subjects in Flex-001, Flex-002 and Flex-003 reported any serious adverse events, or SAEs. However, there is no guarantee that subjects in our future clinical trials will not experience SAEs. For instance, capsaicin, one of the active ingredients in our proprietary treatment, is an irritant and produces a sensation of burning in tissue with which it comes into contact. Given orally, capsaicin can induce the effects associated with the ingestion of spicy food, including an increase of salivation and gastric secretion, warm to intolerable burning and gastrointestinal disorders depending on the dose. Some epidemiological studies have suggested a correlation of stomach cancer incidences with geographic areas known to consume a chili pepper-rich diet. However, the causal connections between capsicum and cancer based on these epidemiological studies is difficult to ascertain given other factors, such as smoking and exposure to environmental pollutants commonly found in developing countries. Further, recent studies utilizing high-purity capsaicin and standardized protocols suggest that the carcinogenic potential of capsaicin is minimal. Capsaicinoids are prescribed as topical analgesics for the treatment of neuropathic pain and in low amounts as an over-the-counter treatment for the temporary relief of muscle pain. Even at low doses capsaicinoids are irritants, causing burning sensation, swelling and pain on the skin and mucous membranes. These or other side effects could affect subject recruitment or the ability of enrolled subjects to complete clinical trials or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Further, if any of our drug product candidates receives marketing approval or we begin marketing our consumer product, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

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- regulatory authorities may withdraw approval for the drug products or impose restrictions on their distribution in the form of a modified REMS;
- regulatory authorities may require additional labeling statements on the drug products such as warnings or contraindications;
- we may be required to create a medication guide for the drug products outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to individuals;
- we could elect to discontinue the sale of our consumer products; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected drug product candidate, if approved, or consumer product, if marketed, and could substantially increase the costs of commercializing our product candidates.

Even if we obtain regulatory approval for any of our drug product candidates, we will be subject to ongoing and extensive regulatory requirements and continued regulatory review, which may result in significant additional expense. Additionally, our drug product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our drug product candidates may be subject to significant restrictions on the indicated uses for which the product may be marketed or impose ongoing requirements for potentially costly post-marketing testing, including Phase IV clinical trials, or post-market surveillance. Any drug product candidate we develop, if approved, will also be subject to ongoing and extensive FDA or comparable foreign regulatory authority requirements governing the labeling, packaging, storage, distribution, export, import, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. In the United States, the holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA to the FDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA regulations, in addition to other potentially applicable federal and state laws and regulations, and are subject to FDA review.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where or the processes by which the product is manufactured, or if we or our third-party manufacturers fail to comply with regulatory requirements, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- impose restrictions on the marketing and/or manufacturing of the product, withdraw the product from the market or require mandatory product recalls;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- seize or detain product or refuse to permit the import or export of the product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue. In addition, regulatory policies may change

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and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Risks Related to Our Reliance on Third-Parties

We rely on third-parties to conduct our clinical trials. If these third-parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to market our consumer product or obtain marketing approval for or commercialize our drug product candidates and our business could be materially harmed.

We rely upon third-party CROs to monitor and manage data for our clinical programs, including our proof-of-concept studies. We rely on these parties for execution of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practices, or GCPs, which are also required by the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our drug product candidates in clinical development. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical studies or trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the proof-of-concept studies of our proprietary treatment are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCPs. Failure to comply with applicable regulations in the conduct of our clinical trials may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us upon reasonable notice or if, among other reasons, we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to timely enter into arrangements with alternative CROs or to do so on commercially reasonable terms, if at all. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug product candidates. Consequently, our results of operations and the commercial prospects for our drug product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely completely on third-parties to manufacture our supplies for our clinical studies and we intend to rely on third-parties to produce commercial supplies of any approved drug product candidate and our consumer products, if

marketed. Our commercialization of any of our drug product candidates or consumer product could be stopped, delayed or made less profitable if those third-parties fail to comply with the regulatory requirements of the FDA, Competent Authorities of the Member States of the EEA or

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comparable regulatory authorities, fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our consumer products or the clinical supplies of our proprietary treatment for our planned proof-of-concept studies, and we lack the resources and the capability to manufacture on a commercial scale. The facilities used by our contract manufacturers to manufacture our drug product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. While we will work closely with our third-party manufacturers on the manufacturing process for our drug product candidates, including by conducting quality audits, we generally will not control the manufacturing process of, and will be completely dependent on, our contract manufacturers or other third-party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both active drug substances and finished drug products for our drug product candidates and dietary supplement cGMP regulatory requirements for our consumer product. If we were to experience an unexpected loss of supply of the TRP activators in our proprietary treatment or drug product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, our clinical trials. We have no control over the ability of our contract manufactuers or other third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our contract manufacturers or other third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities for the drug product candidates and may not be able to continue manufacturing the consumer products under development. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug product candidates or if it withdraws any such approval in the future, or if these facilities are found not to be compliant with the regulatory requirements for the manufacture of drug products or dietary supplements, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug product candidates, if approved, and to market our consumer product.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our proprietary treatment for our proof-of-concept clinical studies and our consumer products and expect to continue to rely on our manufacturers to purchase from third-parties the materials necessary to produce our products if and when they are commercially marketed. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. There may be only a limited number of these suppliers, and we cannot assure you that we will be successful in identifying and qualifying an acceptable supplier of the raw materials we require. Even if successful, the process of identifying and qualifying a replacement supplier or a contract manufacturer or other third-party manufacturer could cause a delay in the supply of a drug product candidate, or the raw material components thereof, for an ongoing clinical trial. Any such significant delay in supply could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our drug product candidates. If our manufacturers or we are unable to purchase the raw materials we require after regulatory approval has been obtained for our drug product candidates, the commercial launch of our drug product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our drug product candidates.

We have not completed the development work for our consumer products. There is no guarantee that once this development work has been completed, we will be able to identify suitable manufacturers for the commercial production of our consumer products or that we will be able to enter into agreements with these manufacturers on favorable terms. If we are not able to identify appropriate manufacturers or enter into reasonable agreements with such manufacturers, our ability to commercialize our consumer products will be limited, which could have a material adverse impact upon our business.

We may not be successful in establishing development and commercialization collaborations, which failure could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Developing drug products, conducting clinical trials, obtaining marketing approval, establishing manufacturing capabilities and marketing approved products is expensive and, therefore, we anticipate exploring collaborations with

third-parties that have more resources and experience than we do. In situations where we enter into a development and commercial collaboration arrangement for a drug product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such drug product candidate. If any of our drug product candidates

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receives marketing approval, we may enter into sales and marketing arrangements with third-parties with respect to otherwise unlicensed or unaddressed territories outside of the United States. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on reasonable and acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell future approved products, if any, in some or all of the territories outside of the United States where it may otherwise be valuable to do so.

Establishing manufacturing and distribution capabilities, and marketing and selling consumer products, is expensive and, therefore, we anticipate entering into collaborations with third-parties that have more resources and experience than we do. In particular, we do not have, nor do we intend to hire, a large sales force to market consumer products under our consumer brand. Until we complete the development of our cornerstone consumer product, we may find it difficult to attract qualified partners. Even after the development of our cornerstone product is completed, we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on reasonable and acceptable terms, if at all, we may be unable to suitably manufacture our consumer products candidates and/or effectively market and sell our consumer products.

To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with the necessary technical expertise. We also cannot assure you that we will be able to establish or maintain effective in-house sales and distribution capabilities.

We may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts.

Even if we are able to establish collaboration arrangements with third-parties, any such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. If we partner with a third-party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third-party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated and our business could be substantially harmed. In some cases, we may be responsible for continuing development of a product candidate or research program under a collaboration, and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. Even if we were successful in establishing a collaboration, conflicts may arise between us and our partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a partner could act in its own self-interest, which may be adverse to our best interests. Any such disagreement between us and a partner could result in the delay or prevent the development or commercialization of our product candidates and, in turn could prevent us from generating sufficient revenue to achieve or maintain profitability.

Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by employees and independent contractors, such as principal investigators, CROs, manufacturers, consultants, commercial partners and vendors. Misconduct by these parties could include the disclosure of unauthorized activities to us or intentional or negligent failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards, to comply with federal and state healthcare fraud and abuse laws, to report financial information or data accurately. 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, but not limited to certain activities related to research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by employees and other third-parties could also involve

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the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical studies and trials. 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.

We have adopted a code of business ethics and conduct, but it is not always possible to identify and deter misconduct by employees and other third-parties, and the precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

Risks Related to Commercialization of Our Drug Product Candidates and Consumer Brand and Products

Complying with new and existing government regulations for our consumer product, both in the United States and abroad, could significantly increase our costs or delay or prevent the development or potential commercialization of our consumer brand.

The processing, formulation, packaging, labeling, advertising, distribution and sale of our consumer products is subject to regulation by several U.S. federal agencies, including the FDA, the Federal Trade Commission, or the FTC, the Postal Service, the Consumer Product Safety Commission, the Department of Agriculture and the Environmental Protection Agency, as well as various state, local and foreign laws and agencies of the localities in which our products are sold. Government regulations may prevent or delay the introduction or require the reformulation of our products. We believe our consumer products for the prevention of EAMC will be regulated as dietary supplements by the FDA, which we believe is an appropriate marketing claim for a dietary supplement and not a disease claim that would render the product subject to regulation as a drug. The FDA regulates, among other things, the manufacture, composition, safety, packaging, labeling, marketing, advertising and distribution of dietary supplements (including vitamins, minerals, herbs, and other dietary ingredients for human use). The FDA may determine that a particular dietary supplement or ingredient that we may market presents an unacceptable health risk. If that occurs, we could be required to cease distribution of and/or recall dietary supplements containing that ingredient.

The FDA or FTC may also determine that certain labeling, advertising and promotional claims, statements or activities with respect to a dietary supplement are not in compliance with applicable laws and regulations and may determine that a particular statement is an unapproved health claim, a drug claim, a false or misleading claim, or a deceptive advertising claim. Any such determination or any other failure to comply with FDA or other regulatory requirements could prevent us from marketing our consumer product as a dietary supplement and subject us to administrative, civil or criminal penalties.

The Food Safety Modernization Act, or FSMA, now requires food companies, including dietary supplement companies, to register with the FDA biennially. The FSMA permits summary suspension of registrations (and elimination of the right to sell products in interstate commerce) based on findings by the FDA that a product might present an unreasonable risk of serious illness, injury or death. In addition, legislation has been introduced in the U.S. Senate which seeks to provide the FDA with increased authority to regulate dietary supplements and to increase labeling requirements with respect to dietary supplements. Other legislation introduced but not passed by Congress would require the FDA Commissioner to obtain a list of all ingredients and claims for dietary supplements and distinguish from among them which products are potentially unsafe and which claims are misleading. FDA and FTC are also cooperating in joint enforcement projects, including the issuance of warning and enforcement letters by both agencies. The FTC exercises jurisdiction over the advertising of dietary supplements and has instituted numerous enforcement actions against dietary supplement companies for failing to have adequate substantiation for claims made in advertising or for using false or misleading advertising claims. The FTC routinely polices the market for deceptive dietary supplement advertising and accepts and reviews complaints from the public concerning such advertising.

In Europe, non-compliance by us or others of relevant legislation can result in regulators bringing administrative or, in some cases, criminal proceedings. European Union regulations and directives are implemented and enforced by individual member states and, so, enforcement priorities and applicable law can occur in multiple countries at one

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time. Failure by us, the manufacturers or suppliers to comply with applicable legislation could result in prosecution and have a material adverse effect on our business, financial condition and results of operations.

Europe has adopted broad regulations and directives on health and nutrition claims. These regulations cover claims that can be made for foods, including dietary supplements, and certain claims may be prohibited or require prior approval. Unless subject to derogation, products that include certain claims cannot be lawfully marketed in EU member states absent preapproval.

In addition, an EU Directive (Directive 2001/95/EC as amended) governing product safety requires manufacturers to notify regulators about unsafe products and gives regulators in each member state the power to order product recalls. As a result, the number of product recalls in Europe has increased substantially. A product recall in Europe could have a material adverse effect on our business, financial condition and results of operations.

We are subject to uncertainty relating to third-party payor coverage and reimbursement policies which, if not favorable to our drug candidates, could hinder or prevent our products' commercial success.

Our ability to commercialize our drug candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors establish appropriate coverage and reimbursement levels for our drug candidates and related treatments. As a threshold for coverage and reimbursement, third-party payors generally require that drug products be approved for marketing by the FDA. A trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. Therefore, as a result of these cost containment measures, coverage and reimbursement may not be available for any drug product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. We do not expect any third-party payors to cover and reimburse for our consumer products.

In the United States, private third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement 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 products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could significantly harm our operating results, our ability to raise capital needed to commercialize our product candidates and our overall financial condition.

Our commercial success depends upon attaining significant market acceptance of our drug product candidates, if approved, among physicians, healthcare payors, patients and the medical community.

Even if we obtain regulatory approval for any drug product candidate, the product may not gain market acceptance among physicians, healthcare payors, patients and the medical community, which is critical to commercial success. Market acceptance of any drug product candidate for which we receive approval depends on a number of other factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of the drug product candidate as well as competitive products;
- the clinical indications for which the drug product candidate is approved;
- acceptance by physicians, the medical community and patients of the drug product candidate as a safe and effective treatment;
- the convenience of prescribing and initiating patients on the drug product candidate;
- the potential and perceived advantages of such drug product candidate over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors including government authorities;
- relative convenience and ease of administration;

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- the prevalence and severity of adverse side effects; and
- the effectiveness of sales and marketing efforts.

Many drug products approved for treatment of a particular disease are not effective in treating all patients suffering from a disease and there is no guarantee that our drug product candidates, if approved, will be effective in treating all patients. In the clinical studies of our proprietary treatment performed to date, 49% of subjects tested produced results that were inconclusive or showed our proprietary treatment did not reduce the subject's electrically induced muscle cramps. Our drug product candidates will be based on the same TRP activators found in our proprietary treatment. If the results of future clinical trials of our drug product candidates produce the same results as the results from the studies of our consumer products, physicians, healthcare payors, patients and the medical community may not accept our drug product candidates as treatment options. If our drug product candidates are approved but fail to achieve an adequate level of acceptance by physicians, healthcare payors, patients and the medical community, we will not be able to generate significant revenue, and we may not become or remain profitable.

We may incur product liability claims, which could increase our costs and/or materially adversely affect our business, reputation, financial condition or results of operations.

The testing and marketing of drug products and consumer products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Retailers and formulators of products designed for human consumption may be subject to product liability claims if the use of their products is alleged to have resulted in illness or injury or if their products include inadequate instructions or warnings. As a dietary supplement that does not contain new dietary ingredients, our consumer products will not be subject to pre-market regulatory approval or review in the United States by the FDA or other governmental authorities. Our consumer products could contain spoiled or contaminated substances, and some of our products may contain ingredients that do not have long histories of human consumption. We could be subject to product liability claims, including among others, that our products include insufficient instructions for use or inadequate warnings concerning possible side effects or interactions with other substances. Any product liability claim against us could result in increased costs and adversely affect our reputation with our customers, which in turn could materially adversely affect our business, financial condition or results of operations.

Insurance coverage, even where available, may not be sufficient to cover losses we may incur, which could increase our costs and lower our profits.

Our business exposes us to the risk of liabilities arising out of our products and operations. For example, we may be liable for claims brought by users of our products or by employees, customers or other third-parties for personal injury or property damage occurring in the course of our operations. We will seek to minimize these risks through various insurance policies from third-party insurance carriers. Currently, we have only limited product liability insurance coverage and the insurance industry has become more selective in offering certain types of insurance, including product liability, product recall and property casualty insurance. There can be no assurance that we will be able to obtain or maintain such coverage or obtain comparable coverage on terms and conditions favorable to us, if at all. Further, we anticipate that any additional insurance coverage we may obtain will be subject to large individual claim deductibles, individual claim and aggregate policy limits and other terms and conditions. We cannot assure you that our insurance will be sufficient to cover our losses. Any losses that are not completely covered by our insurance could have a material adverse effect on our business, financial condition or results of operations, including preventing or limiting the commercialization of drug products and consumer products we develop, alone or with collaborators.

Unfavorable publicity or consumer acceptance of our consumer product or of dietary supplements, generally, could reduce our sales.

We expect to be dependent upon consumer acceptance of the safety, efficacy and quality of our products. Consumer acceptance of products can be significantly influenced by customer reviews, scientific research or findings, national media attention and other publicity about product use. A product may initially be received favorably, resulting in high sales associated with that product that may not be sustainable as consumer preferences change. Alternatively, skepticism of claims made by companies in the dietary supplement industry may limit the number of individuals that believe our consumer products are effective in preventing muscle cramps, which may negatively our ability to

generate significant sales from our consumer products.

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For instance, many consumers currently believe that hydration, stretching and sports drinks are sufficient to prevent EAMC. To successfully market our consumer product, we will need to convince consumers that these treatments, alone, are insufficient in relieving or preventing muscle cramps. Changing consumer behavior patterns may take months or years to accomplish and there is no guarantee that we will be successful in doing so. Furthermore, our proprietary treatment has been shown only to relieve the intensity of muscle cramps if taken prior to the individuals' experiencing a muscle cramp. We do not know if our consumer products will be effective in relieving a muscle cramp that has already begun and, as a result, consumers may need to take our consumer products in advance of activities where they believe a muscle cramp is likely to occur. There is no guarantee that consumers will be willing to use our consumer products as a preventative measure. If consumers are not willing to purchase our products as a preventative measure, our ability to generate significant revenue from the sale of our consumer product may be limited.

Scientific research or publicity could be unfavorable to the dietary supplement industry or any of our particular products. Any research or publicity that is perceived by our consumers as less than favorable or that questions earlier favorable research or publicity could have a material adverse effect on our ability to generate revenue. Adverse publicity in the form of published scientific research, statements by regulatory authorities or otherwise, whether or not accurate, that associates consumption of our products or any other similar products with illness or other adverse events, or that questions the benefits of our or similar products, or that claims that such products are ineffective could have a material adverse effect on our business, reputation, financial condition or results of operations.

If our drug product candidates are not shown to be more effective in relieving muscle cramps than our consumer product, then the market for our drug product candidates may be limited.

Both our consumer products and drug product candidates may include the same TRP activators found in our proprietary treatment. We expect to formulate our consumer products to address the needs of athletes and to formulate our drug product candidates to address the needs of individuals suffering from nocturnal leg cramps and severe neuromuscular disorders. As a dietary supplement, we intend to market our consumer products only to athletes suffering from EAMC and not individuals suffering from a disease. However, if our drug product candidates are not shown to be more effective than our consumer products in preventing muscle cramps, or patients or physicians believe our consumer products are just as effective as any approved drug product candidates, individuals suffering from nocturnal leg cramps or severe neuromuscular diseases may elect to use our consumer products rather than our drug product candidates, if approved, which may limit the market for our drug products candidates.

If we experience product recalls, we may incur significant and unexpected costs and damage to our reputation which in turn could have a material adverse effect on our business, financial condition or results of operations.

We may be subject to product recalls, withdrawals or seizures if any of the products we sell are believed to cause injury or illness or if we are alleged to have violated governmental regulations in the labeling, promotion, sale or distribution of our products. A recall, withdrawal or seizure of any of our products could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our products. In addition, a recall, withdrawal or seizure of any of our products would require significant management attention, would likely result in substantial and unexpected expenditures and could materially adversely affect our business, financial condition or results of operations.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our drug product candidates and affect the prices we may obtain.

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our drug product candidates profitably, if they are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, was enacted, which includes measures that have or will

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significantly change the way healthcare is financed by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical industry are the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50.0% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133.0% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements under the federal Open Payments program, created under Section 6002 of ACA and its implementing regulations that certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to HHS information related to "payments or other transfers of value" made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and that applicable manufacturers and applicable group purchasing organizations report annually to HHS ownership and investment interests held by physicians (as defined above) and their immediate family members, with data collection currently required and reporting to the Centers for Medicare & Medicaid Services required by the 90th day of each calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for non-compliance;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board, which has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

In addition, other legislative changes have been proposed and adopted since ACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the

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government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Further, under the recently enacted Drug Quality and Security Act, drug manufacturers will be subject to product identification, tracing and verification requirements, among other requirements, that are designed to improve the detection and removal of counterfeit, stolen, contaminated or otherwise potentially harmful drugs from the U.S. drug supply chain. These requirements will be phased in over several years and compliance with this new law will likely increase the costs of the manufacture and distribution of drug products, which could have an adverse effect on our financial condition.

We expect that the ACA, as well as other healthcare reform measures or may be adopted in the future, may, among other things, result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Our operations are, and will continue to be, directly, and indirectly, through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons and entities from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The Anti-Kickback Statute is broad and, despite a series of narrow statutory exceptions and regulatory safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry.

