Flex Pharma, Inc.
Form 10-K
March 07, 2018

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, 2017
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)

William McVicar, 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 ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý 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, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

(Check one):

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

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

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

As of June 30, 2017, the last day of the registrant’s most recently completed second fiscal quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $39.7 million, based on the closing price of the registrant’s common stock on June 30, 2017.

As of March 2, 2018, there were 17,972,166 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive Proxy Statement relating to its 2018 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

FLEX PHARMA, INC.
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, 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. 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 clinical trials;
- the expected benefits and growth potential of HOTSHOT;
- 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;
- any potential impact from the announcement that we are conducting a review of strategic alternatives for our consumer business segment;
- our ability to expand the sales of our consumer product;
- our plans to develop 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 product 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 product 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. Any forward-looking statement in this Annual Report 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 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.

Except where the context otherwise requires, in this Annual Report, "we," "us," "our" and the "Company" refer to Flex Pharma, Inc. and, where appropriate, its consolidated subsidiaries. Flex Innovation Group LLC, a Delaware limited liability company, or Flex Innovation, is a wholly owned subsidiary of the Company that contains the Company's consumer-related operations. This Annual Report contains references to our trademarks and to trademarks belonging to other entities, including Flex Innovation. 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 ™ 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.

PART I

Item 1. BUSINESS

Overview

We are a biotechnology company that is developing innovative and proprietary treatments for muscle cramps, spasms and spasticity associated with severe neurological conditions and exercise-associated muscle cramps. Our lead drug product candidate, FLX-787, is currently being studied in an exploratory Phase 2 clinical trial in Australia in patients with multiple sclerosis, or MS, and in two Phase 2 clinical trials in the United States. One Phase 2 clinical trial in the United States is in patients with motor neuron disease, or MND, primarily with amyotrophic lateral sclerosis, or ALS, who suffer from muscle cramps. FLX-787 is being developed for ALS under fast track designation which was granted by the Food and Drug Administration, or FDA, in July 2017. The other Phase 2 clinical trial in the United States is in patients with Charcot-Marie-Tooth disease, or CMT, who suffer from muscle cramps. In 2016, we launched our consumer product, HOTSHOT®, to prevent and treat exercise-associated muscle cramps, or EAMCs.

Muscle cramps and spasms are involuntary, often painful, contractions that can last several minutes and, in many instances, result in prolonged soreness. Muscle cramps and spasms are thought to result from hyperexcitable alpha-motor neurons. Spasticity is characterized by the combination of weakness and velocity-dependent resistance to stretch, in the same muscle. This reflex hyperexcitability may be due to lost inhibition in spinal cord circuits.

FLX-787, HOTSHOT and our other drug product candidates are based on a mechanism of action we describe as chemical neurostimulation. We believe chemical neurostimulation to be a process in which a molecule, such as FLX-787, acts topically on the surfaces of the mouth, throat, esophagus and stomach to produce a sensory signal by activating nerves in those tissues. That signal is thought to ultimately result in a beneficial effect. Specifically, our product candidates activate certain receptors known as transient receptor potential, or TRP, ion channels in primary sensory neurons producing a signal believed to inhibit neuronal circuits and thereby reduce hyperexcitability in the neurons that fire muscles. Reduced alpha-motor neuron hyperexcitability in spinal cord circuits is thought to suppress repetitive firing of alpha-motor neurons, thereby preventing or reducing muscle cramps and spasms, and potentially reducing reflex hyperexcitability and therefore spasticity.

In 2016, we began enrolling an exploratory Phase 2 clinical trial in Australia of FLX-787 in patients suffering from spasticity, and cramps and spasms associated with MS. We expect to announce topline data from this clinical trial in the first quarter of 2018.

In August 2017, we announced the initiation of our Phase 2 clinical trial in patients with MND, referred to as the COMMEND trial, and expect topline data from this clinical trial by early 2019. In 2017, we also announced the initiation of the COMMIT trial, our Phase 2 clinical trial in patients with CMT, and expect topline data from this clinical trial in early 2019.

In November 2017, we announced results from a small, exploratory Phase 2 clinical trial that we completed in Australia in patients with ALS or primary lateral sclerosis, or PLS, with frequent muscle cramps. In that trial, FLX-787 demonstrated a statistically significant ($p<0.05$) percentage reduction from baseline in both cramp-associated pain intensity and stiffness. We believe that the data from this clinical trial provides the first clinical evidence that FLX-787 is active in patients with underlying neurological disease and demonstrates the utility of chemical neurostimulation in treating symptoms arising from motor neuron hyperexcitability.