The federal False Claims Act prohibits persons and entities from among other things, knowingly presenting, or causing to be presented, claims for payments that are false or fraudulent or making or using a false record or statements, to obtain payment from the federal government. Suits filed under the civil False Claims Act, can be brought by any individual on behalf of the government, known as "qui tam" actions, and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of pharmaceutical, medical device and other healthcare companies to have to defend a civil False Claims Act action. When an entity is determined to have violated the civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is 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.

The recently enacted ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it to have committed a violation. 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 civil False Claims Act.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, also 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

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entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The federal Open Payments program, created under the ACA, and its implementing regulations, impose new annual reporting requirements for certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to annually report certain payments and transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members. Additionally, many states have laws comparable to those described above, which may be broader in scope and apply regardless of payor.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

If we cannot compete successfully for market share against other pharmaceutical companies, dietary supplement companies, and consumer brand companies, we may not achieve sufficient product revenue and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking pre-clinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any of our current or future product candidates, or achieve earlier patent protection, marketing approval, product commercialization and market penetration than us. Additionally, technologies developed by our competitors may render some of our current of future product candidates uneconomical or obsolete, and we may not be successful in marketing our products against competitors. If we are unable to compete successfully with these and other potential future competitors, we may be unable to grow and sustain our revenue.

In addition, our consumer products will compete against larger companies developing and marketing dietary supplement and consumer products. We believe the principal elements of competition in the consumer product industry are price, selection, brand recognition, distribution channel offerings and the effectiveness of the product. If our consumer product gains market acceptance, we are likely to experience increased competition for those products as more participants enter the market. Certain of our competitors are larger than us and have longer operating histories, larger customer bases, greater brand recognition and greater resources for marketing, advertising and product promotion. They may be able to secure inventory from vendors on more favorable terms, operate with a lower cost structure or adopt more aggressive pricing policies. Our competitors may also be more effective and efficient in introducing new products. We may not be able to compete effectively, and our attempt to do so may require us to increase marketing and/or reduce our prices, which may result in lower margins. Failure to effectively compete could materially adversely affect our market share, financial condition and growth prospects.

Risks Related to Our Business Operations and Industry

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Our future success depends on our ability to retain key executives and to attract, retain motivate qualified personnel.
Our future success depends on our ability to retain key executives and to attract, retain motivate qualified personnel.
Our future success depends on our ability to retain our founders and to attract, retain and motivate qualified personnel.
We are highly dependent on Christoph Westphal, our President, Chief Executive Officer and Chairman, as well as the other principal members of our management and scientific teams, including our scientific co founders, Bruce Bean, Ph.D. and Roderick MacKinnon, M.D. Although we have an employment agreement with Dr. Westphal, such agreement does not prevent him from terminating his employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.
We will need to grow the size of our organization, and we may experience difficulties in managing this growth.
As of March 6, 2015, we had 19 full time employees and two part time employees. As our development and commercialization plans and strategies develop, we expect to need additional research and development, managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- preparing for and executing on the launch of our consumer brand;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to other third-parties;
- improving our managerial, development, operational and finance systems; and
- developing our compliance infrastructure and processes to ensure compliance with complex regulations and industry standards regarding us and our product candidates.

As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third-parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical studies and trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.
If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.
Our long-term growth strategy is to develop, acquire or in-license and commercialize a portfolio of product candidates. We do not have internal new drug discovery capabilities. As a result, our primary means of expanding our pipeline of product candidates is to select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current target indications, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects may be limited.
Risks Related to Intellectual Property
Our proprietary rights may not adequately protect our intellectual property and potential products, and if we cannot obtain or maintain adequate protection of our intellectual property rights, we may not be able to successfully market our potential products.
Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our products, formulations, processes, methods and other technologies. We will only be able to protect these

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technologies and products from unauthorized use by third-parties to the extent they are covered by valid and enforceable intellectual property rights, including patents, or other market exclusionary rights apply.

We have applied for patent protection in the United States and in some, but not all, foreign countries, including claims directed at mechanisms and methods relating to our product candidates, formulations and enabling technology such as our electrical stimulation technique for inducing muscle cramping. Any changes we make to our formulations, however, may not be covered by our existing patent applications, and we may be required to file new applications or seek other forms of protection as a result. In addition, none of the active ingredients in our proprietary treatment can be protected by a patent covering its chemical composition of matter since each ingredient has long been in the public domain. Consequently, we will rely on method of use and formulation patent protection for our proprietary treatment, and will rely on this patent protection for any drug product candidates and consumer products we develop, which may not provide the same level of protection as composition of matter patent protection. In countries where we have not and do not seek patent protection, third-parties may be able to manufacture and sell our products without our permission, and we may not be able to stop them from doing so.

The patent positions of biotechnology companies, like ours, can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy has emerged in the United States regarding the breadth of claims allowed in patents covering the technology in the pharmaceutical field. The general environment for pharmaceutical patents outside the United States also involves significant uncertainty. Accordingly, we cannot predict the breadth of claims that may ultimately issue on our patent applications, or that the scope of these patent rights will provide a degree of protection on our product candidates and future products and technology sufficient to permit us to gain or maintain our competitive advantage with respect to these products and technology. For example, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third-parties will find ways to design around our patent claims and make, use, sell, offer to sell or import competitive products without infringing our patents;
- if and when patents will issue;
- whether others will obtain patents claiming inventions similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings in connection with patent rights, which may be costly regardless of whether we win or lose.

In addition, others may independently develop similar or alternative products and technologies that may be outside the scope of our intellectual property. For example, a third-party may develop a competitive product that provides therapeutic benefits similar to those of one or more of our product candidates but that has a different composition that falls outside the scope of our patent protection. Furthermore, others may have invented technology claimed by our patents before we did so, and they may have filed patents claiming such technology before we did so, which would weaken our ability to obtain and maintain adequate patent protection for such technology. Should third-parties obtain patent rights to similar products or technology, this may have an adverse effect on our business.

If we or our current licensors or licensees, or any future licensors or licensees, fail to adequately prosecute, maintain and enforce patent protection for our product candidates, our ability to develop and commercialize those product candidates could be harmed and we might not be able to prevent competitors from making, using and selling competing products. Further, the U.S. Patent and Trademark Office, or USPTO, and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Losing our patent rights could enable competitors to enter the market earlier than would otherwise have been the case. Any such failure to properly protect the intellectual property rights relating to our product candidates could harm our business, financial condition and operating results.

If we are unable to prevent disclosure of our trade secrets or other confidential information to third-parties, or to ensure that all inventions are assigned to us, our competitive position may be impaired.

In addition to patents, we may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets, however, are difficult to protect. We seek to protect this information, in part, through the use of non-disclosure and confidentiality agreements with employees, consultants, advisors and others. While we believe that we use reasonable efforts to protect our trade secrets, our

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own or our strategic partners' employees, consultants, contractors or advisors may unintentionally or willfully disclose our information to competitors. In addition, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property or who had access to our proprietary information, nor can we be certain that our agreements with such parties will not be breached. These agreements may not effectively prevent disclosure of confidential and proprietary information and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential and proprietary information. We cannot guarantee that our trade secrets and other confidential proprietary information will not be publicly disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. The failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, to the extent that consultants or key employees apply technological information independently developed by them or by others to our potential products, disputes may arise as to the proprietary rights in such information, which may not be resolved in our favor. Consultants and key employees that work with our confidential and proprietary technologies are required to assign all intellectual property rights in their discoveries to us. However, these consultants or key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors. If our trade secrets become known to competitors with greater experience and financial resources, the competitors may copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. If we were to prosecute a claim that a third-party had illegally obtained and was using our trade secrets, it could be expensive and time consuming and the outcome could be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets than courts in the United States. Moreover, if our competitors independently develop equivalent knowledge, we would lack any contractual or other legal claim to prevent them from using such information, and our business could be harmed.

Third-parties may claim that we or our employees have misappropriated the intellectual property of a third-party, including know-how or trade secrets, or may claim ownership of what we regard as our own intellectual property. Many of our employees, consultants and contractors were previously employed at or engaged by other biotechnology, pharmaceutical, food and dietary supplement companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs.

The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first to file" system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and 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 harm our business, results of

operations and financial condition.

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The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Further, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In particular, under recent Supreme Court precedent, it is unclear to what extent naturally occurring material must be transformed in order to become eligible for patentability. Any future decisions by the Supreme Court, or by another governing body in a jurisdiction where we hold patent protection for our products, that narrow such eligibility would result in the diminishment, and potentially the complete loss, of patent protection afforded our products.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third-parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO. Numerous U.S. and foreign issued patents and pending patent applications owned by third-parties exist in the fields in which we and our collaborators are developing drug product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug product candidates may be subject to third-party claims of patent infringement.

Third-parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our proprietary treatment, our consumer products and/or our drug product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications of which we are unaware that ultimately result in issued patents that our drug product candidates and consumer products may infringe. In addition, third-parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our drug product candidates, any drug substance formed during our manufacturing process or any of our final products themselves, the holders of any such patents may be able to block our ability to commercialize such drug product candidate unless we obtain a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug product candidate unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our drug product candidates. Defense of these claims, regardless of their merit, would subject us to substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third-parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible and in any case would require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third-parties to advance our research, manufacture clinical study and trial supplies or to facilitate commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents will not be

enforced against our products, which could result in either an injunction prohibiting our sales or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third-parties.

We may be required to initiate costly and time-consuming litigation in order to enforce our proprietary rights.

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Even where laws provide us with patent protection covering our products, litigation could become necessary to enforce and determine the scope of our proprietary rights, which would require significant time and expense and divert the resources of management, and the outcome of any such litigation would be highly uncertain. If we or one of our future collaboration partners were to initiate legal proceedings against a third-party to enforce a patent covering the product candidate, the defendant could counterclaim that our asserted patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcomes of proceedings involving assertions of invalidity and unenforceability are unpredictable. It is possible that prior art exists of which we and the patent examiner were unaware during prosecution, which could render our patents invalid. Moreover, it is also possible that existing prior art of which we are aware, but which we do not believe is relevant to our current or future patents, could nevertheless be determined to render our patents invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would harm our business. Moreover, our competitors, some of whom may have substantially greater intellectual property portfolios and resources than we do, could counterclaim in any suit to enforce our patents that we infringe their intellectual property.

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 collaboration 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 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. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates or to prevent others from marketing similar products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the 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 ordinary shares could be significantly harmed.

Our inability or failure to adequately protect our trademarks could have a negative impact on our brand image and limit our ability to penetrate new markets.

We believe trademarks will be an important element of the success of our consumer brand and products. We are currently considering product naming alternatives and will apply for federal registration of any trademarks with the USPTO and the registries of countries where our consumer products are likely to be marketed. There can be no assurance that we will obtain registrations that we apply for or that the registrations we obtain will prevent the imitation of our products or infringement of our intellectual property rights by others. If a third-party copies our products in a manner that projects lesser quality or carries a negative connotation, our brand image could be materially adversely affected.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile and you could lose all or part of your investment.

Prior to our recently completed initial public offering, there was no public market for our common stock. We cannot assure you that an active, liquid trading market for our shares will develop or persist. The market price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

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- adverse results or delays in commencing or completing our proof-of-concept studies and future clinical trials;
- inability to obtain additional funding;
- any delay in filing an IND for any drug product candidate and any adverse development or perceived adverse development with respect to the FDA's review of that IND;
- failure to successfully develop and commercialize our drug product candidates or consumer products;
- failure to generate significant sales for our consumer products;
- changes in laws or regulations applicable to our consumer products or drug product candidates, including without limitation, coverage and reimbursement policies;
- inability to obtain adequate product supply for our drug product candidates or consumer product, or the inability to do so at acceptable prices;
- any delay in launching or otherwise commercializing our consumer brand and products;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry or dietary supplement industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, the stock market in general, and the market for smaller pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

An active trading market for our common stock may not develop.

Prior to our recently completed initial public offering, there has not been a public market for our common stock and an active trading market for our shares may never develop or be sustained. If an active market for our common stock does not develop, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own approximately 47.5% of our voting stock. Therefore, these stockholders will have the ability to exert significant control over us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that

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you may believe are in your best interest as one of our stockholders or entrench our management and/or the board of directors.

We are an "emerging growth company," and the reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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 controls over financial reporting are 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. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

We completed our initial public offering on February 3, 2015. As a newly public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC, and The NASDAQ Global Market have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and

disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and

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regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage. We estimate that we will incur between $1.5 million and $2.0 million per year in legal, accounting and other expenses as a result of being a public company. However, it is difficult to predict or estimate with any certainty the amount of such additional expenses and, as a result, our actual expenses may differ significantly from our estimates.

These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

All of our stockholders prior to our initial public offering are subject to lock-up agreements with the underwriters of our initial public offering that restrict the stockholders' ability to transfer shares of our common stock for at least 180 days from January 28, 2015, the date of the final prospectus for our initial public offering. The lock-up agreements limit the number of shares of common stock that may be sold immediately following our initial public offering. Subject to certain limitations, including sales volume limitations with respect to shares held by our affiliates, substantially all of our outstanding shares prior to our initial public offering will become eligible for sale upon expiration of the lock-up period. In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act, subject to the 180-day lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of 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 the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. 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 common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2015 Equity Incentive Plan, or the 2015 plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2015 plan will automatically increase each year by 4% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2015 plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have

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experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We have broad discretion in the use of the net proceeds from our recently completed initial public offering and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our recently completed initial public offering. Because of the number and variability of factors that will determine our use of the net proceeds from our initial public offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from our initial public offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

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Item 1B. Unresolved Staff Comments
None.

Item 2. Properties
Our corporate headquarters are located at a 7,234 square foot subleased facility in Boston, MA, which is used primarily for corporate and research and development functions. The sublease for our corporate headquarters expires in August 2017. We have leased an office suite in New York, NY to be used for sales and marketing functions. The lease for our New York office expires on October 31, 2016. We believe that our existing facilities are sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings
We are not currently a party to any material legal proceedings.

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

Market Information

Our common stock has been publicly traded on the NASDAQ Global Market under the symbol “FLKS” since January 29, 2015. Prior to that time, there was no public market for our common stock. As a result, we have not set forth quarterly information with respect to the high and low prices for our common stock for the period from February 26, 2014 (Inception) to December 31, 2014 or provided a performance graph. On March 20, 2015, the last reported sale price of our common stock was $20.15.

Holders of Record

As of March 20, 2015, we had approximately 52 holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings to fund the development and growth of our business. We do not expect to pay any cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent sales of unregistered securities.
During the period from February 26, 2014 (inception) to December 31, 2014, we issued and sold the following unregistered securities:

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(1) In March 2014, we issued and sold an aggregate of 4,553,415 shares of common stock to our co-founders for an aggregate purchase price of $1,950. The shares were issued in connection with our incorporation and are subject to repurchase by us under restricted stock agreements with each co-founder.

(2) In April 2014, we issued and sold an aggregate of 867,314 shares of common stock to our co-founders under the 2014 Equity Incentive Plan, or the 2014 plan, and restricted stock agreements with each co-founder for an aggregate purchase price of $371. The shares are subject to repurchase by us under the restricted stock agreements with each co-founder.

(3) From April 2014 to December 31, 2014, we granted stock options under the 2014 Plan to purchase 1,020,234 shares of common stock to our employees, directors, advisors and consultants, having exercise prices ranging from $0.60 to $5.44 per share. Of these, options to purchase 13,572 shares of common stock have been exercised for aggregate consideration of $8,138.

(4) We issued and sold to investors an aggregate of 15,775,221 shares of series A preferred stock in closings that occurred in March, April and May 2014, at a purchase price of $1.00 per share, for aggregate consideration of $15.8 million. Upon the closing of the initial public offering, these shares converted into 3,683,637 shares of common stock.

(5) We issued and sold to investors an aggregate of 14,078,647 shares of series B preferred stock in closings that occurred in July, August, September and October 2014, at a purchase price of $1.8077 per share, for aggregate consideration of $25.4 million. Upon the closing of the initial public offering, these shares converted into 3,287,471 shares of common stock.

The offers, sales and issuances of the securities described in paragraphs (1), (4) and (5) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act and, with respect to paragraph (5) only, Rule 506 promulgated under Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about us.

The offers, sales and issuances of the securities described in paragraphs (2) and (3) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were the Registrant's employees, directors or bona fide consultants and received the securities under the 2014 Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

Use of Proceeds

In February 2015, we completed our initial public offering pursuant to a registration statement on Form S-1 (File No. 333-201276), which the SEC declared effective on January 28, 2015. In our initial public offering, we issued and sold 5,491,191 shares of common stock (inclusive of 91,191 shares of common stock sold by us pursuant to the exercise of an overallotment option granted to the underwriters in connection with the offering) at a public offering price of $16.00 per share, for aggregate gross offering proceeds of $87.9 million. The managing underwriters for our initial public offering were Jefferies LLC, Piper Jaffray & Co., JPM Securities LLC, Cantor Fitzgerald & Co., and Roth Capital Partners, LLC.

The aggregate proceeds received by us from our initial public offering were $79.9 million, net of underwriting discounts and commissions and offering expenses payable by us. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

There has been no material change in the use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on January 28, 2015.

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Item 6. Selected Financial Data

The following table sets forth our selected consolidated financial data. We derived the consolidated statement of operations data for the period from February 26, 2014 (inception) to December 31, 2014, and the consolidated balance sheet data as of December 31, 2014 from our audited consolidated financial statements, included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of results to be expected for any period in the future. The selected consolidated financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes thereto, included elsewhere in this Annual Report on Form 10-K. The selected consolidated financial data in this section is not intended to replace our consolidated financial statements and the related notes thereto.

	Period from February 26, 2014 (Inception) to December 31, 2014
Consolidated Statement of Operations Data:	
Operating expenses:	
Research and development	$4,003,911
General and administrative	4,025,895
Total operating expenses	8,029,806
Loss from operations	(8,029,806)
Interest income	18,946
Net loss attributable to common stockholders	$(8,010,860)
Net loss per share attributable to common stockholders — basic and diluted[1]	$(4.57)
Weighted-average number of common shares outstanding — basic and diluted[1]	1,753,024

(1) See Note 2 and Note 11 of our consolidated financial statements included elsewhere herein for an explanation of the method used to compute basic and diluted net loss per share of common stock and the weighted-average number of shares used in computation of the per share amounts.

	As of December 31, 2014
Consolidated Balance Sheet Data:	
Cash	$33,854,153
Working capital[2]	33,157,388
Total assets	35,611,398
Convertible preferred stock	41,031,167
Total stockholders' deficit	(6,538,340)

(2) We define working capital as current assets less current liabilities.

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. You should carefully read the "Risk Factors" section of this Annual Report on Form 10-K to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a biotechnology company that is developing innovative and proprietary treatments for exercise-associated muscle cramps, nocturnal leg cramps and spasms associated with severe neuromuscular conditions. Our founders' novel insights regarding neuromuscular physiology form the basis of our development efforts. We believe that activation of certain receptors in primary sensory neurons reduces the repetitive firing, or hyperexcitability, of alpha-motor neurons, thereby preventing or reducing the frequency and intensity of muscle cramps and spasms. We also believe that we are the only company developing products based on this mechanism of muscle cramp inhibition. We have conducted three randomized, blinded, placebo-controlled cross-over studies of our proprietary treatment, which have shown a statistically significant reduction in the intensity of muscle cramps induced in healthy normal volunteers. We intend to initially focus our drug development efforts on developing a product to treat nocturnal leg cramps. There is no drug product currently available in the United States that has been approved to treat nocturnal leg cramps. We estimate, based on independent third-party survey results, that approximately four million U.S. adults over the age of 65 suffer from nocturnal leg cramps on a daily basis. In the second quarter of 2015, we expect at least one individual to complete treatment in our first human proof-of-concept study of our proprietary treatment for individuals with nocturnal leg cramps.

We have incurred an operating loss since our inception and we anticipate that we will continue to incur operating losses for at least the next several years. To date, we have financed our operations with net proceeds from the private placement of our preferred stock and our initial public offering. We expect that our research and development and general and administrative expenses will continue to increase from their current levels as we continue the development of our drug product candidates, and we will incur significant sales and marketing expense associated with the launch of our consumer brand, our cornerstone product and future products. As a result, we will need additional capital to fund our future operations.

Components of Operating Results

Revenue

To date, we have not generated any revenue. In the future, we may generate revenue from a combination of drug product sales, consumer product sales, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or a combination of these sources. To the extent any of our products are successfully commercialized, we expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of payments that we receive upon the sale of our products, the timing and amount of license fees, milestone and other payments. If we fail to complete the development of our drug product candidates in a timely manner or obtain regulatory approval for them or fail to successfully commercialize our consumer products, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

Our research and development expenses have related primarily to the development of our proprietary treatment of muscle cramps and spasms. These costs include salaries and other compensation-related costs, such as stock-based compensation, for research and development employees, costs of clinical studies of our proprietary treatment, costs for consultants who we utilize to supplement our personnel, fees paid to third-parties, facilities and overhead

expenses, cost of laboratory supplies and other outside expenses.

Research and development costs are expensed as incurred. Clinical study and other development costs incurred by third-parties are expensed as the contracted work is performed. We accrue for costs incurred as the services are

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being provided by monitoring the status of the study or project and the invoices received from our external service providers. We adjust our accruals as actual costs become known.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase over the next several years as we increase personnel and compensation costs and seek to conduct proof-of-concept clinical studies and preclinical work, prepare regulatory filings for our drug product candidates and commence potential Phase 2 and Phase 3 clinical trials. It is difficult to determine, with certainty, the duration and completion costs of our current or future pre-clinical programs, clinical studies and clinical trials of our drug product candidates.

The duration, costs and timing of clinical studies and clinical trials of our proprietary treatment and drug product candidates will depend on a variety of factors that include, but are not limited to, the following:

- per patient costs;
- the number of patients that participate;
- the number of sites;
- the countries in which the studies and trials are conducted;
- the length of time required to enroll eligible patients;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the efficacy and safety profile of the drug product candidates; and
- timing and receipt of any regulatory approvals.

In addition, the probability of success for each drug product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of our proprietary treatment and each drug product candidate, as well as an assessment of each drug product candidate's commercial potential.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other compensation-related costs, including stock-based compensation, for personnel in executive, finance and accounting, legal, corporate communications and general administration roles. Other significant costs include professional service fees including legal fees relating to patent and corporate matters, costs for consultants who we utilize to supplement our personnel, travel costs, and facility costs not otherwise included in research and development expenses.

General and administrative expenses also include costs related to our consumer brand and cornerstone product. To date, these costs include personnel costs, brand development costs, market research costs and other external costs. As we prepare to launch our cornerstone consumer product in the first half of 2016, costs will increase as we incur costs related to branding, product design, promotion, distribution, and other related sales and promotion activities.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and potential commercialization of our consumer products and drug product candidates and the increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. We expect to incur additional costs associated with being a public company, including expenses related to services associated with maintaining compliance with NASDAQ listing rules and SEC requirements, insurance and investor relations costs.

Interest Income

Interest income consists of interest income on our cash accounts.

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Results of Operations

Period from February 26, 2014 (Inception) to December 31, 2014

The following table sets forth results of operations for the period from February 26, 2014 (inception) to December 31, 2014.

	Period from February 26, 2014 (Inception) to December 31, 2014
Operating expenses:	
Research and development	$4,003,911
General and administrative	4,025,895
Total operating expenses	8,029,806
Loss from operations	(8,029,806)
Interest income	18,946
Net loss	$(8,010,860)

Research and Development Expenses

Research and development expenses were $4.0 million for the period from February 26, 2014 (inception) through December 31, 2014, and primarily consisted of the following:

- $1.9 million of costs related to the clinical studies of our proprietary treatment;
- $1.4 million of personnel related costs including salaries and other compensation-related costs, including stock-based compensation;
- $0.5 million of external consulting costs incurred to supplement our research and development personnel;
- $0.1 million related to allocated facility and office-related expenses; and
- $0.1 million of employee travel-related costs.

General and Administrative Expenses

General and administrative expenses were $4.0 million for the period from February 26, 2014 (inception) to December 31, 2014, and were primarily related to:

- $2.5 million of personnel costs including salaries and other compensation-related costs, such as stock-based compensation;
- $0.4 million of costs related to developing our consumer brand and cornerstone product;
- $0.4 million of professional service fees, including corporate legal costs and accounting fees, as well as intellectual property legal and filing costs;
- $0.3 million of external consulting costs incurred to supplement our general and administrative personnel;
- $0.2 million of travel and entertainment-related costs; and
- $0.2 million of facility and office-related costs.

Liquidity and Capital Resources

Overview

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Since inception, we have incurred an operating loss and we anticipate that we will continue to incur operating losses for at least the next several years. To date, we have not generated any revenues. We expect that our research and development and general and administrative expenses will continue to increase, and we will incur significant sales and marketing expense associated with the launch of our consumer brand and our cornerstone product. As a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. As of December 31, 2014, we had $33.9 million in unrestricted cash. Our funds are held in bank deposit accounts.

Sources of Liquidity

Since our inception, we have financed our operations through private placements of equity securities and our initial public offering, or IPO, which we completed in February 2015.

From March 2014 through May 2014, we issued an aggregate of 15,775,221 shares of series A convertible preferred stock at $1.00 per share and received aggregate proceeds of $15.6 million, net of issuance costs. From July 2014 through October 2014, we issued an aggregate of 14,078,647 shares of series B convertible preferred stock at $1.81 per share and received aggregate proceeds of $25.4 million, net of issuance costs. Our initial public offering resulted in net proceeds to the company of $79.9 million, including net proceeds from the sale of additional shares of our common stock pursuant to to the exercise of an overallotment option granted to the underwriters in connection with the offering. All shares of the previously issued and outstanding series A and series B convertible preferred stock converted into 6,971,108 shares of common stock upon the close of the initial public offering.

As of December 31, 2014, we had no long-term debt.

We currently have no ongoing material financial commitments, such as lines of credit or guarantees that are expected to affect our liquidity over the next five years, other than leases.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical costs, third-party research and development services, legal and other regulatory expenses, marketing, promotion and manufacturing costs related to our consumer brand and products, external consulting costs and general administrative and overhead costs. Our future funding requirements will be heavily reliant upon the resources required to support our drug product candidates as well as our consumer brand and products.

Pre-Clinical Drug Product Candidates

The successful development of any drug product candidate is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of our future drug product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of drug product candidates. This is due to the numerous risks and uncertainties associated with developing drug products, including the uncertainty of:

- successful enrollment in, and completion of, clinical studies and trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others.

A change in the outcome of any of these variables with respect to the development of any of our drug product candidates would significantly change the costs and timing associated with the development of that drug product candidate.

As all of our drug product candidates are in the pre-clinical phase of development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our drug product candidates.

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Consumer Brand and Products

The development and launch of our consumer brand, our cornerstone product and future products is uncertain, including the timing and resources needed to support successful commercialization. Our future success depends, in large part, on our ability to implement a launch and growth strategy that establishes distribution and placement of our products and attracts consumers to our cornerstone product and future product offerings. Our success will rely on our ability, among others, to:

- enter into distribution and other strategic arrangements with third-party retailers and other potential distributors of our products;
- attract customers to our consumer brand and products through marketing and promotion efforts; and
- establish and maintain brand loyalty.

Our future funding requirements will be impacted by our ability to successfully launch and grow our consumer brand and products. Delays or unexpected costs related to the brand and cornerstone product launch and growth plans could significantly change the costs and the timing of such costs associated with our consumer products.

We expect that we will require additional funding to support the growth of our consumer brand and products and to develop and commercialize our drug product candidates. In addition, if we receive regulatory approval for any of our drug product candidates, and if we choose not to grant any licenses to partners, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we chose to commercialize. We also expect to incur additional costs to support our operations as well as the costs associated with operating as a public company. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity or debt financings or collaboration arrangements. Additional funds may not be available on reasonable terms, or at all, and such, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we raise funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate development or future commercialization efforts or grant rights to develop and market our drug product candidates or consumer products that we would otherwise prefer to develop and market ourselves.

To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders.

Outlook

Based on our research and development plans, our consumer brand and product launch plans and our expectations of timing related to the progress of our clinical programs, we expect that our existing cash resources will enable us to fund our operating expenses and capital expenditure requirements through mid-2018. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect. Additionally, the process of testing drug product candidates in clinical trials is costly, as are the resources required to launch a consumer brand and products, and the timing of progress of these efforts is uncertain.

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Cash Flows

	Period from February 26, 2014 (Inception) to December 31, 2014
Net cash (used in) provided by:	
Operating activities	$(6,480,866)
Investing activities	(76,141)
Financing activities	40,411,160
Net increase in cash	$33,854,153

Operating activities

Net cash used in operating activities was $6.5 million during the period from February 26, 2014 (inception) to December 31, 2014. Cash used in operating activities was primarily the result of operating expenses related to our research and development efforts, which included clinical study costs and personnel costs, personnel and other costs needed to support our operations and costs associated with our consumer product development.

Investing Activities

Net cash used in investing activities was approximately $0.1 million during the period from February 26, 2014 (inception) to December 31, 2014. The use of cash from investing activities was for the acquisition of property and equipment.

Financing Activities

Net cash provided by financing activities was $40.4 million during the period from February 26, 2014 (inception) to December 31, 2014. The increase in cash provided by financing activities was the result of $15.6 million in aggregate net proceeds received from the issuance of series A convertible preferred stock from March 2014 through May 2014, and $25.4 million in net proceeds received from the issuance of series B convertible preferred stock from July 2014 through October 2014. These amounts were partially offset by deferred IPO issuance costs of $0.6 million.

Contractual Obligations

The following summarizes our significant contractual obligations as of December 31, 2014.

Contractual Obligations	Total	Less Than 1 Year	1 - 3 Years
Operating lease obligations[1]	$824,173	$332,190	$491,983
Total	$824,173	$332,190	$491,983

(1) Consists of our lease agreement for an approximate 7,200 square foot facility used for administrative and research and development activities in Boston, Massachusetts, as well as a facility in New York, New York to support our consumer brand personnel. The Boston lease commenced on April 29, 2014 and has a 40-month term expiring August 31, 2017, and we established a letter of credit in support of this lease in the amount of $126,595. The New York lease commenced on November 1, 2014 and is scheduled to expire on October 31, 2016, and we have a security deposit in support of this lease in the amount of $39,000.

We have employment agreements with certain members of our management team that require the funding of specific payments, if certain events occur, such as the termination of employment without cause. These potential payment obligations, which in the case of our named executive officers are described in "Executive and Director Compensation — Potential Payments Upon Termination or Change of Control," are not included in the table above. We enter into contracts in the normal course of business with clinical research organizations, or CROs, for clinical studies and clinical supply manufacturing, and with vendors for research studies, research supplies and other

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services and products for operating purposes. These contracts generally provide for termination upon notice and do not include any minimum purchase commitments, and therefore, are cancelable contracts and not included in the table above.

We have entered into a royalty agreement with certain of our founders under which these founders will be paid a royalty of 2%, in the aggregate, of gross sales of any product sold by us or by any of our licensees for use in the treatment of any neuromuscular disorder, and that uses, incorporates or embodies (or is made using) any of our intellectual property (including any know-how). The royalty payments are not included in the table above as they have not met the recognition criteria, and the timing of these payments is not yet determinable as it is dependent upon the achievement of the earlier mentioned revenue recognition.

Net Operating Loss Carryforwards

We have deferred tax assets of $2.9 million and deferred tax liabilities of $0.2 million as of December 31, 2014. The deferred tax assets have been offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of a federal net operating loss, or NOL, tax carryforward. As of December 31, 2014, we have a federal NOL carryforward of $6.9 million available to reduce future taxable income, if any. This federal NOL carryforward is available to offset future taxable income, if any, through 2034. In general, if we experience a greater than 50% aggregate change in ownership of certain significant stockholders over a three-year period, or a Section 382 ownership change, utilization of our pre-change NOL carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended. Such limitations may result in expiration of a portion of the NOL carryforward before utilization and may be substantial. We have not conducted an assessment to determine whether there may have been a Section 382 ownership change. If we experience a Section 382 ownership change in connection with our initial public offering or as a result of future changes in our stock ownership, some of which changes are outside of our control, the tax benefits related to the NOL carryforward may be limited or lost.

Off-Balance Sheet Arrangements

We did not have during the period presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheet and the reported amounts of revenue and expenses during the reporting period. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our financial statements prospectively from the date of the change in estimate.

We define our critical accounting policies as those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our audited consolidated financial statements appearing elsewhere in this prospectus, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Research and Development

Research and development costs are expensed as incurred. Clinical study, clinical trial and other development costs incurred by third-parties are expensed as the contracted work is performed. We accrue for costs incurred as the services are being provided by monitoring the status of the work and the invoices received from our external service providers. We adjust our accruals as actual costs become known.

Stock-Based Compensation

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Stock-based compensation for stock options granted to employees is measured at the date of grant based on the estimated fair value of the award, net of estimated forfeitures. We estimate the grant date fair value and the resulting stock-based compensation expense using the Black-Scholes option pricing model. The grant date fair value of stock-based awards is recognized as an expense over the requisite service period of the award on a straight-line basis. For stock awards to employees, such as the restricted stock sold to one of our founders and Chief Executive Officer, if the fair market value of the stock exceeds the sale price, the excess is expensed as stock-based compensation over the requisite service period.

Stock-based awards issued to non-employees, including stock options and restricted stock, are recorded at their fair values, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service periods on a straight-line basis. The fair value of options granted to non-employees is measured using the Black-Scholes option pricing model reflecting an expected life that is assumed to be the remaining contractual term of the option. The fair value of stock awards is based upon the fair value of the Company's common stock.

We recorded total non-cash stock-based compensation expense to employees and non-employees of $1.5 million for the period from February 26, 2014 (inception) to December 31, 2014. At December 31, 2014, we had $12.6 million total unrecognized compensation cost related to non-vested equity awards. Total unrecognized compensation cost will be adjusted for the re-measurement of non-employee awards as well as future changes in employee and non-employee forfeitures, if any. We expect to recognize the unrecognized compensation over a remaining weighted-average period of 3.27 years. We expect our stock-based compensation expense to grow in future periods due to potential increases in the value of our common stock and increased number of awards granted to employees and non-employees.

The intrinsic value of all outstanding options as of December 31, 2014 was approximately $6.8 million, of which approximately $40,000 related to vested options and the remainder related to unvested options. We expect to continue to grant stock options in the future, and, to the extent that we do, our actual stock-based compensation expense recognized in future periods will increase.

Determining fair value of stock options

Our Black-Scholes option-pricing model requires the input of highly subjective assumptions, including the fair value of the underlying common stock, the expected volatility of the price of our common stock, the expected term of the option, risk-free interest rates and the expected dividend yield of our common stock. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

- Fair value of our common stock — Because our stock was not publicly traded prior to the completion of our initial public offering, we estimated the fair value of our common stock, as discussed below. As a result of the completion of our initial public offering in February 2015, our common stock will now be valued by reference to the publicly-traded price of our common stock.
- Risk-free interest rate — The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options for each option group.
- Expected term — The expected term represents the period that our stock-based awards are expected to be outstanding.
- Expected volatility — As we do not have a significant trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the volatility for industry peers over a period equivalent to the expected term of the stock option grants. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available.
- Expected dividend yield — We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

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The following table presents the weighted-average assumptions used to estimate the fair value of options granted during the period presented:

	Period from February 26, 2014 (Inception) to December 31, 2014
Expected volatility	75.8% to 76.4%
Risk-free interest rate	1.59% to 2.71%
Expected term	6 - 10 years
Expected dividend yield	0%

We will continue to use judgment in evaluating the assumptions utilized for our stock-based compensation expense calculations on a prospective basis.

In addition to the assumptions used in the Black-Scholes option-pricing model, the amount of stock-based compensation expense we recognize in our consolidated financial statements includes an estimate of stock option forfeitures. We are required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from its estimates. We record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised.

Prior to the completion of our initial public offering, our board of directors determined the fair value of our common stock considering, in part, the work of an independent third-party valuation specialist. The board determined the estimated per share fair value of our common stock at various dates considering valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, or Practice Aid. Following the consummation of our or IPO in February 2015, the fair value of our common stock will be determined based on the quoted market price of our common stock. In conducting the valuations, the independent third-party valuation specialist considered all objective and subjective factors that it believed to be relevant for each valuation conducted in accordance with the Practice Aid, including our best estimate of our business condition, prospects and operating performance at each valuation date. Other significant factors included:

- Our operating and financial performance, including our levels of available capital resources;
- Our stage of development;
- Current business conditions and projections;
- Trends and developments in our industry;
- The valuation of publicly traded companies in our sector, as well as recently completed mergers and acquisitions of peer companies;
- The rights, preferences and privileges of our common stock compared to the rights, preferences and privileges of our other outstanding equity securities;
- Equity market conditions affecting comparable public companies, as reflected in comparable companies' market multiples, initial public offering valuations and other metrics;
- U.S. and global economic and capital market conditions;
- The likelihood of achieving a liquidity event for the shares of common stock, such as an initial public offering or an acquisition of our company given prevailing market and sector conditions;
- The illiquidity of our securities by virtue of being a private company;
- Business risks; and
- Management and board experience.

We engaged an independent third-party valuation specialist to perform contemporaneous valuations on or around the dates of our option grants, as well as December 31, 2014 in order to revalue awards to non-employees. The

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valuations we obtained were prepared in accordance with the guidelines in the Practice Aid, which prescribes several valuation approaches for setting the value of an enterprise, such as the cost, market and income approaches, and various methodologies for allocating the value of an enterprise to its common stock. In accordance with the Practice Aid, we considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date.

In September 2014, based on overall capital market conditions and the market for biotechnology initial public offerings, our board of directors directed management to begin preparation and submission of a confidential draft registration statement for an IPO. Based upon this decision, we re-examined the contemporaneous valuations performed and the basis of these valuations to determine if any of the fair value amounts determined at the grant date should be re-assessed for financial reporting purposes. Based upon this review, we engaged the valuation specialist to perform a retrospective valuation as of June 30, 2014. The results of that retrospective valuation as compared to the initial June 30, 2014 contemporaneous valuations are detailed and discussed below.

The following table illustrates our stock option grant information from February 26, 2014 (inception) through December 31, 2014, including the estimated fair value of our common stock on the date of grant. All share numbers, as well as all option exercise prices and estimated fair values of common stock, have been retroactively adjusted to reflect a one-for-4.2825 reverse stock split of our issued and outstanding common stock that occurred in January 2015:

Grant Date	Number of Shares Subject to Options Granted	Option Exercise Price	Estimated Fair Value of Common Stock per Share at Date of Grant
April 9, 2014	193,107	$0.60	$0.60
May 19, 2014	170,459	$0.77	$0.77
July 2, 2014	11,791	$1.67	$3.73
October 15, 2014	449,203	$4.28	$4.28
November 14, 2014	195,674	$5.44	$5.44

For the stock options granted in April 2014 and May 2014, the cost-based approach was used to determine the fair value of the common stock. The use of the cost-based approach was based upon our lack of operating history at those points in time, uncertainty regarding our products and their development and our likelihood of success. Based on these facts, the fair value of equity was deemed equivalent to the investment value of the series A convertible preferred stock issued as of the respective valuation dates. Given the uncertainty of our future and the expected time to liquidity as of the valuation dates, the equity values were then allocated to the various share classes using the Option Pricing Method, or OPM. The OPM is a commonly used methodology for allocating value between multiple classes of securities (e.g., preferred and common stock, options and warrants) especially when the future potential exits are highly uncertain or unclear and/or additional financing will be needed to reach a successful exit.

For the July 2, 2014 stock option grants and in order to revalue non-employee awards, we performed an initial valuation as of June 30, 2014 that determined the fair value of our common stock to be $1.67 per share. In light of subsequent progress toward the potential initial public offering, we engaged the valuation specialist to perform a restrospective valuation as of June 30, 2014 for financial reporting purposes only. The June 30, 2014 retrospective valuation was performed using the market approach, specifically the OPM backsolve. The OPM backsolve estimates a total value of equity that is consistent with a recent arm's length transaction given the rights and preferences of each of the classes of equity and the expected time to a liquidity event. This valuation took into account the expected purchase

price of the series B convertible preferred stock based on the information, specifically the terms and conditions, known as of the June 30, 2014 valuation date. The use of the expected series B convertible preferred stock financing in the OPM backsolve was done in order to take into account the positive clinical studies results received by us in late-May 2014 and early-June 2014. Those results were a significant development in regards to our consumer product as well as the potential for a drug product candidate. Based upon this valuation, the fair value of the common stock was retrospectively determined to be $3.73 per share

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as compared to the initial fair value of $1.67 per share. Stock-based compensation expense for stock options granted on July 2, 2014 was calculated using the the fair value of $3.73 per share.

For all option grant dates subsequent to September 2014, the date at which we began preparation and submission of a confidential draft registration statement for an initial public offering, the valuations of our common stock were based on a hybrid method, or Hybrid Method. The Hybrid Method is a hybrid between Probability-Weighted Expected Return Method, or PWERM and OPM, estimating the probability weighted value across multiple scenarios, but using OPM to estimate the allocation of value within one or more of those scenarios. The Hybrid Method can be a useful alternative to explicitly modeling all PWERM scenarios in situations where the company has transparency into one or more near term exits, in our case an initial public offering, but is unsure about what will occur if the anticipated exit does not occur.