HOTSHOT is our consumer beverage containing a proprietary formulation of TRP activators. Historically, we have marketed HOTSHOT to endurance athletes who drink it before, during and after exercise to prevent and treat EAMCs. We recently expanded our efforts to address a larger target market of both endurance and non-endurance athletes and to promote an additional set of benefits. In a recent in-home study, the vast majority of endurance and non-endurance athletes surveyed reported that HOTSHOT was also effective in helping reduce muscle soreness and muscle pain. We have started to promote these additional benefits, along with the anti-cramping benefit, to endurance and non-endurance athletes in order both to attract new consumers and to increase use occasions among current consumers.

The majority of HOTSHOT sales are generated through our branded website and third-party websites. We also sell HOTSHOT to select specialty retailers in a limited number of geographic areas with strong endurance sports markets

and are beginning to target larger, national retailers in select cities in order to increase our retail presence. Concurrent with our efforts to grow HOTSHOT, on January 22, 2018, we disclosed that we engaged an investment banking firm to assist with the consideration of strategic alternatives for our consumer business segment.

Our Scientific Approach

Research has shown that muscle cramping is caused by the uncontrolled and repetitive firing of alpha-motor neurons that control muscle contraction, which results in maintained contraction of the muscle. We believe that by inhibiting 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 reduce neuronal and muscle activity, known as “inhibitory” input, and 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 excitatory input. The activation of a particular set of ion channels, and the resulting effect on the inhibitory/excitatory balance in the system, forms the basis of our scientific approach. Our scientific co-founder, Roderick MacKinnon, M.D., is a world leader in this field. Dr. MacKinnon was awarded the Nobel Prize in 2003 for his work determining the structure and function of potassium channels, and in particular showing the mechanism by which channels select for particular ions (Doyle, et al., The Structure of the Potassium Channel: Molecular Basis of K+ Conduction and Selectivity, April 1998, Science). The TRP vanilloid-1, or TRPV1, receptor is important to diverse physiological functions. The TRPV1 ion channel acts as a sensor that reacts to multiple sensory inputs including: heat, low pH and a variety of pungent chemical agents. 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 also pungent chemical agents. TRPA1 and TRPV1 ion channels are expressed in primary sensory neurons and carry signals directly to the spinal cord.

We refer to the mechanism of action of our product candidates as chemical neurostimulation. We believe chemical neurostimulation to be a process in which a molecule, such as FLX-787, acts topically on the surfaces of the mouth, throat, esophagus and stomach to produce a sensory signal by activating nerves in those tissues. That signal is thought to ultimately result in a beneficial effect, through the activation of TRPV1 and TRPA1 ion channels. These sensory neurons project 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 and thereby prevents or reduces the frequency and intensity of muscle cramps and spasms, and potentially reduces reflex hyperexcitability and therefore spasticity. Muscle cramps and spasms are thought to result from hyperexcitable alpha-motor neurons, and spasticity is thought to result from reflex hyperexcitability.

We believe the biologically active components of HOTSHOT, and FLX-787 activate specific TRP ion channel receptors found on the surface of the mouth, throat, esophagus and stomach, triggering signals in sensory neurons that are relayed to the spinal cord. This sensory signaling, once processed, is thought to increase inhibition in spinal cord circuits, reducing alpha-motor neuron hyperexcitability, preventing muscle cramps and spasms, and potentially reducing reflex hyperexcitability and therefore spasticity.

In our studies to date, using sensitive, validated bioanalytical methods, we have not been able to detect FLX-787 in the bloodstream following clinically relevant doses, which we believe limits the potential for systemic side-effects. The lack of systemic exposure should also reduce the potential for any drug-drug interactions. To date, there have been no serious treatment related adverse events reported in our trials.