For the October 15, 2014 option grants, and in order to revalue non-employee awards at September 30, 2014, we performed a valuation as of September 30, 2014 assuming an IPO scenario and a sale/merger scenario. For the IPO scenario, we assumed a likely probability of 30% at that point in time due to our short operating history, lack of operating success to date and the volatility of the public markets. The equity value under the IPO scenario was estimated based on discussions with our investment banks as of the September valuation date. We attributed a 70% likelihood to a merger/sale of the Company within two years. Considering the arms-length nature of the series B preferred stock financing round, and its proximity to the September valuation date, the equity value under the merger/sale scenario was estimated such that the weighted-average series B convertible preferred stock price implied by the Hybrid Method would be equal to the issue price of $1.81 per share. Based upon this approach, it was determined that the fair value of our common stock was $4.28 per share at September 30, 2014.

For the November 14, 2014 option grants, we performed a valuation as of that date using the Hybrid Method. The equity value used in the IPO scenario was kept consistent with that used in the September 30, 2014 valuation, as we felt that the prevailing IPO market conditions and the very preliminary feedback from investors did not warrant an increase in the estimated equity value. Based upon our continued progress towards a potential IPO, the Hybrid Method weighted the IPO scenario at 50% and the merger/sale scenario at 50%. The resulting fair value of the our common stock was $5.44 per common share.

In order to revalue non-employee awards at December 31, 2014, we performed a valuation as of December 31, 2014 using the Hybrid Method. Since our November 14, 2014 valuation, the overall biotechnology market had improved and several biotechnology companies had completed successful initial public offerings. Additionally, we held meetings with potential investors in reliance on Section 5(d) of the Act, receiving positive feedback from several potential investors. As a result of these factors, the board of directors increased its expectations regarding the anticipated probability of an IPO and the value of the Company, weighting the IPO scenario at 90% and the merger/sale scenario at 10% and increased the estimated equity value. The resulting fair value of of our common stock was $10.79 per share.

There is inherent uncertainty in these estimates, and if we had made different assumptions than those used, the amount of our stock-based compensation expense, net loss and net loss per share amounts could have been significantly different. Following the closing of the initial public offering in February 2015, the fair value per share of our common stock for purposes of determining stock-based compensation expense will be the closing price of our common stock as reported on the applicable grant date.

Emerging Growth Company Status

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- reduced disclosure about our executive compensation arrangements;
- no non-binding stockholder advisory votes on executive compensation or golden parachute arrangements; and

- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

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We have taken advantage of reduced reporting burdens in this Annual Report on Form 10-K. In particular, in this Annual Report on Form 10-K, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.0 billion in annual revenues as of the end of any fiscal year, if we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC, or if we issue more than $1.0 billion of non-convertible debt over a three-year period.

Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of December 31, 2014, we had cash of $33.9 million. We generally hold our cash in bank deposit, interest-bearing accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. An immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash.

Item 8. Financial Statements and Supplementary Data

Our financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-19 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file under the Securities Exchange Act of 1934, as amended, the Exchange Act, with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including the chief executive officer and the principal financial and accounting officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon, and as of the date of, this evaluation, the chief executive officer and the principal financial and accounting officer concluded that our disclosure controls and procedures were effective. Accordingly, management believes that the consolidated financial statements included in this report fairly present in all material respects our financial condition, results of operations and cash flow for the

period presented.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) or an attestation report of our

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independent registered accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 10. Directors, Executive Officers and Corporate Governance

Executive Officers and Directors

The following table sets forth certain information regarding our executive officers and directors as of the date of this Annual Report:

Name	Age	Position(s)
Executive Officers and Key Employees		
Christoph Westphal, M.D., Ph.D. [3]	47	President, Chief Executive Officer and Chairman of the Board
Jennifer Cermak, Ph.D.	42	Vice President, Research and Development
Robert Hadfield	37	General Counsel and Secretary
Marina Hahn	57	President, Consumer
John McCabe	45	Vice President, Finance and Treasurer
Thomas Wessel, M.D., Ph.D.	59	Chief Medical Officer
Elizabeth Woo	48	Senior Vice President, Investor Relations and Corporate Communications
Non-Employee Directors		
Peter Barton Hutt [1][2][3]	80	Director
Marc Kozin [1]	53	Director
Roderick MacKinnon, M.D.	59	Director
Stuart Randle [1][2]	55	Director
John Sculley [3]	75	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers and Key Employees

Christoph Westphal, M.D., Ph.D., has served as the Chairman of our board of directors since co-founding the Company in February 2014. Dr. Westphal has served as our President and Chief Executive Officer since April 2014. Dr. Westphal has been a partner of Longwood Fund, LP, a venture capital investment fund, since 2010. Dr. Westphal co-founded Verastem, Inc. in August 2010, served as Verastem's Chairman since March 2011, and Executive Chairman since July 2013, and was Verastem's Chief Executive Officer from September 2011 to July 2013 and as its President from September 2011 until January 2013. Dr. Westphal served on the board of OvaScience, Inc. from 2011 to 2014. Dr. Westphal served as the President of SR One, the corporate venture capital arm of GlaxoSmithKline, from

2010 until 2011. Dr. Westphal has previously been involved in founding a number of biotechnology companies. Dr. Westphal co-founded Sirtris Pharmaceuticals, Inc., which was acquired by GlaxoSmithKline plc in 2008, and served as its Chief Executive Officer from 2004 to 2010. He also co-founded

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Alnara Pharmaceuticals, Inc., Concert Pharmaceuticals, Inc., Acceleron Pharma, Inc., serving as its Chief Executive Officer in 2003, Alnylam Pharmaceuticals, Inc., serving as its Chief Executive Officer in 2002, and Momenta Pharmaceuticals, Inc., serving as its Chief Executive Officer in 2001. Dr. Westphal serves on the Board of Fellows of Harvard Medical School and the Board of Overseers for the Boston Symphony Orchestra, is a member of the Research Advisory Council at the Massachusetts General Hospital and is a member of the Biotechnology Industry Organization (BIO) Emerging Companies Section Governing Board. He earned his M.D. from Harvard Medical School, his Ph.D. in Genetics from Harvard University and his B.A. from Columbia University. The board of directors believes that Dr. Westphal's qualifications to sit on the Board include his experience as a senior executive, entrepreneur and venture capitalist and his service on the boards of directors of other life sciences companies.

Jennifer Cermak, Ph.D. served as our Vice President of Program Management from March 2014 until December 2014, when she became our Vice President of Research and Development. Dr. Cermak joined us from Pfizer Inc., where she was the Senior Director, R&D Business Operations, Biotherapeutics from July 2013 to March 2014. From 2008 until 2013, Dr. Cermak served as the Senior Director, Portfolio Management at Sirtris Pharmaceuticals, Inc. and was a member of the executive management team. Dr. Cermak also served as the Director, Portfolio Management at CombinatoRx, Inc. from 2004 until 2008, Associate Director, Clinical Research & Development at Unither, a wholly-owned subsidiary of United Therapeutics, from 2003 to 2004 and a Senior Medical Research Specialist for Research Pharmaceutical Services based at Serono from 2002 to 2003. Dr. Cermak completed her postdoctoral fellowship in the Division of Ophthalmology, Department of Surgery at Harvard Medical School and earned a Ph.D. in Pathology and Laboratory Medicine from Boston University School of Medicine, a M.A., Medical Sciences from Boston University School of Medicine and a B.A. in Biology from Boston University.

Robert Hadfield has served as our General Counsel and Secretary since April 2014. Mr. Hadfield joins us from Cooley LLP, where he was an attorney in the firm's business department from August 2007 to August 2011 and then from April 2012 to April 2014. From August 2011 to April 2012, Mr. Hadfield served as the Corporate Counsel at Kiva Systems, Inc. prior to its acquisition by Amazon.com, Inc. Mr. Hadfield also worked as an attorney at Goulston & Storrs PC and began his career as a financial analyst in the health care investment banking group of SG Cowen Securities Corporation. Mr. Hadfield holds a B.S. degree in Finance from Providence College, and a J.D. from the Georgetown University Law Center.

Marina Hahn has served as our President, Consumer since September 2014. Ms. Hahn joins us from Quirky Inc., where she served as Chief Strategy Officer/Chief Marketing Officer from September 2012 to December 2013. From 2003 to 2012, Ms. Hahn served as Chief Marketing Officer of Spirits Marque One LLC, makers of SVEDKA vodka and a division of Constellation Brands. From 1998 to 2001, Ms. Hahn served as Executive Vice President of J. Walter Thompson Company. Previously, Ms. Hahn was employed in various capacities by the William Morris Agency, Inc., Sony Electronics, Inc., Pepsi-Cola Company and DDB Needham Worldwide, Inc. From May 2000 until November 2014, Ms. Hahn served on the Board of Directors of The Hain Celestial Group, Inc. Ms. Hahn holds a B.A. degree in French Literature and Political Science from Wellesley College.

John McCabe has served as our Vice President, Finance since May 2014. Mr. McCabe joins us from ARIAD Pharmaceuticals, Inc. where he was Vice President and Chief Accounting Officer from May 2013 to May 2014. Previously, Mr. McCabe served as Vice President and Corporate Controller at Charles River Associates from June 2009 to May 2013. Previously, Mr. McCabe was the Director, Strategic Business Unit Controller at Biogen Inc. from 2007 until 2009. Mr. McCabe has also held positions at Performance Technologies, Inc., IP.com Inc. and Arthur Andersen LLP. Mr. McCabe earned an M.B.A. from the University of Massachusetts at Amherst and B.S. degrees in Accounting and Management Information Systems from Babson College.

Thomas Wessel, M.D., Ph.D., has served as our Chief Medical Officer since December 2014. Prior to joining us, Dr. Wessel was an independent consultant to several biotechnology and large pharmaceutical companies, including Concert Pharmaceuticals, Inc., Alkermes plc, Sanofi SA and Novartis AG. Previously, Dr. Wessel was the Chief Medical Officer of Acorda Therapeutics, Inc. from November 2008 until September 2011. Between March 2002 and October 2008, Dr. Wessel was employed in various leadership positions at Sepracor, Inc., including Senior Vice President of Clinical Research. Before joining Sepracor, Dr. Wessel worked on several CNS projects at Janssen Pharmaceuticals in Europe and the U.S. Before working in the pharmaceutical industry, Dr. Wessel held several

academic and research positions. Dr. Wessel received his M.D. from the University of Munich School of Medicine and completed his Ph.D. in experimental neurobiology at the Max-Planck-Institute for Psychiatry in Martinsried, Germany. He completed his residency in neurology at New York Hospital and Memorial Sloan-Kettering Cancer Center (Cornell University Medical Center).

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Elizabeth Woo served as our Vice President, Investors Relations and Corporate Communications from October 2014 until March 2015, when she became Senior Vice President, Investor Relations and Corporate Communications. Ms. Woo previously served an investor relations consultant to Cubist Pharmaceuticals, Inc. from August 2013 to December 2013 and as an investor relations consultant to Ironwood Pharmaceuticals, Inc. from February 2011 to June 2012. Ms. Woo also served as Vice President, Investor Relations at Biogen Idec Inc. from 1998 to 2010. Ms. Woo earned an M.B.A. from The Kellogg Graduate School of Management, and graduated summa cum laude and Phi Beta Kappa with bachelor degrees in Biochemistry and History from the University of California, Berkeley.

Non-Employee Directors

Peter Barton Hutt, L.L.B., L.L.M., has been a member of our board of directors since March 2014. Mr. Hutt is a senior counsel at the law firm of Covington & Burling LLP and has been an attorney with that firm since 1960. He served as Chief Counsel for the U.S. Food and Drug Administration from 1971 through 1975. Mr. Hutt is a member of the Institute of Medicine of the National Academy of Sciences and teaches a course on Food and Drug Law each winter term at Harvard Law School. He co-authored the casebook used to teach Food and Drug Law and has published numerous papers on the subject. Mr. Hutt is a member of the board of directors of DBV Technologies, Q Therapeutics, Xoma Ltd., BIND Therapeutics, Inc., Concert Pharmaceuticals Inc., and several privately-held life sciences companies. During the last five years, Mr. Hutt also served as a member of the board of directors of Celera Genomics, Introgen Therapeutics, Inc., Momenta Pharmaceuticals, Inc. and Ista Pharmaceuticals, Inc. Mr. Hutt received his B.A., magna cum laude, from Yale University, his L.L.B. from Harvard University and his L.L.M. from New York University. Mr. Hutt's qualifications to sit on the board include his 50 years of experience and expertise in food and drug regulation, including his service at the U.S. Food and Drug Administration and at Covington & Burling LLP, and his experience serving on other boards of directors in the biotechnology industry.

Marc Kozin has served as a member of our board of directors since October 2014. Mr. Kozin has been a Senior Advisor to L.E.K. Consulting, a global strategy consulting firm, since July 2011. Prior to that, Mr. Kozin served as president of L.E.K.'s North American practice for 15 years. Mr. Kozin currently serves as a member of the board of directors of UFP Technologies, Inc., DYAX Corp., Endocyte, Inc., OvaScience, Inc. and two privately-held companies. He also serves on the strategic advisory board for Healthcare Royalty Partners. Mr. Kozin holds a B.A., with distinction, in Economics from Duke University and an M.B.A., with distinction, from The Wharton School, University of Pennsylvania. We believe that Mr. Kozin is qualified to serve on our board due to his nearly 30 years of experience in corporate and business unit strategy consulting, merger and acquisition advisory services, and value management both domestically and internationally.

Roderick MacKinnon, M.D. has served as a member of our board of directors since February 2015. Dr. MacKinnon is currently the Co-Chair of our Scientific Advisory Board and the Investigator at Howard Hughes Medical Institute and the John D. Rockefeller Jr. Professor, Laboratory of Molecular Neurobiology and Biophysics at the Rockefeller University. Dr. MacKinnon was a faculty member at Harvard Medical School before moving to Rockefeller in 1996. Dr. MacKinnon is a member of the National Academy of Sciences and is the recipient of numerous scientific awards, including the 2003 Nobel Prize in Chemistry, the 2003 Louisa Gross Horwitz Prize, the 2001 Gairdner Foundation International Award, the 2001 Perl-UNC Neuroscience Prize, the 2000 Lewis S. Rosenstiel Award for Distinguished Work in Basic Medical Science and the 1999 Albert Lasker Basic Medical Research Award. Dr. MacKinnon received his B.A. in biochemistry from Brandeis University and his M.D. from Tufts University School of Medicine. He completed his medical residency at Beth Israel Hospital, Harvard Medical School, and postdoctoral work at Brandeis. We believe that Dr. MacKinnon is qualified to serve on our board due to his deep scientific experience and his scientific leadership of the Company.

Stuart Randle has served as a member of our board of directors since October 2014. Mr. Randle served as the Chief Executive Officer of GI Dynamics Inc. from 2004 through September 2014. Prior to GI Dynamics, Mr. Randle served as the President and Chief Executive Officer of ACT Medical, Inc. from 1998 to 2001. Prior to 1998, Mr. Randle was Corporate Vice President and responsible for the northeastern region of the United States for Allegiance Healthcare Corporation. Mr. Randle previously worked for Baxter Healthcare Corporation in roles including President, New England region, General Manager of anesthesia, and various sales and marketing roles. Mr. Randle has also held various sales and engineering roles with Ingersoll-Rand Corporation. Mr. Randle is a member of the board of directors

of Teleflex, Inc. and Beacon Roofing Supply, Inc. and previously served as a member of the board of directors of GI Dynamics Inc. from 2003 until November 2014. Mr. Randle earned an M.B.A. from The Kellogg Graduate School of Management at Northwestern University and a B.S. degree in Mechanical Engineering from Cornell University. We believe that Mr. Randle is qualified to serve on our board of directors due to his over 20 years' experience in the life sciences industry in engineering, sales, marketing, senior

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management and leadership roles in developing companies and also divisions of major medical corporations, which enables him to provide valuable insights to the board of directors regarding a variety of business, management and technical issues.

John Sculley has served as a member of our board of directors since August 2014. Between 1983 and 1993, Mr. Sculley served as the Chief Executive Officer of Apple Computer, Inc. From 1978 to 1983, Mr. Sculley served as Chief Executive Officer of Pepsi-Cola Company. Since leaving Apple, Mr. Sculley has focused on investing in early stage companies as a venture capitalist and co-founder of several companies. Mr. Sculley currently serves on the board of directors of Pivot Technology Solutions. Mr. Sculley earned a Master of Business Administration degree from the Wharton School at the University of Pennsylvania and is a graduate of Brown University. We believe that Mr. Sculley is qualified to serve on our board of directors due to his experience developing consumer brands and expertise in corporate leadership.

Board Composition

Our business and affairs are organized under the direction of our board of directors, which currently consists of six members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors has determined that all of our directors other than Drs. MacKinnon and Westphal are independent directors, as defined by Rule 5605(a)(2) of the NASDAQ Listing Rules.

Our board of directors is divided into three staggered classes, as follows:

- Class I, which consists of Mr. Kozin and Dr. MacKinnon, whose terms will expire at our annual meeting of stockholders to be held in 2016;
- Class II, which consists of Messrs. Randle and Sculley, whose terms will expire at our annual meeting of stockholders to be held in 2017; and
- Class III, which consists of Mr. Hutt and Dr. Westphal, whose terms will expire at our annual meeting of stockholders to be held in 2018.

At each annual meeting of stockholders, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently six members. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock.

Lead Independent Director

Our board of directors has appointed Mr. Randle to serve as our lead independent director. As lead independent director, Mr. Randle will preside over periodic meetings of our independent directors and perform such additional duties as our board of directors may otherwise determine and delegate.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage

excessive risk-taking.

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Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee.

Audit Committee

Our audit committee consists of Messrs. Kozin, Hutt and Randle. Our board of directors has determined that each of the members of our audit committee satisfies the NASDAQ Stock Market and SEC independence requirements. Mr. Kozin serves as the chair of our audit committee. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;
- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that Mr. Kozin qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the NASDAQ Listing Rules. In making this determination, our board has considered Mr. Kozin's business background and previous experience. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Compensation Committee

Our compensation committee consists of Messrs. Randle and Hutt. Mr. Randle serves as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of

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1934, as amended, or Exchange Act, is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, and satisfies the NASDAQ Stock Market independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and approving the compensation and other terms of employment of our executive officers;
- reviewing and approving performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing the adequacy of its charter on a periodic basis;
- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis the performance of the compensation committee.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Dr. Westphal and Messrs. Hutt and Sculley. Our board of directors has determined that each member of this committee, other than Dr. Westphal, satisfies the NASDAQ Stock Market independence requirements. Dr. Westphal serves as the chair of our nominating and corporate governance committee. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- determining the minimum qualifications for service on our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;

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- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;
- considering questions of possible conflicts of interest of directors as such questions arise;
- reviewing the adequacy of its charter on an annual basis; and
- annually evaluating the performance of the nominating and corporate governance committee.

Procedures for Stockholders to Recommend Director Nominees

The Nominating and Corporate Governance Committee will consider director candidates recommended by stockholders. The Nominating and Corporate Governance Committee does not intend to alter the manner in which it evaluates candidates based on whether or not the candidate was recommended by a stockholder. Stockholders who wish to recommend individuals for consideration by the Nominating and Corporate Governance Committee to become nominees for election to the Board may do so by delivering a written recommendation to the Nominating and Corporate Governance Committee at the following address: 800 Boylston Street, 24th Floor, Boston, Massachusetts 02199, Attn: Secretary, no later than the 90th day and no earlier than the 120th day prior to the one year anniversary of the preceding year's annual meeting. Submissions must include (1) the name and address of the Company stockholder on whose behalf the submission is made; (2) number of Company shares that are owned beneficially by such stockholder as of the date of the submission; (3) the full name of the proposed candidate; (4) description of the proposed candidate is business experience for at least the previous five years; (5) complete biographical information for the proposed candidate; (6) a description of the proposed candidate is qualifications as a director and (7) any other information required by our Bylaws. The Company may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as an independent director of the Company or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such proposed nominee.

Section 16(a) Beneficial Ownership Reporting Compliance

We did not have any class of equity securities registered pursuant to Section 12 of the Exchange Act during our most recent fiscal year. As a result, none of our directors, officers or other affiliated persons were subject to Section 16 of the Exchange Act during such year.

Corporate Governance

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on our website at www.flex-pharma.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website.