Our Strategy

Our strategy is to become a leading biotechnology company focused on treating muscle cramps, spasms and spasticity associated with severe neurological conditions. The key elements of our strategy are as follows:

- Advance FLX-787 for treatment across severe neurological conditions with significant unmet need. FLX-787 is currently being evaluated in three clinical trials in three neurological conditions. Our Australian Phase 2 exploratory MS clinical trial is a randomized, blinded, placebo-controlled cross-over clinical trial in patients suffering from cramps, spasms and spasticity associated with MS. The COMMEND and COMMIT clinical trials are randomized, controlled, double-blinded, parallel designed trials studying patients with MND and CMT who suffer from muscle cramps. We believe that there is opportunity to address a significant unmet need in each of these indications. It is estimated that 84% of MS patients experience spasticity while many ALS patients experience painful muscle cramps at some point in their disease progression and a large majority of CMT patients experience muscle cramps, which can be frequent.
-

Drive adoption and recurring use of HOTSHOT for the prevention and treatment of EAMCs and expand usage occasions to include helping to reduce muscle soreness and muscle pain. We are

working to build awareness, adoption and repetitive use of HOTSHOT among key opinion leaders, endurance athletes and non-endurance athletes. In addition to its application as a product scientifically proven to prevent and treat muscle cramps, we recently completed an in-home study of 288 endurance and non-endurance athletes that used HOTSHOT before or after a workout for a two week period. The vast majority of athletes surveyed reported less muscle soreness and muscle pain. We have started to promote these additional benefits to endurance athletes and are now promoting the broader set of HOTSHOT benefits to a larger target market of non-endurance athletes.

- Collaborate selectively to augment and accelerate the research and development of our drug product candidates. 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 neurological indications in which our potential collaborator has particular expertise or for which we need access to additional markets and research, development or commercialization resources.
- Explore strategic alternatives for our consumer business segment. On January 22, 2018, we disclosed that we hired an investment banking firm to help us explore strategic alternatives for our consumer business segment.
- Expand development to additional indications. Based upon our research and development efforts, we believe that there are additional indications that we can address through the use of our chemical neurostimulation technology, such as dysphagia, or difficulty swallowing, in ALS and other indications, as well as cramping in renal failure patients during or between dialysis sessions. We expect to begin development efforts in these indications in 2018.
- Evaluate 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 may make us an attractive partner.

FLX-787

FLX-787 is a single molecule, chemically synthesized, dual TRP V1/A1 ion channel activator that has demonstrated dose dependent clinical efficacy in our electrically-induced cramp model. In our recently completed ALS clinical trial in Australia, FLX -787 demonstrated a statistically significantly reduction in both cramp-associated pain intensity and stiffness. We believe that FLX-787 may relieve cramps, spasms and spasticity affecting individuals suffering from severe neurological conditions, including MS, CMT and motor neuron diseases such as ALS.

Human Efficacy Demonstrated in Electrically-Induced Cramp Model

We have tested the efficacy of FLX-787 in reducing the intensity of muscle cramps in our electrically-induced human cramp model. In this model, we induce muscle cramping in the flexor hallucis brevis muscle, a small muscle on the bottom of the big toe, using electrical stimulation. We then measure 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. To measure a subject's muscle cramp, we calculate the area under the curve, or AUC, produced by the electromyogram. Muscle cramp intensity and duration vary by subject, so each study begins by inducing a cramp in each subject in order to create a “baseline AUC.” This baseline AUC is later compared to the AUC after the subject receives either the study article or a vehicle control without active ingredients. The time at which the subject receives the study article or vehicle control is referred to as timepoint zero. We then attempt to induce muscle cramps using electrical stimulation at various times following timepoint zero. At each timepoint, we measure the subject's cramp intensity and duration using the EMG recording sensors and then compare each AUC against the baseline AUC. We believe that if a subject's AUC at the subsequent timepoints is smaller than the subject's baseline AUC, then the study article successfully prevented, or reduced the intensity of, the subject's muscle cramp.

FLX-787 and FLX-788 are constituent molecules of the original extract formulation of TRP activators developed by our co-founders, and FLX-797 and FLX-798 are combinations of the constituent molecules in this extract formulation. FLX-787, FLX-788, FLX-797 and FLX-798 were each tested in nine healthy volunteers using our electrically-induced cramp model and were observed to decrease cramp intensity (see Figure 1 below). Using a generalized linear mixed model (Tukey-Kramer post-hoc), FLX-787, FLX-788, FLX-797 and FLX-798 treatment

arms significantly reduced cramp intensity relative to control ($p<0.01$), with both FLX-787 and FLX-788 providing a significant improvement in efficacy compared to the extract formulation.

In a separate study of five subjects, FLX-787, formulated as an orally disintegrating tablet, or ODT, reduced the intensity and duration of electrically-induced muscle cramps in a dose-dependent manner ($p<0.05$). Six doses (0.5, 2.5, 7, 19, 33 and 56 mg) of FLX-787 showed an effect consistent with a classic sigmoidal dose response curve, with virtually no effect at the lowest doses and a maximal effect at the highest doses (see Figure 2 below).