Limitation of Liability and Indemnification

We have entered into, and intend to continue to enter into, separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

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PART III

Item 11. Executive Compensation

Our named executive officers for the period ending December 31, 2014, which consist of our principal executive officer and the two other most highly compensated executive officers who were serving as executive officers as of December 31, 2014, are:

- Christoph Westphal, M.D., Ph.D., our President, Chief Executive Officer and Chairman of the Board;
- Marina Hahn, our President, Consumer
- John McCabe, our Vice President of Finance and Treasurer

Summary Compensation Table

The following table provides information regarding the compensation provided during the period beginning on February 26, 2014 (inception) and ending on December 31, 2014 to our named executive officers:

Name and Principal Position	Salary ($)	Bonus ($)[1]	Option Awards ($)[2]	Stock Awards ($)[3]	Non-Equity Incentive Plan Compensation ($)[4]	All Other Compensation ($)	Total ($)
Christoph Westphal, M.D., Ph.D., President, Chief Executive Officer, Chairman of the Board[5]	$337,500	—	—	$375,804	$172,603	—	$885,907
Marina Hahn[6] President, Consumer	$76,154	$100,000	$703,379	—	$34,027	—	$913,560
John McCabeVice President of Finance and Treasurer[7]	$169,871	—	$151,250	—	$50,749	—	$371,870

(1) Amount shown represents a $100,000 signing bonus paid to Ms. Hahn under the terms of her offer letter.

(2) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during the respective fiscal year computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 9 to our financial statements.

(3) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the restricted common stock awards granted during the respective fiscal year. Discussion of restricted common stock is included in Note 8 to our financial statements.

(4) Amounts shown represent annual performance based bonuses for 2014. For more information see "-Annual Performance Based Bonus Opportunity" below.

(5) Dr. Westphal joined us as our President and Chief Executive Officer on April 9, 2014 at an annual salary of $450,000. Amounts shown represent the compensation earned by Dr. Westphal from his April 9, 2014 start date through December 31, 2014.

(6) Ms. Hahn joined us as our President, Consumer on September 30, 2014 at an annual salary of $300,000. Amounts shown represent the compensation earned by Ms. Hahn from her September 30, 2014 start date through December 31, 2014.

(7) Mr. McCabe joined us as our Vice President of Finance on May 12, 2014 at an annual salary of $265,000. Amounts shown represent the compensation earned by Mr. McCabe from his May 12, 2014 start date through December 31, 2014.

Annual Base Salary

Base salaries are intended to provide a fixed level of compensation that is commensurate with their responsibilities and competitive market conditions. When considered in combination with other elements of our executive compensation, we believe our base salaries are sufficient to attract and retain an effective management team.

The annual base salary of Dr. Westphal, our chief executive officer, is set forth in his offer letter and was determined and approved by our board of directors and was effective on April 9, 2014 (the date Dr. Westphal commenced

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employment with us). The 2014 annual base salary of our other executive officers was included in each of their offer letters. The 2014 annual base salary for our named executive officers is as follows:

Name	2014 Base Salary
Christoph Westphal, M.D., Ph.D.	$450,000
Marina Hahn	$300,000
John McCabe	$265,000

In November 2014, following the recommendation of the compensation committee, our board of directors approved a 2% increase to the base salaries of eligible employees, including our named executive officers. This salary increase became effective on January 1, 2015.

Annual Performance-Based Bonus Opportunity

In addition to base salaries, our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve defined annual corporate goals and to reward our executives for individual achievement towards these goals. The annual performance-based bonus that each executive officer is eligible to receive is set out in the individual's offer letter and will be based on the individual's target bonus, as a percentage of base salary, or target bonus percentage, and the extent to which we achieve the corporate goals and the executive achieves his personal goals, if any, established for each year.

Our corporate objectives for 2014 were related to financial stability, completion of certain clinical studies and development of our consumer and clinical products. Our board of directors concluded that each of our 2014 corporate objectives had been achieved and, in December 2014, we paid each of our named executive officers the full amount of their target bonus. The performance based bonus paid to each executive was calculated by multiplying the executive’s annual base salary by the executive’s target bonus percentage. For 2014, each of the executive’s performance based bonuses were prorated for the duration of their employment for 2014. There was no minimum bonus percentage or amount established for the named executive officers and, as a result, the bonus amounts may vary from year to year based on corporate and individual performance.

Each named executive officer's 2014 target bonus percentage and actual bonus amount paid are set forth below:

Name	Target bonus (% of base salary)	2014 Bonus Amount
Christoph Westphal, M.D., Ph.D.	50 %	$172,603
Marina Hahn	45 %	$34,027
John McCabe	30 %	$50,749

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our longer-term interests and the longer-term interests of our shareholders with those of our employees and consultants, including our named executive officers. The board of directors or the compensation committee of the board of directors, or the committee, is responsible for approving equity grants. We have generally granted stock options to our named executive officers and employees as incentive compensation because we believe in using equity compensation to reward our named executive officers and other employees for stock price appreciation; however, we entered into a restricted stock purchase agreement and a restricted stock award agreement with Dr. Westphal in connection with and shortly after our formation. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. We anticipate awarding to our executives an initial equity grant upon commencement of employment. Additional grants

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may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Dr. Westphal was issued 3,278,459 shares of common stock in March 2014 and an additional 624,468 shares of common stock in April 2014. The shares issued to Dr. Westphal in March 2014 were issued in connection with our formation, pursuant to a restricted stock purchase award agreement. The shares issued to Dr. Westphal in April 2014 were issued pursuant to both a restricted stock agreement and the 2014 Equity Incentive Plan, or the 2014 Plan, the terms of which are described below under "— Equity Benefit Plans." The shares issued to Dr. Westphal were issued at $0.0001 per share and vest ratably on a monthly basis over four years from February 26, 2014 subject to his continued service with 25% of the shares vested on the date of grant. In the event Dr. Westphal is terminated for cause or he voluntarily terminates his relationship with the company, we have an option to repurchase his unvested shares for a period of 90 days following such termination, as described below under "— Potential Payments Upon Termination or Change of Control."

Prior to our initial public offering, we granted all stock options pursuant to the 2014 pre IPO plan and all options are granted with a per share exercise price equal to no less than the fair market value of a share of our common stock on the date of grant of each award. Generally our stock option awards vest over a four year period. On October 15, 2014, in connection with the commencement of Ms. Hahn’s employment, the board of directors granted Ms. Hahn an option to purchase 248,855 shares of common stock at an exercise price of $4.28 per share. Ms. Hahn’s options are subject to a four year vesting schedule subject to her continued service and also include an early exercise provision pursuant to which Ms. Hahn may exercise a portion of her options in advance of their vesting. In addition, Ms. Hahn has the right to exercise any vested options for a period of one year following any termination of her employment. If, in connection with a change of control, Ms. Hahn is terminated for cause or she voluntarily terminates her relationship with the company, then an additional 50% of the shares subject to the options will vest. For additional information, see the section below titled “- Potential Payments Upon Termination or Change of Control.” On May 19, 2014, in connection with the commencement of Mr. McCabe’s employment, the board of directors granted an option to purchase 87,565 shares of common stock to Mr. McCabe at an exercise price of $0.77 per share. On November 14, 2014, the board of directors granted an option to purchase 29,188 shares of common stock to Mr. McCabe at an exercise price of $5.44 per share. Each grant made to Mr. McCabe included a four year vesting schedule subject to his continued service.

Agreements with our Executive Officers

Below are written descriptions of our offer letters with our named executive officers.

Christoph Westphal, M.D., Ph.D. We entered into an offer letter with Dr. Westphal in May 2014, who has been our President and Chief Executive Officer since April 2014. The offer letter provides for an annual base salary of $450,000 and that Dr. Westphal is eligible for an annual bonus based on company and individual performance. The target amount of Dr. Westphal's annual performance bonus equals 50% of his annual base salary and will be based on parameters determined by Dr. Westphal and the board of directors or committee. Dr. Westphal's offer letter does not include a term and Dr. Westphal will not be entitled to any cash severance if his employment is terminated by us for any reason but is entitled to certain severance and change of control benefits pursuant to his restricted stock agreements, the terms of which are described below under "— Potential Payments Upon Termination or Change of Control."

John McCabe. We entered into an offer letter with Mr. McCabe in April 2014, who became our Vice President, Finance and Treasurer in May 2014. The offer letter provides for an annual base salary of $265,000 and that Mr. McCabe is eligible for an annual bonus based on company and individual performance equal to 30% of his annual base salary. Pursuant to the agreement, Mr. McCabe was granted an option to purchase 87,565 shares of our common stock, which vests over a four year period, with 25% vesting on May 12, 2015 and ratably each month thereafter. Mr. McCabe is additionally entitled to certain severance benefits, the terms of which are described below under "— Potential Payments Upon Termination or Change of Control."

Marina Hahn. We entered into an offer letter with Ms. Hahn in September 2014, who became our President, Consumer on September 30, 2014. The offer letter provides for an annual base salary of $300,000 and that Ms. Hahn is eligible for an annual bonus based on company and individual performance. The target amount of Ms. Hahn's annual performance bonus equals 45% of her annual base salary and will be based on parameters determined by the

board of directors or committee after consultation with Ms. Hahn. Pursuant to the agreement, Ms. Hahn was granted an option to purchase 248,855 shares of our common stock on October 15, 2014, which vests over a four-year period, with 25% vesting on September 30, 2015 and ratably each month thereafter. Pursuant to Ms. Hahn's offer letter, we paid Ms. Hahn a $100,000 signing bonus. The bonus must be repaid if

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Ms. Hahn does not remain an employee of the company for at least one year. Ms. Hahn is additionally entitled to certain severance benefits and payments upon a change of control, the terms of which are described below under "— Potential Payments Upon Termination or Change of Control."

Restrictive Covenant Agreements. In connection with entering into offer letters with the Company, each of our named executive officers entered into an Employee Non Solicitation, Non Competition, Confidential Information and Inventions Assignment Agreement with us, or the Restrictive Covenant Agreement, each of which became effective upon signing. Under the Restrictive Covenant Agreement, the named executive officer generally is subject to: (1) a perpetual covenant not to disclose or use any of our or third party confidential information (except under limited circumstances); (2) an invention disclosure and assignment provision pursuant to which he or she agrees to assign to us (and will cooperate with us to enforce) all his or her rights, title, and interest in and to any and all inventions (and intellectual property rights with respect thereto) made, conceived, reduced to practice or learned by him or her, either alone or with others, during his or her employment with us; (3) a non competition provision pursuant to which he or she has agreed not to compete with any competing organization during employment and for twelve (12) months thereafter; (4) a non solicitation provision pursuant to which he or she has agreed not to solicit any of our employees, independent contractors or consultants to terminate his, her or its relationship with us during employment and for twelve (12) months thereafter; and (5) a covenant to return all company property to us upon any termination employment or upon our request. In addition, each named executive officer has agreed to indemnify us and certain other parties, for all verdicts, judgments, settlements and other losses incurred by us in the event we are the subject of any legal action resulting from the breach of any of the named executive officer's obligations under the Restrictive Covenant Agreement, as well as any reasonable attorneys' fees and costs if the plaintiff is the prevailing party in any such action.

Potential Payments Upon Termination or Change of Control

Regardless of the manner in which a named executive officer's service terminates, the named executive officer is entitled to receive amounts earned during his or her term of service, including salary and unused vacation pay. Pursuant to his offer letter, Mr. McCabe will be entitled to three months of his then current base salary if he is terminated for any reason, provided that such severance payments will cease at such time as he becomes employed by another company.

Under Dr. Westphal's restricted stock purchase agreements, we may only exercise our repurchase rights with respect to unvested shares of common stock if Dr. Westphal's employment is terminated by us for cause or Dr. Westphal terminates his employment for any reason, in each case, within 90 days of such termination. In addition, Dr. Westphal's shares shall vest with respect to all of the shares held by Dr. Westphal in the event he is terminated by us without cause or due to his death or disability, or upon the occurrence of a corporate transaction. For purposes of Dr. Westphal's restricted stock agreements:

- "cause" generally means (i) Dr. Westphal's willful failure to perform, or gross negligence in the performance of, Dr. Westphal's material duties and responsibilities to us which is not remedied within 30 days of written notice thereof; (ii) material breach by Dr. Westphal of any material provision of the restricted stock agreements or any other agreement with us which is not remedied within 30 days of written notice thereof; (iii) fraud, embezzlement or other dishonesty with respect to us, which, in the case of such other dishonesty, causes or could reasonably be expected to cause material harm to us; or (iv) Dr. Westphal's conviction of a felony.
- "corporate transaction" includes (A) an acquisition, which generally means (i) any consolidation or merger of us with or into any other corporation or other entity or person, or any other corporate reorganization; or (ii) any transaction or series of related transactions to which the we are a party in which in excess of 50% of our voting power is transferred; and (B) any asset transfer, which generally means a sale, lease, exclusive license or other disposition of all or substantially all of our assets.

Under Ms. Hahn's offer letter, if during the period beginning 30 days prior to and ending twelve (12) months following a change of control, we terminate Ms. Hahn's employment other than for cause or Ms. Hahn terminates her employment for good reason, then an additional 50% of the shares of common stock subject to Ms. Hahn's initial stock option shall automatically vest. Additionally, Ms. Hahn will continue to receive her annual base salary for a period of nine months if her employment is terminated at any time by us without cause or she resigns for good reason.

For purposes of Ms. Hahn's offer letter:

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- "cause" generally means (i) Ms. Hahn's willful failure to perform, or gross negligence in the performance of, her material duties and responsibilities which is not remedied within 30 days of written notice thereof; (ii) a material breach by Ms. Hahn of her offer letter, her Restrictive Covenant Agreement or other material, written agreement with us that is not remedied within 30 days of written notice thereof; (iii) Ms. Hahn's fraud, embezzlement or other dishonesty with respect to us, which, in the case of such other dishonesty, causes or could reasonably be expected to cause material harm to us; or (iv) Ms. Hahn's conviction of a felony or of any other crime involving fraud, dishonesty or moral turpitude.
- "good reason" generally means Ms. Hahn's resignation for up to 60 days following her becoming aware of the occurrence of one of the following events which is not cured by us after having provided 30 days of written notice: (i) a material reduction in Ms. Hahn's duties or responsibilities, (ii) a reduction in Ms. Hahn's title, except a change in title as a result of a change of control; (iii) a reduction of at least 10% of Ms. Hahn's gross base salary (unless the reduction was applicable to all of our executives on an equivalent basis) or (iv) a relocation of Ms. Hahn's principal workplace outside of New York, New York.
- "change of control "generally means (i) the acquisition of securities of the company representing a majority or more of the combined voting power of our outstanding securities, other than an acquisition of securities for investment purposes pursuant to a bona fide financing; (ii) our merger or consolidation with any other corporation in which the holders of our voting securities prior to the merger or consolidation cease to own more than 50% of the total voting securities of the surviving corporation; or (iii) the sale or disposition by us of all or substantially all of our assets other than a sale or disposition of assets to an affiliate or a holder of all or a majority of our securities.

Outstanding Equity Awards at December 31, 2014

The following table sets forth certain information regarding outstanding equity awards granted to our named executive officers that remain outstanding as of December 31, 2014.

		Option Awards[1]				Stock Awards		Equity Incentive Plan Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price Per Share[2]	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)	Number of unearned shares that have not vested (#)	Market value of unearned shares that have not vested ($)
Christoph Westphal, M.D., Ph.D.	3/5/2014	—	—	—	—	1,946,585[3]	21,003,652[4]		
	4/9/2014	—	—	—	—			370,781[3]	4,000,727[4]
Marina Hahn	10/15/2014	156,378[5]	92,477[5]	$4.28	10/14/2024				
John McCabe	5/19/2014	—	87,565[6]	$0.77	5/18/2024				
	11/14/2014	—	29,188[7]	$5.44	11/13/2024				

(1) All of the option awards listed in the table above were granted under the 2014 Plan, the terms of which are described below under "— Equity Benefit Plans." Except as otherwise indicated, each option award becomes exercisable as it becomes vested and all vesting is subject to the executive's continuous service with us through the vesting dates.

(2) All of the option awards listed in the table above were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors with the assistance of a third-party valuation expert.

(3)

The shares vest at the rate of 1/4th of the total number of shares on the date of issuance, with 1/48th of the shares vesting monthly over four years measured from February 26, 2014, and subject to vesting acceleration as described above under "— Potential Payments Upon Termination or Change of Control."

(4) Computed based on the fair market value of a share of our common stock as of December 31, 2014, which was $10.79

(5) The option vests at the rate of 1/4th of the total number of shares subject to the option one year after September 30, 2014, with 1/48th of the shares vesting monthly thereafter over the next three years. The option is subject to vesting acceleration as described above under “- Potential Payments Upon Termination or Change of Control.” Notwithstanding the vesting schedule of Ms. Hahn’s option, Ms. Hahn’s Stock Option Grant Notice provides that 156,378 shares were exerciseable as of the date of grant and an additional 23,119 shares are exerciseable on January 1 of each year beginning in 2015 and ending in 2018.

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(6) The option vests at the rate of 1/4th of the total number of shares subject to the option one year after May 12, 2014, with 1/48th of the shares vesting monthly thereafter over the next three years.

(7) The option vests at the rate of 1/4th of the total number of shares subject to the option one year after November 14, 2014, with 1/48th of the shares vesting monthly thereafter over the next three years.

Perquisites, Health, Welfare and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical and dental insurance plans, in each case on the same basis as all of our other employees. We provide a 401(k) plan to our employees, including our named executive officers, as discussed in the section below entitled "— 401(k) Plan."

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation up to certain Code limits, which are updated annually. Beginning in 2015, we began making matching contributions equal to 100% of the first 3% of the eligible compensation that an employee contributes to the 401(k) Plan. Pre-tax contributions by employees and any employer contributions that we make to the 401(k) Plan and the income earned on those contributions are generally not taxable to employees until withdrawn. Employee contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their own contributions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code, with the related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan are deductible by us when made, and contributions and earnings on those amounts are not taxable to the employees until withdrawn or distributed from the 401(k) plan.

Non-qualified Deferred Compensation

None of our named executive officers participate in or have account balances in non-qualified defined contribution plans or other non-qualified deferred compensation plans maintained by us. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other non-qualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Equity Benefit Plans

2015 Equity Incentive Plan

Our board of directors adopted the 2015 Equity Incentive Plan, or 2015 Plan, in January 2015, and our stockholders approved the 2015 plan in January 2015. The 2015 plan became effective as of January 28, 2015, the date of the final prospectus for our initial public offering.

Awards. The 2015 plan provides for the grant of incentive stock options, or ISOs, non statutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance based stock awards, and other forms of equity compensation, collectively stock awards. Additionally, the 2015 plan provides for the grant of performance cash awards. ISOs may be granted only to employees of us and our affiliates. All other awards may be granted to employees, including officers, and to non employee directors and consultants of us and our affiliates.

Share Reserve. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2015 plan is the sum of (i) 889,494 shares, plus (ii) the 65,489 shares that remained available for grant under our 2014 plan at the time our 2015 plan became effective, plus (iii) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to our 2014 plan (such as upon the expiration or termination of a stock award prior to vesting). Additionally, the number of shares of our common stock reserved for issuance under our 2015 plan will automatically increase on January 1 of each year, beginning on January 1, 2016, and continuing through and including January 1, 2025, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under our 2015 plan is 5,919,390 shares.

No person may be granted stock awards covering more than 934,033 shares of our common stock under our 2015 plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is

determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value on the date the stock award is granted. Additionally, no person may be granted in a calendar year a

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performance stock award covering more than 350,262 shares or a performance cash award having a maximum value in excess of $3,000,000. Such limitations are designed to help assure that any deductions to which we would otherwise be entitled with respect to such awards will not be subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to any covered executive officer imposed by Section 162(m) of the Code.

In addition, the maximum number of shares subject to awards granted during a single fiscal year to any non-employee director, taken together with any cash fees paid to such non-employee director during the fiscal year, shall not exceed $350,000 in total value (calculating the value of any such awards based on the grant date fair value of such awards for financial reporting purposes and excluding, for this purpose, the value of any dividend equivalent payments paid pursuant to any award granted in a previous fiscal year).

If a stock award granted under the 2015 plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2015 plan. In addition, the following types of shares under the 2015 plan may become available for the grant of new stock awards under the 2015 plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2015 plan may be previously unissued shares or reacquired shares bought by us on the open market. As of the date hereof, stock awards covering a total of 90,750 shares of our common stock have been issued under the 2015 plan.

Administration. Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2015 plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees who are not officers (other than himself or herself) to be recipients of certain stock awards, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2015 plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2015 plan. Subject to the terms of our 2015 plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. Incentive and non-statutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2015 plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2015 plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2015 plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that the issuance of shares of our common stock upon the exercise of the option or the same of such shares following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

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Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements or restricted stock purchase agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (1) cash, check, bank draft or money order, (2) services rendered to us or our affiliates, or (3) any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Tax Limitations On Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2015 plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2015 plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provides otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2015 plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to a covered executive officer imposed by Section 162(m) of the Code. To help assure that the

compensation attributable to performance-based awards will so qualify, our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.

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The performance goals that may be selected include one or more of the following: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization; (4) earnings before interest, taxes, depreciation, amortization and legal settlements; (5) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (6) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (7) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (8) total stockholder return; (9) return on equity or average stockholder's equity; (10) return on assets, investment or capital employed; (11) stock price; (12) margin (including gross margin); (13) income (before or after taxes); (14) operating income; (15) operating income after taxes; (16) pre-tax profit; (17) operating cash flow; (18) sales or revenue targets; (19) increases in revenue or product revenue; (20) expenses and cost reduction goals; (21) improvement in or attainment of working capital levels; (22) economic value added (or an equivalent metric); (23) market share; (24) cash flow; (25) cash flow per share; (26) share price performance; (27) debt reduction; (28) implementation or completion of projects or processes (including, without limitation, clinical trial initiation, clinical trial enrollment, clinical trial results, new and supplemental indications for existing products, regulatory filing submissions, regulatory filing acceptances, regulatory or advisory committee interactions, regulatory approvals and product supply); (29) user satisfaction; (30) stockholders' equity; (31) capital expenditures; (32) debt levels; (33) operating profit or net operating profit; (34) workforce diversity; (35) growth of net income or operating income; (36) billings; (37) bookings; (38) the number of users, including but not limited to unique users; (39) employee retention; (40) initiation of phases of clinical trials and/or studies by specific dates; (41) patient enrollment rates; (42) budget management; (43) submission to, or approval by, a regulatory body (including, but not limited to the U.S. Food and Drug Administration) of an applicable filing or a drug product candidate; (44) regulatory milestones; (45) progress of internal research or clinical programs; (46) progress of partnered programs; (47) partner satisfaction; (48) timely completion of clinical trials; (49) submission of INDs and NDAs and other regulatory achievements; (50) research progress, including the development of programs; (51) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property, and (52) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by our board of directors.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item; and (13) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the FDA or any other regulatory body. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (a) the class and maximum number of shares reserved for issuance under the 2015 plan, (b) the class and maximum number of shares by which the share reserve may increase automatically each year, (c) the class and maximum number of shares that may be issued upon the exercise of ISOs, (d) the class and maximum number of shares subject to stock awards that can be

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granted in a calendar year (as established under the 2015 plan pursuant to Section 162(m) of the Code) and (e) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or
- make a payment equal to the excess of (a) the value of the property the participant would have received upon exercise of the stock award over (b) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2015 plan, a corporate transaction is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets, (ii) a sale or other disposition of at least 90% of our outstanding voting securities, (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change of Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. Under the 2015 plan, a change of control is generally (i) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (ii) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; (iii) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets; (iv) our complete liquidation or dissolution (or the approval by our stockholders or our board of directors of our complete liquidation or dissolution); or (v) members of the incumbent board cease for any reason to constitute at least a majority of the members of the board.

Amendment and Termination. Our board of directors has the authority to amend, suspend, or terminate our 2015 plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2015 plan.

2014 Equity Incentive Plan

Our board of directors and our stockholders approved our 2014 Equity Incentive Plan, or the 2014 Plan, which became effective in March 2014. Through December 31, 2014, we granted a total of 1,887,548 awards under our 2014 Plan, 79,830 of which have been subsequently forfeited back into the pool of stock awards available for grant. No additional awards will be granted under the 2014 Plan, and all awards granted under the 2014 Plan that are repurchased, forfeited, expire, are cancelled or otherwise not issued will become available for grant under the 2015 plan in accordance with its terms.

Stock Awards. The 2014 Plan provides for the grant of stock awards, which include ISOs, NSOs, restricted stock awards, restricted stock unit awards and stock appreciation rights. ISOs may be granted only to employees of us

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and our affiliates. All other awards may be granted to employees, including officers, and to non-employee directors and consultants of us and our affiliates.

Share Reserve. The aggregate number of shares of our common stock originally reserved for issuance pursuant to stock awards under the 2014 Plan was 116,754 shares. In April 2014, our board of directors approved an increase in the 2014 Plan reserve by 1,334,333 shares and in September 2014 our board of directors approved an increase in the 2014 Plan reserve by 619,113 shares. The maximum number of shares that may be issued pursuant to stock awards under our 2014 Plan was 2,070,200 shares.

If a stock award granted under the 2014 Plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2014 Plan. In addition, the following types of shares under the 2014 Plan may become available for the grant of new stock awards under the 2014 Plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2014 Plan may be previously unissued shares or reacquired shares bought by us on the open market.

Administration. Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2014 Plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate officers and employees to be recipients of certain stock awards; provided, however, that an officer may not grant a stock award to himself, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2014 Plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted, and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted, and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2014 Plan. Subject to the terms of our 2014 Plan, the plan administrator has the authority to reduce the exercise or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2014 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2014 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2014 Plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us or any of our affiliates ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

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Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (1) past or future services rendered to us or our affiliates, or (2) any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Tax Limitations On Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options, or portions thereof, that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the option is not exercisable after the expiration of five years from the date of grant.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (a) the class and maximum number of shares reserved for issuance under the 2014 Plan, (b) the class and maximum number of shares that may be issued upon the exercise of ISOs, and (c) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award to the extent not vested or exercised prior to the effective time of the corporate transaction; or
- make a payment equal to the excess of (1) the value of the property the participant would have received upon exercise of the stock award over (2) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2014 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our consolidated assets, (2) a sale or other disposition of at least 50% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change in control. Under the 2014 Plan, a change in control is generally (1) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (2) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; (3) a complete dissolution or liquidation; or (4) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets.

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Amendment and Termination. The 2014 Plan will terminate on March 21, 2024. However, our board of directors has the authority to amend, suspend, or terminate our 2014 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent.

2015 Employee Stock Purchase Plan

Our board of directors adopted the 2015 Employee Stock Purchase Plan, or the ESPP, in January 2015 and our stockholders approved the ESPP in January 2015. The ESPP became effective as of January 28, 2015, the date of the final prospectus for our initial public offering. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward our success and that of our affiliates.

Share Reserve. The ESPP authorizes the issuance of 175,131 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2016 through January 1, 2025 by the least of (a) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (b) 233,508 shares, or (c) a number determined by our board of directors that is less than (a) and (b). The ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Code. As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Administration. Our board of directors has delegated its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors: (a) customarily employed for more than 20 hours per week, (b) customarily employed for more than five months per calendar year or (c) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large non-recurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (a) the number of shares reserved under the ESPP, (b) the maximum number of shares by which the share reserve may increase automatically each year and (c) the number of shares and purchase price of all outstanding purchase rights.

Corporate Transactions. In the event of certain significant corporate transactions, including: (i) a sale of all our assets, (ii) the sale or disposition of 90% of our outstanding securities, (iii) the consummation of a merger or consolidation where we do not survive the transaction, and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its

parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used

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to purchase shares of our common stock within 10 business days prior to such corporate transaction, and such purchase rights will terminate immediately.

Plan Amendments, Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Director Compensation

Historically, we have not paid cash or equity compensation to directors who are also our employees for service on our board of directors, nor have we paid cash or equity compensation to our non-employee directors who are associated with our principal stockholders for service on our board of directors. We have reimbursed and will continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors.

Beginning in August 2014, we began paying our non-employee directors, other than Stephen Kraus, an annual cash retainer of $40,000 payable quarterly in arrears as well as reimbursement for their reasonable expenses incurred in attending meetings. Upon joining our board of directors, Mr. Hutt was granted an initial option under our 2014 Plan to purchase 28,021 shares, and then in October 2014 was granted an additional option under our 2014 Plan to purchase 7,005 shares. Upon joining our board of directors, Messrs. Kozin, Randle and Sculley were each granted an option under our 2014 Plan to purchase 35,026 shares. Each of Mr. Hutt's options vest over a four-year period measured from April 9, 2014, subject to his continued service to us. Mr. Sculley's options vest over a four-year period measured from August 25, 2014, subject to his continued service to us. Messrs. Kozin and Randle's options vest over a four-year period measured from October 15, 2014, subject to their continued service to us.

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the period beginning on the date of our inception and ending on December 31, 2014 to each of our non-employee directors:

Name[1]	Option Awards[2]	All Other Compensation	Total
Peter Barton Hutt	$30,600	$20,000	$50,600
Stephen Kraus[3]	—	—	—
Marc Kozin	$99,000	$9,022	$108,022
Roderick MacKinnon, M.D.[4]	—	—	—
Stuart Randle	$99,000	$9,022	$108,022
John Sculley	$99,000	$13,913	$112,913

(1) Dr. Westphal was an employee director during 2014 and his compensation is fully reflected in the "— Summary Compensation Table" above. Dr. Westphal did not receive any compensation in 2014 for services provided as a member of our board of directors.

(2) Each of Messrs. Hutt, Kozin, Randle and Sculley have been granted stock options covering 35,026 shares. In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during the respective fiscal year computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 9 to our financial statements.

(3) Mr. Kraus resigned from our board of directors on January 27, 2015.

(4) Dr. MacKinnon joined our board of directors on February 23, 2015.

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Our board of directors adopted a new compensation policy that became effective on January 28, 2015 and that will be applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the following compensation for service on our board of directors:

- an annual cash retainer of $40,000;
- an additional annual cash retainer of $7,500 for service as a member of the audit committee or $15,000 for service as chair of the audit committee;
- an additional annual cash retainer of $5,000 for service as a member of the compensation committee or $10,000 for service as chair of the compensation committee; and
- an additional annual cash retainer of $3,500 for service as a member of the nominating and corporate governance committee or $7,500 for service as chair of the nominating and corporate governance committee.

In the future, our Board will determine the options that will be granted to directors upon first joining the board of directors as well as the automatic annual grants for directors whose terms continue on the date of our annual meeting each year. The options will be granted under our 2015 plan, the terms of which are described in more detail above under “- Equity Benefit Plans - 2015 Equity Incentive Plan.”

Compensation Committee Interlocks and Insider Participation

We have established a compensation committee which has and will make decisions relating to compensation of our executive officers. Our board of directors has appointed Messrs. Randle and Hutt to serve on the compensation committee. Neither of these individuals has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

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Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information regarding beneficial ownership of our common stock as of March 13, 2015 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our executive officers; and
- all of our current executive officers and directors as a group.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before May 12, 2015, which is 60 days after March 13, 2015. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Percentage of beneficial ownership is based on 17,933,664 shares of common stock outstanding as of March 13, 2015. Except as otherwise noted below, the address for each person or entity listed in the table is c/o Flex Pharma, Inc., 800 Boylston Street, 24th Floor, Boston, MA 02199.

Name of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned	
5% or greater stockholders			
Longwood Fund II, L.P.(1)	2,697,264	15.04	%
Entities affiliated with Bessemer Venture Partners(2)	1,218,216	6.79	%
Directors and executive officers			
Peter Barton Hutt(3)	21,161	*	
Marc Kozin	—	—	
Roderick MacKinnon, M.D.(4)	423,612	2.36	%
Stuart Randle	—	—	
John Sculley(5)	55,570	*	
Christoph Westphal, M.D., Ph.D.(6)	3,902,927	21.76	%
John McCabe(7)	21,891	*	
Maria Hahn(8)	179,497	*	
All directors and executive officers as a group (total of 11 persons)(9)	7,459,444	40.75	%

* Represents beneficial ownership of less than one percent.

(1) Represents shares of common stock held by Longwood Fund II, L.P. Longwood Fund II GP, LLC (the "General Partner") is the general partner of Longwood Fund II, L.P. and exercises voting and investment power with respect to securities owned directly by Longwood Fund II, L.P. Richard Aldrich, Michelle Dipp, M.D., Ph.D. and Christoph Westphal, M.D., Ph.D. are the managers of the General Partner and share voting and dispositive power with respect to the securities held by Longwood Fund II, L.P, each of whom disclaims beneficial ownership of the shares held by Longwood Fund II, L.P. except to the extent of his or her pecuniary interest therein. The address for Longwood Fund II, L.P. is 800 Boylston Street, Suite 1555, Boston, MA 02199.

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(2) Includes (a) 553,070 shares of common stock held by Bessemer Venture Partners VIII L.P. and (b) 665,146 shares of common stock held by Bessemer Venture Partners VIII Institutional L.P. (together with Bessemer Venture Partners VIII L.P., the "Bessemer Venture Partner Entities"). Each of Deer VIII & Co. L.P. ("Deer VIII L.P."), the general partner of the Bessemer Venture Partner Entities, and Deer VIII & Co. Ltd. ("Deer VIII Ltd."), the general partner of Deer VIII L.P., may be deemed to have voting and dispositive power over the shares held by the Bessemer Venture Partner Entities. J. Edmund Colloton, David J. Cowan, Byron B. Deeter, Robert P. Goodman, Jeremy S. Levine and Robert M. Stavis are the directors of Deer VIII Ltd. Investment and voting decisions with respect to the shares held by the Bessemer Venture Partners Entities are made by the directors of Deer VIII Ltd. acting as an investment committee. No stockholder, partner, director, officer, manager, member or employee of Deer VIII L.P. or Deer VIII Ltd. has beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of any shares held by the Bessemer Venture Partners Entities. The address for each of these entities is c/o Bessemer Venture Partners, 1865 Palmer Avenue, Suite 104, Larchmont, New York 10538.

(3) Includes 11,675 shares of common stock and 9,486 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 13, 2015.

(4) Includes 421,277 shares of common stock and 2,335 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 13, 2015.

(5) Includes (a) 54,402 shares of common stock held by John and Diane Sculley, Tenants in the Entirety and (b) 1,168 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 13, 2015.

(6) Includes 3,902,927 shares of common stock held by Christoph Westphal, M.D., Ph.D. This number does not include 2,697,264 shares of common stock held by Longwood Fund II, L.P. The ultimate general partner of Longwood Fund II, L.P. is Longwood Fund II GP, LLC. Voting and investment power with respect to the shares held by Longwood Fund, LP are vested in Richard Aldrich, Michelle Dipp, M.D., Ph.D. and Christoph Westphal, M.D., Ph.D., the managers of Longwood Fund II GP, LLC, each of whom disclaims beneficial ownership of the shares held by Longwood Fund L.P. except to the extent of any pecuniary interest therein.

(7) Represents shares of common stock issuable upon the exercise of options exercisable within 60 days of March 13, 2015.

(8) Represents shares of common stock issuable upon the exercise of options exercisable within 60 days of March 13, 2015.

(9) Includes (a) 4,390,281 shares held by all current executive officers and directors as a group, (b) 371,899 shares that all current executive officers and directors as a group have the right to acquire from us within 60 days of March 13, 2015 pursuant to the exercise of stock options, and (c) shares of common stock held by Longwood Fund II, L.P., which are deemed to be beneficially owned by Dr. Westphal.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2014, with respect to shares of our common stock that may be issued under our existing equity compensation plans:

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options,warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))

Equity compensation plans approved by stockholders[1]:			
2014 Equity Incentive Plan[2]	926,832[3]	3.40	262,482
2015 Equity Incentive Plan[4]	---	---	---
2015 Employee Stock Purchase Plan[5]	---	---	---
Equity compensation plans not approved by stockholders:			
None			

1. For a description of our equity compensation plans, see Item 11. Executive Compensation.

2. Effective as of January 28, 2015, no additional awards will be granted under the 2014 Plan, and all awards granted under the 2014 Plan that are repurchased, forfeited, expire, are cancelled or otherwise not issued will become available for grant under the 2015 plan in accordance with its terms.

3. All shares issuable upon exercise of options.

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4. The 2015 plan became effective on January 28, 2015. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2015 plan is the sum of (i) 889,494 shares, plus (ii) the 65,489 shares that remained available for grant under our 2014 plan at the time our 2015 plan became effective, plus (iii) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to our 2014 Plan (such as upon the expiration or termination of a stock award prior to vesting). Additionally, the number of shares of our common stock reserved for issuance under our 2015 plan will automatically increase on January 1 of each year, beginning on January 1, 2016, and continuing through and including January 1, 2025, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under our 2015 plan is 5,919,390 shares.

5. The ESPP became effective on January 28, 2015. The ESPP authorizes the issuance of 175,131 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2016 through January 1, 2025 by the least of (a) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (b) 233,508 shares, or (c) a number determined by our board of directors that is less than (a) and (b).

Item 13. Certain Relationships and Related Transactions, and Director Independence

The following includes a summary of transactions since February 26, 2014, the date of our inception, to which we have been a party, in which the amount involved in the transaction exceeded $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Item 11. Executive Compensation."

Initial Public Offering

In February 2015, we completed our initial public offering pursuant to which we issued and sold an aggregate of 5,491,191 shares of our common stock at a price to the public of $16.00 per share. The following table sets forth the number of shares of common stock purchased in our initial public offering by Longwood Fund II, L.P., a holder of more than 5% of our common stock:

Name	Shares of Common Stock	Purchase Price
Longwood Fund II, L.P.[(1)]	312,500	$5,000,000

(1) Additional detail regarding Longwood Fund II, L.P. and its equity holdings is provided under "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters." Christoph Westphal, M.D., Ph.D., our Chief Executive Officer and Chairman, is a manager of Longwood Fund II GP, LLC, which is the general partner of Longwood Fund II, L.P.

Indemnification of Officers and Directors

We have entered into, and intend to continue to enter into, separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed

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to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Convertible Preferred Stock Financings

Series A Preferred Stock Financing

In March 2014, we entered into a Series A Preferred Stock Purchase Agreement, or the March Purchase Agreement, pursuant to which we issued and sold to investors an aggregate of 10,000,000 shares of our Series A convertible preferred stock at a purchase price of $1.00 per share, for aggregate consideration of $10.0 million. In April and May 2014, at additional closings pursuant to the March Purchase Agreement, we issued and sold to investors an aggregate of 5,775,221 additional shares of our series A convertible preferred stock at a purchase price of $1.00 per share, for aggregate consideration of $5.8 million.

Series B Preferred Stock Financing

In July 2014, we entered into a Series B Preferred Stock Purchase Agreement, or the July Purchase Agreement, pursuant to which we issued and sold to investors an aggregate of 8,892,506 shares of our series B convertible preferred stock at a purchase price of $1.81 per share, for aggregate consideration of $16.1 million. In August, September and October 2014, at additional closings pursuant to the July Purchase Agreement, we issued and sold to investors an aggregate of 5,186,141 additional shares of our series B convertible preferred stock at a purchase price of $1.81 per share, for aggregate consideration of $9.4 million.

All outstanding convertible preferred stock converted into common stock upon the closing of our initial public offering in February 2015.

The participants in the convertible preferred stock financings described above included the following directors, executive officers or holders of more than 5% of our capital stock or entities affiliated with them. The following table presents the number of shares issued to these related parties in these financings:

Participants[1]	Shares of Series A Preferred Stock	Series A Preferred Stock Purchase Price	Shares of Series B Preferred Stock	Series B Preferred Stock Purchase Price
5% or greater stockholders				
Longwood Fund II, L.P.[2]	8,000,000	$8,000,000	2,212,756	$3,999,999
Entities affiliated with Bessemer Venture Partners[3]	4,000,000	$4,000,000	1,217,015	$2,199,998
Directors				
Peter Barton Hutt	50,000	$50,000	—	—
Sculley Gibbs I, LLC[4]	300,000	$300,000	82,978	$149,999

(1) Additional details regarding these stockholders and their equity holdings is provided in "Principal Stockholders."

(2) Christoph Westphal, M.D., Ph.D., our President, Chief Executive Officer and Chairman of the Board, is a Manager of Longwood Fund II, GP, LLC which is the general partner of Longwood Fund II, L.P.

(3) Represents shares held, in the aggregate, by Bessemer Venture Partners VIII Institutional L.P. and Bessemer Venture Partners VIII L.P.

(4) John Sculley, a member of our board of directors, is a member of Sculley Gibbs I, LLC.

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Agreements with Our Stockholders

In connection with our convertible preferred stock financings, we entered into amended and restated investor rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of our convertible preferred stock and certain holders of our common stock, including our principal stockholders and their affiliates. All of the provisions of these agreements terminate upon the closing of our initial public offering, except for the registration rights granted under our amended and restated investor rights agreement in July 2014 between us and the investors listed therein, or the Investor Rights Agreement, as more fully described below in "Description of Capital Stock — Registration Rights."

Employment Arrangements

We have entered into employment arrangements with our executive officers, as more fully described in "Executive and Director Compensation — Agreements with our Executive Officers," and "— Potential Payments Upon Termination or Change of Control."

Stock and Stock Options Granted to Executive Officers and Directors

We have issued stock and granted stock options to our executive officers and directors, as more fully described in "Executive and Director Compensation."