Figure 1 Figure 2

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.

Clinical Trials of FLX-787 in Patients with Severe Neurological Conditions

The FDA has never approved a drug to treat cramping in a neurological condition and, as a result, we are evaluating a number of different endpoints in our trials. Our exploratory Phase 2 clinical trials in Australia in MS and ALS were designed as trials to determine the effect of FLX-787 across a broad range of potential endpoints with no pre-specified primary endpoint. Our Phase 2 clinical trials in the United States in patients with MND and CMT include changes in cramp frequency as the primary endpoint along with several secondary endpoints. We have chosen change in cramp frequency as the primary endpoint based, in part, upon feedback we received from the FDA for a proposed trial in patients with nocturnal leg cramps.

Multiple Sclerosis

Background. MS is an autoimmune disease in which inflammatory processes cause worsening demyelination and cell degeneration over years, resulting in a variety of neurological deficits such as loss of muscle control, sensation and vision. Spasticity is common in MS and is characterized by the combination of weakness and velocity-dependent resistance to stretch, in the same muscle. This reflex hyperexcitability may be due to lost inhibition in the spinal cord circuits, as descending pathways demyelinate. The need to treat spasticity increases as the disease progresses and goes hand in hand with worsening muscle weakness, leading to complications such as contractures, 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. We believe that a significant number of MS patients also experience muscle cramps and/or spasms.

Limitations of Current Treatment. Patients suffering from MS spasticity may be treated with antispasticity drugs, 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.

MS Clinical Trial. In 2016, we began enrolling a randomized, blinded, placebo-controlled, exploratory clinical trial of 19 mg of FLX-787 twice daily, formulated as a liquid, in MS patients. The trial includes a 14-day run-in period during which patients receive a placebo and record their experience with spasticity, cramps and spasms. At the end of this run-in period, patients are excluded from the trial if they were deemed to have responded to placebo. Following this run-in period, patients receive either FLX-787 or a placebo during the first 14-day treatment period before "crossing-over" to the other treatment for an additional 14-day treatment period. The trial will evaluate a number of endpoints relating to spasticity, cramp/spasm frequency, pain, quality of life, sleep and safety. We expect to announce topline data from this trial in the first quarter of 2018.

Motor Neuron Disease and ALS

Background. Motor neuron disease is a progressive disease that leads to motor neuron degeneration, dysfunction and eventual neuronal death in the brain and spinal cord. Motor neuron disease includes diseases such as ALS, PLS, and progressive muscular atrophy and related disorders that affect the upper and lower motor neurons. Motor neuron degeneration leads to progressive loss of voluntary motor control and is often associated with muscle cramps, spasms and spasticity resulting in increased pain, reduced function and decreased quality of life. ALS is a neurological disease that affects approximately 20,000 people in the United States and causes muscle weakness and impacts physical function. In most patients, doctors do not know why ALS occurs. These cases are referred to as sporadic cases. A small number of familial cases are known to occur. ALS often begins with muscle twitching and weakness in an arm or leg, or sometimes with slurring of speech. Eventually, ALS can affect the ability to control the muscles needed to move, speak, eat and breathe. ALS patients commonly experience fasciculations, which are persistent muscle twitches that can interfere with sleep, and many patients with ALS experience painful muscle cramps.

Limitations of Current Treatment. The October 2009 American Academy of Neurology ALS Care Guidelines found insufficient data to support or refute any specific interventions for the treatment of muscle cramps, twitches and spasticity in ALS patients. The guidelines did note that in diseases such as MS, effective treatments for similar problems include benzodiazepines, baclofen, dantrolene and tizanidine, all of which cause sedation in patients. However, there are no FDA-approved therapies for cramping associated with ALS, or any other disease state, and some drugs that have been used to treat cramps (e.g. quinine and mexiletine) carry FDA safety warnings due to potentially life-threatening side effects.

Motor Neuron Disease and ALS Clinical Trials. In 2016, we began enrolling an exploratory clinical trial of FLX-787, formulated as an ODT, in ALS patients in Australia. The trial was a randomized, blinded, placebo-controlled Phase 2 clinical trial that originally planned to enroll up to 60 subjects with ALS or PLS, with frequent muscle cramps. This trial included a 14-day run-in period with no treatment to establish baseline characteristics, followed by 14-day treatment periods during which patients received FLX-787 or placebo in the first treatment period before "crossing-over" to the other treatment for an additional 14-day treatment period. Patients were given 19 mg of FLX-787, or placebo control, two or three times daily. The exploratory trial was designed to evaluate a number of endpoints relating to cramping including cramp frequency, cramp-associated pain, spasticity, stiffness, global impression of change by the patient and the clinician, quality of life, sleep, as well as and safety and tolerability. We elected to terminate this trial early in order to focus our efforts on the COMMEND trial, our larger Phase 2 trial ongoing in the United States.