Founders Agreement

On February 25, 2014, Bruce Bean, Roderick MacKinnon and Donald MacKinnon, or the Scientific Founders, and Christoph Westphal entered into a founders agreement, which was adopted by us on February 27, 2014. The founders agreement was amended on March 21, 2014 to terminate all of the parties' rights and obligations, other than the founders' anti-dilution protection and certain miscellaneous provisions. The founders agreement was terminated in its entirety on April 10, 2014. Under the founders agreement, we agreed to issue the Scientific Founders an aggregate of 910,683 shares of our common stock. The founders agreement also provided anti-dilution protection to the Scientific Founders and Business Founders, as defined therein, such that the aggregate number of shares held by the Scientific Founders and Business Founders was to remain equal to 13% of our fully diluted capitalization until the consummation of a Qualified Financing, as defined therein. Pursuant to the terms of the founders agreement, if a dilutive event occurred prior to the Qualified Financing, including the Qualified Financing or an increase in the size of our employee incentive pool, the Scientific Founders and Business Founders would be issued the number of additional shares necessary to maintain their aggregate ownership of 13% of our fully diluted capitalization. The additional shares issued to the Scientific Founders and Business Founders would be allocated to the individuals pro rata based on their previous ownership. In addition, the founders agreement required the Scientific Founders to transfer to us the existing intellectual property relating to our business, outlined the terms of the advisory services to be provided by the Scientific Founders, described the vesting terms for the shares to be issued to the founders and granted the founders a royalty relating to any future sales of our products. The parties' obligations under each of these provisions were subsequently implemented pursuant to a patent assignment agreement, technology assignment agreement, restricted stock purchase agreements and a royalty agreement among the parties. Christoph Westphal was issued shares of our common stock as described above in "Executive and Director Compensation — Equity-Based Incentive Awards."

Royalty Agreement

In connection with the transfer of certain intellectual property to us by the Scientific Founders and by Christoph Westphal, or collectively the Founders, on March 20, 2014, we entered into a royalty agreement with the founders. Pursuant to the royalty agreement we are obligated to pay the Founders a royalty of 2%, in the aggregate of gross sales of any product sold by us or by any of our licensees for use in the treatment of any neuromuscular disorder, and that uses, incorporates or embodies, or is made using any of our intellectual property, including any know-how. The royalty agreement grants the Founders certain audit rights and requires any license or sublicense granted by us be consistent with the terms and conditions of the royalty agreement. Each Founder may assign his rights and obligations under the royalty agreement to a third-party upon prior written notice to us. We may not assign our rights and obligations thereunder except in the event of a change in control relating to our company. The term of the royalty agreement is perpetual.

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Technology Assignment Agreement

On March 20, 2014, we entered into a Technology Assignment Agreement with the Scientific Founders and Catalyst Research, LLC which was formed primarily for the purpose of paying costs associated with the preparation and prosecution of patent applications. Pursuant to the agreement, the Scientific Founders and Catalyst Research, LLC assigned to us all of the technology, and intellectual property rights related to the technology, described in the patent applications set forth on Exhibit A to the agreement. The Technology Assignment Agreement was entered into in partial consideration for the parties entering into the royalty agreement with the founders.

Patent Assignment Agreement

On March 20, 2014, we entered into a Patent Assignment Agreement with the Scientific Founders, pursuant to which the Scientific Founders irrevocably assigned to us certain pending patent applications.

License Agreement

On May 1, 2014, we entered into a license agreement with ECLDS, LLC for the license of a portion of our office space that we sublease at 800 Boylston Street, 24th Floor, Boston, Massachusetts. ECLDS, LLC is owned by Christoph Westphal, M.D., Ph.D., our President, Chief Executive Officer and Chairman. The license agreement provided that ECLDS, LLC will license 2,647 square feet of office space from us for $7,721 per month. Under the license agreement, ECLDS, LLC pays us the same price per square foot that we pay our sublessor for the space. The initial term of the license is from May 1, 2014 to August 30, 2017 and may be terminated by either party with 90 days written notice. In September 2014, we amended the license agreement to reduce the amount of space ECLDS, LLC licenses from us to 2,362 square feet and reduced the amount ECLDS, LLC pays to us to $6,890 per month. In January 2015, we further amended the license agreement to reduce the amount of space ECLDS, LLC licenses from us to 1,837 square feet and reduced the amount ECLDS pays to us to $5,687 per month.

Strategic Advisory Board Agreement

Dr. MacKinnon is a Co-chair of our Scientific Advisory Board, and on March 7, 2014, we entered into a letter agreement with Dr. MacKinnon in connection with his service on the Scientific Advisory Board. Under the letter agreement, Dr. MacKinnon is entitled to receive a $60,000 annual retainer, payable quarterly, which amount has been increased to $90,000. The letter agreement also provides that Dr. MacKinnon will receive the same number of stock options granted to other members of the Scientific Advisory Board. To date, the Company has granted Dr. MacKinnon an aggregate of 56,041 stock options, which vest over a four-year period from the dates of grant.

Restricted Stock Purchase Agreements

In connection with our formation, on March 7, 2014 and April 9, 2014, Dr. MacKinnon and the Company entered into a restricted stock purchase agreement and a restricted stock award agreement, respectively, pursuant to which the Company issued Dr. MacKinnon an aggregate of 416,978 shares of our common stock in accordance with the Founders Agreement. The shares of Common Stock issued to Dr. MacKinnon are subject to a repurchase option in favor of us, which vests over a four-year period tied to Dr. MacKinnon's continuous service with us, subject to certain acceleration provisions.

Policies and Procedures for Transactions with Related Persons

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-person transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds $120,000.

Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director or a holder of more than 5% of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

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Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or other independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third-parties or to or from our employees generally.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

Independence of the Board of Directors

As required under the Nasdaq Listing Rules, a majority of the members of a listed company's board of directors must qualify as "independent" as affirmatively determined by its board of directors. Our board of directors consults with the Company's counsel to ensure that the the board of directors' determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, our board of directors has affirmatively determined that, with the exception of Drs. MacKinnon and Westphal, all of our directors are independent directors within the meaning of the applicable Nasdaq Listing Rules. In making this determination, the board of directors found that none of these directors had a material or other disqualifying relationship with the Company.

Item 14. Principal Accountant Fees and Services

Auditors' Fees

The following table summarizes the fees of Ernst & Young LLP, our registered public accounting firm, billed to us since our inception on February 26, 2014.

Audit Fees[(1)]	$733,110
Total Fees	$733,110

(1) Audit fees consist of fees for the audit of our consolidated financial statements and services associated with our registration statement on Form S-1, and the audit of our consolidated financial statements as of December 31, 2014 and the period from February 26, 2014 (Inception) to December 31, 2014.

All such accountant services and fees were pre-approved by our audit committee in accordance with the "Pre-Approval Policies and Procedures" described below.

Pre-Approval Policies and Procedures

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Our Audit Committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our registered public accounting firm. This policy generally provides that we will not engage our registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our Audit Committee or the engagement is entered into pursuant to one of the pre-approval procedures described below.

From time to time, our Audit Committee may pre-approve specified types of services that are expected to be provided to us by our registered public accounting firm during the next 12 months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

PART IV

Item 15. Exhibits and Consolidated Financial Statement Schedules

Consolidated Financial Statements

The following consolidated financial statements are filed as a part of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheet as of December 31, 2014

Consolidated Statement of Operations and Comprehensive Loss for the period from February 26, 2014 (inception) to December 31, 2014

Consolidated Statement of Convertible Preferred Stock and Stockholders' Deficit for the period from February 26, 2014 (inception) to December 31, 2014

Consolidated Statement of Cash Flows for the period from February 26, 2014 (inception) to December 31, 2014

Notes to Consolidated Financial Statements

Consolidated Financial Statement Schedules

All consolidated financial statement schedules are omitted because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

Exhibits

For a list of exhibits filed with this Annual Report on Form 10-K, refer to the exhibit index.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

FLEX PHARMA, INC.

By: /s/ Christoph Westphal,
Christoph Westphal, M.D., Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

Know All Persons By These Presents, that each person whose signature appears below constitutes and appoints Christoph Westphal, M.D., Ph.D. and John McCabe, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Christoph Westphal, Christoph Westphal, M.D., Ph.D.	President, Chief Executive Officer, Chairman of the Board of Directors (Principal Executive Officer)	March 24, 2015
/s/ John McCabe John McCabe	Vice President, Finance (Principal Financial and Accounting Officer)	March 24, 2015
/s/ Peter Barton Hutt Peter Barton Hutt	Member of the Board of Directors	March 24, 2015
/s/ Marc Kozin Marc Kozin	Member of the Board of Directors	March 24, 2015
/s/ Roderick MacKinnon Roderick MacKinnon, M.D.	Member of the Board of Directors	March 24, 2015
/s/ Stuart Randle Stuart Randle	Member of the Board of Directors	March 24, 2015
/s/ John Sculley John Sculley	Member of the Board of Directors	March 24, 2015

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EXHIBIT INDEX

Exhibit number		Description of Document
3.1	(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2	(1)	Amended and Restated Bylaws of the Registrant.
4.1	(2)	Form of Common Stock Certificate of the Registrant.
4.2	(2)	Amended and Restated Investors' Rights Agreement, dated July 23, 2014, by and among the Registrant and certain of its stockholders.
10.1	+(2)	Form of Indemnity Agreement by and between the Registrant and its directors and officers.
10.2	+(2)	Flex Pharma, Inc. 2014 Equity Incentive Plan, as amended, and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder.
10.3	+(2)	Flex Pharma, Inc. 2015 Equity Incentive Plan.
10.4	+	Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice under the Flex Pharma, Inc. 2015 Equity Incentive Plan.
10.5	+(2)	Flex Pharma, Inc. 2015 Employee Stock Purchase Plan.
10.6	+(2)	Flex Pharma, Inc. Non-Employee Director Compensation Policy.
10.7	+(2)	Offer Letter by and between the Registrant and Christoph Westphal, M.D., Ph.D.
10.8	+(2)	Offer Letter by and between the Registrant and John McCabe.
10.9	+(2)	Offer Letter by and between the Registrant and Marina Hahn.
10.10	(2)	Royalty Agreement, dated March 20, 2014, by and between the Registrant, Bruce Bean, Donald MacKinnon, Roderick MacKinnon and Christoph Westphal.
10.11	(2)	Founders Agreement, dated February 25, 2014, by and among Bruce Bean, Donald MacKinnon, Roderick MacKinnon and Christoph Westphal, as adopted by the Company on February 27, 2014, as amended.
10.12	(2)	Technology Assignment Agreement, dated March 20, 2014, by and between the Registrant, Catalyst Research, LLC, Bruce Bean, Donald MacKinnon and Roderick MacKinnon.
10.13	(2)	Patent Assignment Agreement, dated March 20, 2014, by and between the Registrant, Bruce Bean, Donald MacKinnon and Roderick MacKinnon.
10.14	(2)	Sublease, dated April 29, 2014, between the Registrant and Fireman Capital Partners, LLC.
10.15	(2)	License Agreement, dated May 1, 2014, by and between the Registrant and ECLDS, LLC, as amended.

23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney is made to the signature page hereto.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.

+ Indicates management contract or compensatory plan.
(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on February 9, 2015.
(2) Incorporated by reference to the Registrant's Registration Statement of Form S-1 (File No. 333-201276), as amended.

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Flex Pharma, Inc.
Index to Consolidated Financial Statements
As of December 31, 2014 and for the period from February 26, 2014 (Inception) to December 31, 2014

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Report of Independent Registered Public Accounting Firm
The Board of Directors and Stockholders of
Flex Pharma, Inc.

We have audited the accompanying consolidated balance sheet of Flex Pharma, Inc. (the "Company") as of December 31, 2014, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for the period from February 26, 2014 (Inception) to December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit 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, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Flex Pharma, Inc. at December 31, 2014, and the consolidated results of its operations and its cash flows for the period from February 26, 2014 (Inception) to December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 24, 2015

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FLEX PHARMA, INC.
CONSOLIDATED BALANCE SHEET

	December 31, 2014
Assets	
Current assets:	
Cash	$33,854,153
Prepaid expenses and other current assets	370,396
Total current assets	34,224,549
Property and equipment, net	85,144
Deferred IPO issuance costs	1,074,794
Deferred tax assets	50,103
Other assets	50,000
Restricted cash	126,808
Total assets	$35,611,398
Liabilities, convertible preferred stock and stockholders' deficit	
Current liabilities:	
Accounts payable	$578,653
Accrued expenses and other current liabilities	416,524
Deferred tax liabilities	50,103
Deferred rent, current portion	21,881
Total current liabilities	1,067,161
Deferred rent, net of current portion	35,968
Other long term liabilities	15,442
Total liabilities	1,118,571
Commitments and contingencies (Note 6)	
Convertible preferred stock:	
Series A convertible preferred stock, $0.0001 par value; 16,000,000 shares authorized and 15,775,221 shares issued and outstanding at December 31, 2014 (aggregate liquidation preference of $15,775,221 at December 31, 2014)	15,637,032
Series B convertible preferred stock, $0.0001 par value; 14,500,000 shares authorized and 14,078,647 shares issued and outstanding at December 31, 2014 (aggregate liquidation preference of $25,449,970 at December 31, 2014)	25,394,135
Stockholders' deficit:	
Common stock, $0.0001 par value; 61,000,000 shares authorized, 5,434,301 shares issued and 2,215,711 shares outstanding at December 31, 2014	221
Additional paid-in capital	1,472,299
Accumulated deficit	(8,010,860)
Total stockholders' deficit	(6,538,340)
Total liabilities, convertible preferred stock and stockholders' deficit	$35,611,398

See accompanying notes to consolidated financial statements.

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FLEX PHARMA, INC.
CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS

	Period from February 26, 2014 (Inception) to December 31, 2014
Operating expenses:	
Research and development	$4,003,911
General and administrative	4,025,895
Total operating expenses	8,029,806
Loss from operations	(8,029,806)
Interest income	18,946
Net loss	$(8,010,860)
Comprehensive loss	$(8,010,860)
Net loss attributable to common stockholders	$(8,010,860)
Net loss per share attributable to common stockholders — basic and diluted	$(4.57)
Weighted-average number of common shares outstanding — basic and diluted	1,753,024

See accompanying notes to consolidated financial statements.

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FLEX PHARMA, INC.
CONSOLIDATED STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at February 26, 2014 (Inception)	—	$—	—	$—	—	$—	$—	$—	$—
Issuance of Series A convertible preferred stock, net of issuance costs of $138,189	15,775,221	15,637,032	—	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $55,835	—	—	14,078,647	25,394,135	—	—	—	—	—
Sale of restricted common stock to founders	—	—	—	—	—	—	2,321	—	2,321
Vesting of restricted common stock	—	—	—	—	2,202,139	220	(220)	—	—
Issuance of common stock from option exercises	—	—	—	—	13,572	1	8,137	—	8,138
Stock-based compensation expense	—	—	—	—	—	—	1,462,061	—	1,462,061
Net loss	—	—	—	—	—	—	—	(8,010,860)	(8,010,860)
Balance at December 31, 2014	15,775,221	$15,637,032	14,078,647	$25,394,135	2,215,711	$221	$1,472,299	$(8,010,860)	$(6,538,340)

See accompanying notes to consolidated financial statements

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FLEX PHARMA, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS

	Period from February 26, 2014 (Inception) to December 31, 2014
Operating activities	
Net loss	$(8,010,860)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization	11,997
Stock-based compensation	1,462,061
Other non-cash items	55,221
Changes in operating assets and liabilities:	
Restricted cash	(126,808)
Prepaid expenses and other current assets	(370,396)
Other assets	(50,000)
Accounts payable	254,253
Accrued expenses	220,375
Deferred rent	57,849
Other long term liabilities	15,442
Net cash used in operating activities	(6,480,866)
Investing activities	
Purchases of property and equipment	(76,141)
Net cash used in investing activities	(76,141)
Financing activities	
Proceeds from issuance of Series A convertible preferred stock, net of issuance costs	15,581,811
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	25,394,135
Proceeds from sale of restricted common stock to founders	2,321
Proceeds from exercise of common stock	8,138
Deferred IPO issuance costs	(575,245)
Net cash provided by financing activities	40,411,160
Net increase in cash	33,854,153
Cash at beginning of period	—
Cash at end of period	$33,854,153
Supplemental cash flow information	
Issuance of Series A convertible preferred stock in satisfaction of accounts payable	$55,221
Deferred IPO issuance costs in accounts payable and accrued expenses	$499,549
Property and equipment purchases in accrued expenses	$21,000

See accompanying notes to consolidated financial statements.

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FLEX PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and operations

The Company

Flex Pharma, Inc. (the "Company") is a biotechnology company that was incorporated in Delaware on February 26, 2014 and has a principal place of business in Boston, Massachusetts. The Company is developing innovative and proprietary treatments for nocturnal leg cramps and and spasms associated with severe neuromuscular conditions. The Company believes that activation of certain receptors in primary sensory neurons reduces the repetitive firing, or hyperexcitability, of alpha-motor neurons, thereby preventing or reducing the frequency and intensity of muscle cramps and spasms. The Company also believes that it is the only company developing products based on this mechanism of muscle cramp and spasm inhibition.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, risks of failure of pre-clinical studies, clinical studies and clinical trials, the need to obtain marketing approval for its drug product candidates, the need to successfully commercialize and gain market acceptance of its drug product candidates and its consumer products, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations and ability to transition from pilot-scale manufacturing to large-scale production of products.

Liquidity

The Company has incurred an accumulated deficit of $8,010,860 since February 26, 2014 (inception) through December 31, 2014, and will require substantial additional capital to fund its research and development and the launch of its consumer brand. The Company had an unrestricted cash balance of $33,854,153 at December 31, 2014. The Company believes that the net proceeds from its initial public offering ("IPO") completed in 2015, together with its existing unrestricted cash, will be sufficient to allow the Company to fund its current operating plan for at least the next 12 months. Management expects the Company to incur a loss for the foreseeable future. The Company's ability to achieve profitability in the future is dependent upon the successful development, approval and commercialization of its drug product candidates and successful commercialization of its consumer products, and achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through additional private or public debt or equity offerings, and may seek additional capital through arrangements with collaborators or from other sources. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

2. Summary of significant accounting policies

Basis of presentation and use of estimates

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to clinical study accruals, stock-based compensation expense, and amounts of expenses during the reported period. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company utilized various valuation methodologies in accordance with the framework of the 2004 and 2013 American Institute of Certified Public Accountants Technical Practice Aids, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a

number of objective and subjective factors, including external market conditions affecting the

biotechnology industry sector, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or a sale of the Company. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date and materially affect the financial statements.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, TK Pharma, Inc., a Massachusetts Securities Corporation. All significant intercompany balances and transactions have been eliminated in consolidation.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision maker, the Company's Chief Executive Officer, view the Company's operations and manage its business as one operating segment, which is the business of developing and commercializing products for nocturnal leg cramps, spasms associated with severe neuromuscular conditions and exercise associated muscle cramps. The Company operates in only one geographic segment, the United States.

Concentrations of credit risk and off-balance sheet risk

Cash is a financial instrument that potentially subjects the Company to a concentration of credit risk. The Company's cash is held in accounts at a financial institution that management believes is creditworthy. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no financial instruments with off-balance sheet risk of loss.

Deferred IPO issuance costs

Deferred IPO issuance costs, which primarily consist of direct incremental legal and accounting fees relating to the Company's IPO, are capitalized. The deferred IPO issuance costs were offset against IPO proceeds upon the closing of the offering in February 2015. Approximately $1,075,000 of deferred issuance costs were incurred and capitalized as of December 31, 2014.

Property and equipment

Property and equipment is stated at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred, while costs of major additions and betterments are capitalized. Upon disposal, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

Asset type	Estimated useful life
Computers and computer equipment	3 years
Laboratory equipment	3 years

Impairment of long-lived assets

The Company evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value. The Company has not recognized any impairment losses through December 31, 2014.

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FLEX PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Research and development expenses

Research and development costs are charged to expense as incurred in performing research and development activities. The costs include employee compensation costs, clinical study costs, external consultant costs, regulatory costs and facilities and overhead costs. Facilities and overhead costs primarily include the allocation of rent, utility and office-related expenses attributable to research and development personnel. The Company records payments made to outside vendors in advance of services performed or goods being delivered for use in research and development activities as prepaid expenses, which are expensed as services are performed or goods are delivered.

Stock-based compensation expense

The Company accounts for its stock-based compensation awards to employees and directors in accordance with FASB ASC Topic 718, Compensation-Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations and comprehensive loss based on their grant date fair values. Compensation expense related to awards to employees is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. The Company accounts for stock-based compensation arrangements with non-employees based upon the fair value of the consideration received or the equity instruments issued, whichever is more reliably measurable, in accordance with the provisions of FASB ASC Topic 505-50, Equity-Based Payments to Non-Employees. The measurement date for non-employee awards is generally the date performance of services required from the non-employee is complete, resulting in periodic adjustments to stock-based compensation expense during the vesting period for changes in the fair value of the awards. Stock-based compensation costs for non-employee service awards are recognized as services are provided, which is generally the vesting period, on a straight-line basis. The unvested portion of the awards is subject to re-measurement over the vesting period.