In November 2017, we announced topline data from this trial. In the eight patients who completed the trial per protocol, FLX-787 demonstrated a statistically significant ($p<0.05$) percentage reduction from baseline in both cramp-associated pain intensity and stiffness, relative to placebo control, based on daily patient assessments by Numerical Rating Scale, or NRS. Strong and consistent trends were demonstrated on multiple other endpoints, including: percentage reduction in the number of cramps from baseline ($p=0.08$), increase in cramp free days from baseline ($p=0.09$), and improvements on both the Patient Global Impression of Change, or PGIC, ($p=0.06$) and Clinician Global Impression of Change, or CGIC, ($p=0.06$). FLX-787 was generally well tolerated.

In the patients completing both cross-over periods per protocol:

- FLX-787 showed a median 31% reduction in cramp frequency from baseline versus 0.1% reduction for patients while on placebo control;

- Patients had a median 4.4 cramp free days versus 0 for placebo control;
- Patients evaluated themselves as improved with FLX-787 treatment 50% of the time versus 12.5% with placebo control (PGIC); and
- Clinicians blinded to treatments evaluated 50% of patients as improved with FLX-787 versus 0% for placebo control (CGIC).

In a post-hoc analysis, we analyzed the Period 1 and Period 2 results of all patients randomized in the trial and believe the overall results are not driven by a cross-over bias or unblinding effect.

Clinically-assessed baseline spasticity levels as measured by either the Modified Ashworth or Tardieu scales were minimal, and were not improved by treatment.

We believe the data from this trial provides the first clinical evidence that FLX-787 has an anti-cramping effect in patients with underlying neurological disease, demonstrating the utility of chemical neurostimulation for treating symptoms arising from motor neuron hyperexcitability.

In August 2017, we announced the initiation of the COMMEND trial, a Phase 2 clinical trial in the United States. The COMMEND trial is designed to evaluate FLX-787 in patients with MND, focused on ALS, who suffer from cramps. This randomized, controlled, double-blinded, parallel design trial will include a 28-day run-in period to establish a baseline in cramp frequency. Patients will then be randomized to treatment with 30 mg of FLX-787, formulated as an ODT, administered three times a day, or to a control, for 28 days. Patients will be evaluated for changes in cramp frequency as the primary endpoint, with a number of secondary endpoints. We expect to report topline data from this clinical trial by early 2019.

Charcot-Marie-Tooth

Background. CMT is the most common form of inherited neuromuscular disease, affecting an estimated 150,000 people in the United States. It occurs in populations worldwide with a prevalence of about 1 in 2,500 individuals. The primary clinical features of this disease are slowly progressive distal weakness, muscle atrophy affecting the feet and legs and sensory loss. The presence of muscle cramps in hands, fingers and other muscles commonly experienced by CMT patients is a result of peripheral degeneration which disturbs sensory motor integration in the spinal cord which can lead to hyperexcitability and muscles cramps. Patients with CMT usually do not suffer from spasticity or other central nervous system symptoms, as the underlying pathology affects the peripheral nerve. A large majority of CMT patients experience muscle cramps frequently, in many muscles, which can interfere with motor performance, exercise, activities of daily living, sleep and quality of life.

Limitations of Current Treatment. There are no drug products approved by the FDA to treat cramps in patients with CMT. Several symptomatic therapies are used but data from randomized controlled trials of these therapies are lacking.

CMT Clinical Trial. In October 2017, we announced the initiation of the COMMIT trial, a Phase 2 clinical trial in the United States in patients that suffer from cramps associated with CMT. The COMMIT trial is designed to evaluate FLX-787 in patients with CMT who suffer from cramps. This randomized, controlled, double-blinded, parallel design trial will include a run-in period to establish a baseline in cramp frequency. Patients will then be randomized to 30 mg of FLX-787, formulated as an ODT, administered three times a day or to a control, for 28 days. Patients will be evaluated for changes in cramp frequency as the primary endpoint, with a number of secondary endpoints. We expect to report topline data from this clinical trial in early 2019.