The Company estimates the fair value of its stock options using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate, (d) expected dividends and (e) the estimated fair value of the Company's common stock on the measurement date. Due to the lack of a public market for the trading of its common stock and a lack of company specific historical and implied volatility data, the Company based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. The Company computes historical volatility data using the volatility for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. Due to the lack of Company specific historical option activity, the Company has estimated the expected term of its employee stock options using the "simplified" method, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term for non-employee awards is the remaining contractual term of the option. The risk-free interest rates are based on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid, and does not expect to pay dividends in the foreseeable future.

The Company is also required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from its estimates. The Company records stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company's estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised.

Income taxes

Income taxes are recorded in accordance with FASB ASC Topic 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets

unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. The Company has evaluated available evidence and concluded that the Company may not realize the benefit of its deferred tax assets; therefore a valuation allowance has been established for the full amount of the deferred tax assets.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2014, the Company does not have any significant uncertain tax positions. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense.

Net loss per share attributable to common stockholders

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period, determined using the treasury stock method and the if-converted method, for convertible securities, if inclusion of these is dilutive.

For the period from February 26, 2014 (inception) to December 31, 2014, the Company has excluded the effects of all potentially dilutive shares, which include Series A convertible preferred stock, Series B convertible preferred stock and outstanding common stock options, from the weighted-average number of common shares outstanding as their inclusion in the computation for the period would be anti-dilutive due to the net loss per share incurred by the Company.

Comprehensive loss

Comprehensive loss consists of net income or loss and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company's net loss equals comprehensive loss for the period presented.

Recent accounting pronouncements

In June 2014, the FASB issued ASU No. 2014-10 "Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation". Under this ASU, the definition of a development stage entity was removed from the ASC, thereby removing the financial reporting distinction between development stage entities and other reporting entities under GAAP. This standard is effective for annual reporting periods beginning after December 15, 2014. Early adoption is permitted for certain entities. The Company was eligible for early adoption and adopted this standard in the accompanying financial statements.

In August 2014, the FASB issued ASU No. 2014-15 "Presentation of Financial Statements - Going Concern (Subtopic 205-40)". The ASU requires all entities to evaluate for the existence of conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the issuance date of the financial statements. The accounting standard is effective for interim and annual periods ending after December 15, 2016, and will not have a material impact on the consolidated financial statements, but may impact the Company's footnote disclosures.

The Company believes that the impact of other recently issued standards that are not yet effective will not have a material effect on its financial position or results of operations upon adoption.

Reverse stock split

In January 2015, the Company effected a one-for-4.2825 reverse stock split of its issued and outstanding common stock. All share and per share amounts related to issued and outstanding common stock and outstanding options exercisable for common stock included in the Company's financial statements and notes to financial statements

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FLEX PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

have been retroactively adjusted for all periods presented to reflect the reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. The conversion ratios of the Company's convertible preferred stock have also been adjusted to reflect the reverse stock split.

Subsequent events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements for potential recognition or disclosure in the consolidated financial statements. Subsequent events have been evaluated through the date these consolidated financial statements were issued for potential recognition or disclosure in the consolidated financial statements (Note 14).

3. Restricted cash

As of December 31, 2014, the Company had $126,808 restricted cash of in the form of a letter of credit. The Company maintains this letter of credit as a security deposit on the lease of its office space in Boston, Massachusetts (Note 6).

4. Property and equipment, net

Property and equipment, net consists of the following:

	December 31, 2014
Computers and computer equipment	$62,773
Laboratory equipment	13,368
Capital in progress	21,000
Total property and equipment	97,141
Accumulated depreciation	(11,997)
Property and equipment, net	$85,144

Depreciation expense was $11,997 for the period from February 26, 2014 (inception) to December 31, 2014.

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31, 2014
Deferred IPO issuance costs	$175,149
Research and development costs	125,067
Payroll and employee-related costs	34,218
Consumer brand-related costs	23,635
Professional fees	15,500
Other	42,955
Total	$416,524

6. Commitments and contingencies

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FLEX PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Lease commitments

On April 29, 2014, the Company leased office space in Boston, Massachusetts under an operating lease that is scheduled to expire on August 31, 2017. Additionally, on October 21, 2014, the Company leased office space in New York, New York under an operating lease that is scheduled to expire on October 31, 2016. As of December 31, 2014, the minimum future lease payments under the Company's operating leases are as follows:

2015	$332,190
2016	323,190
2017	168,793
Total minimum lease payments	$824,173

Rent expense is being recognized on a straight-line basis. The Company recorded approximately $152,000 of rent expense for the period from February 26, 2014 (inception) to December 31, 2014.

Royalty agreement

In March 2014, the Company entered into a royalty agreement with certain of its founders. Under the agreement, the Company agreed to pay the founders an aggregate royalty of 2% of gross sales of the Company's products in perpetuity. No royalty amounts were owed to the founders as of December 31, 2014.

Litigation

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities as of December 31, 2014.

7. Convertible preferred stock

As of December 31, 2014, the Company had authorized 16,000,000 shares of Series A convertible preferred stock ("Series A Preferred Stock"), $0.0001 par value per share, for issuance. During March, April and May 2014, the Company issued an aggregate of 15,775,221 shares of Series A Preferred Stock for $1.00 per share, resulting in net proceeds to the Company of $15,637,032, which is also the carrying value of the Series A Preferred Stock as of December 31, 2014.

As of December 31, 2014, the Company had authorized 14,500,000 shares of of Series B convertible preferred stock ("Series B Preferred Stock"), $0.0001 par value per share, for issuance. From July to October 2014, the Company issued an aggregate of 14,078,647 shares of Series B Preferred Stock for $1.81 per share, resulting in net proceeds to the Company of $25,394,135, which is also the carrying value of the Series B Preferred Stock as of December 31, 2014.

In conjunction with the Company's IPO in February 2015, all shares of the Series A and Series B Preferred Stock converted into common stock (Note 14). As of December 31, 2014, the rights and privileges of the Series A and Series B Preferred Stock were as follows:

Voting

The holders of the Series A Preferred Stock and Series B Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote, except with respect to matters on which Delaware General Corporation Law requires that a vote will be by a separate class. Each Series A and Series B Preferred Stock holder is entitled to the number of votes equal to the number of shares of common stock into which each preferred share is convertible at the time of such vote. The holders of the outstanding Series A and Series B Preferred Stock, voting together as a single class, are entitled to elect two directors to the Company's Board of Directors. Certain actions undertaken by the Company require approval from 75% of the holders of the outstanding Series A Preferred Stock and 60% of the Series B Preferred Stock. These actions include a liquidation,

dissolution or winding up of the Company, certain amendments to the certificate of incorporation, altering the terms of the existing preferred stock and increasing the number of authorized shares of preferred stock.

Dividends

The Company shall not declare, pay or set aside any dividends unless the holders of each series of convertible preferred stock then outstanding shall receive first, or simultaneously, in the case of a dividend on common stock, on a pari passu basis, a dividend in an amount that is at least equal to the amount that would have been received by the holders of the Series A and Series B Preferred Stock had all the Series A and Series B Preferred Stock been converted to common stock. In the event of a dividend on a class of stock that is not convertible to common stock, the holders shall receive a dividend in proportion to that received by the other classes of stock.

Liquidation preference

In the event of any liquidation, dissolution, winding up of the affairs or deemed liquidation event of the Company, the holders of the then-outstanding Series A and Series B Preferred Stock are entitled to receive, on a pari passu basis, in preference to the common stock holders, an amount equal to the greater of (1) $1.00 per share of Series A Preferred Stock and $1.81 per share of Series B Preferred Stock, plus all declared but unpaid dividends, or (2) such amount per share of Series A Preferred Stock and Series B Preferred Stock payable as if converted into common stock. Any remaining assets of the Company shall be distributed ratably among the holders of common stock. If the assets or surplus funds to be distributed to the holders of the Series A and Series B Preferred Stock are insufficient to permit the payment to such holders of their full preferential amount, the assets and surplus funds legally available for distribution shall be distributed ratably among the holders of the Series A and Series B Preferred Stock, pro rata, based upon the number of shares held.

In the event of certain deemed liquidation events, holders of the Series A and Series B Preferred Stock may require the Company to redeem their shares at a price equal to the liquidation amount at that time.

Conversion

Each share of Series A and Series B Preferred Stock, at the option of the holder, is convertible into a number of fully paid shares of common stock as determined by dividing $1.00 for the Series A Preferred Stock and $1.81 for the Series B Preferred Stock, by the conversion price in effect at the time. The conversion price of Series A Preferred Stock and Series B Preferred Stock is $4.28 and $7.74 per share, respectively, as of December 31, 2014. The conversion price is subject to adjustment in accordance with provisions contained in the Company's certificate of incorporation. Conversion is automatic immediately upon the closing of a firm commitment underwritten public offering in which shares are sold to the public at a price of at least $8.57 per share (subject to appropriate adjustment for stock splits, stock dividends, combinations and other similar recapitalizations affecting the number of such shares issued and outstanding) for gross proceeds of at least $40,000,000, or upon the written election of 1) the holders of at least 75% of the then-outstanding shares of Series A Preferred Stock and 2) the holders of at least 60% of the then-outstanding shares of Series B Preferred Stock.

The Company evaluated the Series A Preferred Stock and Series B Preferred Stock and determined both should be considered "equity hosts" and not "debt hosts" as defined by ASC 815, Derivatives and Hedging. These evaluations are necessary in order to determine if any embedded features of the Series A Preferred Stock or Series B Preferred Stock require bifurcation and, therefore, separate accounting as derivative liabilities. The Company's analyses followed the "whole instrument approach," which compares the individual features against the entire preferred stock instruments which include those features. The Company's analyses were based on consideration of the Series A Preferred Stock and Series B Preferred Stock's economic characteristics and risks, and more specifically, evaluated all the stated and implied substantive terms and features, including (i) whether the Series A Preferred Stock or Series B Preferred Stock included redemption or put features, (ii) whether the preferred stockholders were entitled to dividends, (iii) the voting rights of the Series A Preferred Stock and Series B Preferred Stock and (iv) the existence and nature of any conversion rights. As a result of the Company's determination that the Series A Preferred Stock and Series B

Preferred Stock are "equity hosts," the embedded conversion features do not require bifurcation as derivative liabilities. In addition, as the contingent put features described above contain gross settlement provisions, these features also do not require bifurcation as derivative liabilities.

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FLEX PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. Common stock

As of December 31, 2014, the Company had authorized 61,000,000 shares of common stock, $0.0001 par value per share. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the rights and privileges of the Series A and Series B Preferred Stock.

Restricted common stock

In March 2014, the Company sold 4,553,415 shares of restricted common stock to the founders of the Company ("recipients"), for $0.0004 per share, for total proceeds of $1,950. In April 2014, based upon anti-dilution provisions granted to the founders, an additional 867,314 shares of restricted common stock were sold to the same founders, after which the anti-dilution provisions were terminated. The restricted common stock vested 25% upon issuance, and the remaining 75% vests ratably over four years, during which time the Company has the right to repurchase the unvested shares held by a recipient if the relationship between such recipient and the Company ceases. If the relationship terminates, the Company has 90 days to repurchase unvested shares at $0.0004. Such shares are not accounted for as outstanding until they vest. There were 2,202,139 shares of restricted common stock outstanding as of December 31, 2014.

The following is a summary of restricted common stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Non-vested at February 26, 2014	—	$ —
Issued	5,420,729	0.10
Vested	(2,202,139)	0.10
Forfeited	—	—
Non-vested at December 31, 2014	3,218,590	$ 0.10

The total fair value of shares vested for the period from February 26, 2014 (inception) to December 31, 2014 was approximately $3,620,000.

Shares reserved for future issuance

The Company has reserved the following number of shares of common stock for future issuance:

	December 31, 2014
Vesting of restricted common stock	3,218,590
Conversion of Series A Preferred Stock	3,683,637
Conversion of Series B Preferred Stock	3,287,471
Stock-based compensation awards	1,189,314
Total	11,379,012

9. Stock-based compensation

In March 2014, the Company adopted the Flex Pharma, Inc. 2014 Equity Incentive Plan (the "Plan"), under which it may grant incentive stock options, non-qualified stock options, restricted stock awards, restricted stock units and stock appreciation rights to purchase up to 116,754 shares of common stock. In April 2014, the Company amended the Plan to reserve for the issuance of up to 1,451,087 shares of common stock pursuant to equity awards. In

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FLEX PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

September 2014, the Company further amended the Plan to reserve for the issuance of up to 2,070,200 shares of common stock pursuant to equity awards. Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the Plan. For options granted from February 26, 2014 (inception) to December 31, 2014, the exercise price equaled the fair market value of the common stock as determined by the board of directors on the date of grant. As of December 31, 2014, there were 262,482 shares remaining available for the grant of stock awards under the Plan.

For the period from February 26, 2014 (inception) to December 31, 2014, the Company granted a total of 137,765 stock options to non-employee consultants and members of its Scientific Advisory Board, which are included in the following table. The options generally vest over a four-year period, and have a contractual term of ten years. The total stock-based compensation expense related to all non-employee stock options for the period from February 26, 2014 (inception) to December 31, 2014 was approximately $149,000. The following table summarizes stock option activity for employees and non-employees:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Granted	1,020,234	$ 3.19		
Exercised	(13,572)	0.60		
Cancelled or forfeited	(79,830)	1.14		
Outstanding at December 31, 2014	926,832	$ 3.40	9.67	$6,846,054
Exercisable at December 31, 2014	3,891	$ 0.60	9.29	$39,649
Vested or expected to vest at December 31, 2014	867,333	$ 3.39	9.66	$6,421,021

During the period from February 26, 2014 (inception) to December 31, 2014, the Company granted stock options to purchase an aggregate of 1,020,234 shares of its common stock with a weighted-average grant date fair value of $2.20. There were 13,572 stock options exercised with a weighted-average exercise price of $0.60 during the period from February 26, 2014 (inception) to December 31, 2014. The intrinsic value of stock options exercised during the period from February 26, 2014 (inception) to December 31, 2014 was $51,719. The intrinsic value is calculated as the difference between the fair value of the Company's common stock and the exercise price of the options at the date of exercise.

The Company estimates the fair value of each stock option award on the grant date using the Black-Scholes option-pricing model based on the following assumptions and the assumptions regarding the fair value of the underlying Common Stock on each measurement date:

	Period from February 26, 2014 (Inception) to December 31, 2014
Expected volatility	75.8% to 76.4%
Risk-free interest rate	1.59% to 2.71%
Expected term	6 - 10 years
Expected dividend yield	0 %

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FLEX PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Total stock-based compensation expense recognized for employee and non-employee restricted common stock, and stock options granted to employees and non-employees is included in the Company's statement of operations and comprehensive loss as follows:

	Period from February 26, 2014 (Inception) to December 31, 2014
Research and development	$648,001
General and administrative	814,060
Total	$1,462,061

As of December 31, 2014, there was approximately $12,632,000 of total unrecognized compensation cost related to non-vested equity awards. Total unrecognized compensation cost will be adjusted for the re-measurement of non-employee awards as well as future changes in employee and non-employee forfeitures, if any. The Company expects to recognize that cost over a remaining weighted-average period of 3.27 years.

10. Income taxes

For the period from February 26, 2014 (inception) to December 31, 2014, the Company did not record a current or deferred income tax expense or benefit. The Company's loss before income taxes consists solely of a domestic loss. Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets are comprised of the following:

	December 31, 2014
Deferred tax assets:	
U.S. and state net operating loss carryforwards	$2,708,861
Accruals and other temporary differences	23,829
Amortization	36,742
Stock-based compensation	57,120
Tax credit carryforward	87,762
Total deferred tax assets	2,914,314
Less valuation allowance	(2,751,295)
Deferred tax assets	163,019
Deferred tax liabilities:	
Stock-based compensation	(162,779)
Depreciation	(240)
Accruals and other temporary differences	—
Deferred tax liabilities	(163,019)
Net deferred tax assets	$—

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The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's operating loss, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets as of December 31, 2014. The valuation allowance increased by $2,751,295 during the period from February 26, 2014 (inception) to December 31, 2014, due primarily to the generation of a net operating loss during the period. The valuation allowance is allocated to both short term and long term gross deferred tax assets, resulting in a long term deferred tax asset and a current deferred tax liability of $50,103.

A reconciliation of income tax expense computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	Period from February 26, 2014 (Inception) to December 31, 2014	
Federal income tax expense at statutory rate	35.0	%
State income tax, net of federal benefit	3.7	%
Permanent differences	(0.3	)%
Stock compensation	(5.3	)%
Research credits	1.2	%
Change in valuation allowance	(34.3	)%
Effective tax rate	0.0	%

As of December 31, 2014, the Company had a U.S. federal net operating loss carryforward of approximately $6,850,000, which may be available to offset future income tax liabilities and expires in 2034. As of December 31, 2014, the Company also had a tax effected U.S. state net operating loss carryforward of approximately $481,000, which may be available to offset future income tax liabilities and expires in 2034.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company completed financings since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2014, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statement of operations and comprehensive loss.

11. Net loss per share

Because the Company has reported a net loss for the period presented, diluted net loss per common share is the same as basic net loss per common share.

The following potentially dilutive securities outstanding, prior to the use of the treasury stock method or if-converted method, have been excluded from the computation of diluted weighted-average shares outstanding, because such

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securities had an antidilutive impact due to the loss reported from the period from February 26, 2014 (inception) to December 31, 2014:

	Period from February 26, 2014 (Inception) to December 31, 2014
Series A Preferred Stock	15,775,221
Series B Preferred Stock	14,078,647
Options to purchase common stock	926,832
Unvested restricted common stock	3,218,590
Total	33,999,290

12. Related party

The Company licenses a portion of its office space to an entity controlled by the Company's Chief Executive Officer. Under the terms of the license, the entity is charged the same rental rate as that is charged to the Company. Either party can terminate the agreement with 90 days notice and the license expires in August 2017. During the period from February 26, 2014 (inception) to December 31, 2014, the Company received approximately $34,000 in license fees from the aforementioned related party, and such amounts received have been recorded as a reduction to rent expense.

13. Quarterly financial information (unaudited)

	Period from February 26, 2014 (Inception) to March 31, 2014	Second Quarter Ended June 30, 2014	Third Quarter Ended September 31, 2014	Fourth Quarter Ended December 31, 2014
Operating expenses:				
Research and development	$30,023	$1,099,644	$909,123	$1,965,121
General and administrative	62,700	1,092,665	1,084,240	1,786,290
Total operating expenses	92,723	2,192,309	1,993,363	3,751,411
Loss from operations	(92,723)	(2,192,309)	(1,993,363)	(3,751,411)
Interest income	—	2,658	6,926	9,362
Net loss	$(92,723)	$(2,189,651)	$(1,986,437)	$(3,742,049)
Net loss per share attributable to common stockholders — basic and diluted	$(0.07)	$(1.42)	$(1.11)	$(1.82)
Weighted-average number of common shares outstanding — basic and diluted	1,370,125	1,539,463	1,797,664	2,061,132

14. Subsequent events

The Company has completed an evaluation of all subsequent events after the balance sheet date of December 31, 2014 through the date these consolidated financial statements were issued. The Company has concluded that no subsequent events have occurred that require disclosure, except as described below.

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Reverse stock split

In January 2015, the Company effected a one-for-4.2825 reverse stock split of its issued and outstanding common stock. All share and per share amounts related to issued and outstanding common stock and options for common stock included in the Company's financial statements and notes to financial statements have been retroactively adjusted for all periods presented to reflect the reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. The conversion ratios of the Company's convertible preferred stock have also been adjusted to reflect the reverse stock split.

Completion of initial public offering (unaudited)

In February 2015, the Company closed the IPO of its common stock pursuant to a registration statement on Form S-1, as amended. An aggregate of 5,491,191 shares of common stock registered under the registration statement were sold at a price of $16.00 per share, including 91,191 shares of common stock sold by the Company pursuant to the exercise of an overallotment option granted to the underwriters in connection with the offering. Net proceeds of the IPO were approximately $79.9 million. In conjunction with this transaction, all shares of the Company’s Series A and Series B Preferred Stock were converted into 6,971,108 shares of common stock.

In connection with the Company's IPO:

i. The Company's board of directors adopted and the Company's stockholders approved the 2015 Equity Incentive Plan ("2015 Plan"), which became effective immediately prior to the closing of the Company's IPO. The 2015 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights, performance-based stock awards, and other stock-based awards. Additionally, the 2015 Plan provides for the grant of performance-based cash awards. ISOs may be granted only to the Company's employees. All other awards maybe granted to the Company's employees, including officers, and to non-employee directors and consultants.

ii. The Company's board of directors adopted and the Company's stockholders approved the 2015 Employee Stock Purchase Plan ("the ESPP"), which became effective upon the date of execution of the underwriting agreement pursuant to which the Company's common stock was priced in connection with the IPO.