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 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 conducted three studies in subjects with nocturnal leg cramps. In the first study, reported in February 2016, we evaluated our extract formulation in a randomized, blinded, placebo-controlled, cross-over design study of 50 subjects. Statistically significant effects were demonstrated on key endpoints in the study, including cramp frequency ($p<0.05$), cramp-free days ($p<0.01$), the physician-rated Clinical Global Impression of Change ($p<0.01$),

cramp pain measures ($p<0.05$), and specific sleep disturbance measures ($p<0.05$). There were no serious adverse events reported in the study.

In a second study, reported in October 2016, we evaluated multiple dosages of FLX-787, formulated as both a liquid and an ODT, in four rapidly successive cross-over periods. The 29 subjects in this study had participated in our prior nocturnal leg cramps study. Muscle cramp frequency was reduced ($p<0.05$) at two weeks in the parallel portion of the first phase. In the cross-over data sets, efficacy ($p<0.05$) was generally seen for the pre-specified endpoints of muscle cramp frequency and cramp free nights in the early study arms. In the latter arms, FLX-787 did not show statistical significance versus placebo, which we believe may have resulted from a potential carryover effect. There were no serious adverse events reported in the study.

In October 2016, we also reported results from the first portion of the third study, which evaluated FLX-787 in 72 subjects who reported to suffer from nocturnal leg cramps. The study did not demonstrate a statistically significant difference versus placebo on the pre-specified endpoints of muscle cramp frequency or cramp-free nights. A number of concerns have been identified that we believe impact the data interpretation from this study, including concerns relating to patient selection. These issues appear to have been concentrated at one of the three clinical recruitment sites in the study. When data from this site are excluded and analysis is restricted to patients from the two other sites ($n=37$), FLX-787 shows a strong statistical trend in reducing muscle cramp frequency ($p=0.06$) during the initial two-week parallel portion of the study versus placebo as compared to the baseline run-in period. The data we received from the second part of this study were generally consistent with the data from the first part of the study. There were no serious adverse events reported in either part of the study.

Given the subsequent concerns regarding patient selection in our third study, we conducted an analysis of subjects likely to have NLC based upon a questionnaire administered after the study was completed. Of the respondents to the questionnaire, 26 subjects were identified, in a blinded manner, as likely having nocturnal leg cramps. An analysis of the first treatment exposure in both parts of the study for the subjects showed a statistically significant effect in the reduction in cramp frequency when compared to placebo ($p=0.03$).

In January 2017, we decided to delay further development of FLX-787 for nocturnal leg cramps and focus our drug development efforts on severe neurological conditions.

Other Potential Indications

Based upon our research and development efforts, we believe that there are additional indications that we can address through the use of our chemical neurostimulation technology, such as dysphagia, or difficulty swallowing, in ALS and other indications, as well as cramping in renal failure patients during and between dialysis sessions. We expect to begin development efforts in these indications in 2018.

HOTSHOT

In June 2016, we launched our consumer product, HOTSHOT, which was our only source of revenue during 2016 and 2017. HOTSHOT's efficacy is based on the same potential mechanism of action of chemical neurostimulation as our drug product candidates but is formulated as a consumer beverage with a lower amount of TRP activators.

Historically, we have marketed HOTSHOT to endurance athletes who drink it before, during and after exercise to prevent and treat EAMCs. We recently expanded our efforts to address a larger target market of both endurance and non-endurance athletes and to promote an additional set of benefits. In a recent in-home study, the vast majority of 288 endurance and non-endurance athletes surveyed reported that HOTSHOT was also effective in helping reduce muscle soreness and muscle pain. We have started to promote these additional benefits, along with the anti-cramping benefit, to endurance and non-endurance athletes in order to both attract new consumers and to increase use occasions among current consumers.

Concurrent with our efforts to grow HOTSHOT, on January 22, 2018, we disclosed that we hired an investment banking firm to help us explore strategic alternatives for our consumer business segment.

Exercise-Associated Muscle Cramps

Background. EAMCs are painful, involuntary contractions of a skeletal muscle that occur 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 endurance activities, such as triathlons, marathons and cycling events.

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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. While there are other companies that market their muscle cramping products to endurance athletes participating in high-intensity sports, we believe HOTSHOT is the only product that has been shown to be scientifically effective in treating muscle cramps.

HOTSHOT for the Prevention and Treatment of Exercise-Associated Muscle Cramps

HOTSHOT is a beverage that athletes take before, during and after exercise to prevent and treat muscle cramps. It is based on our founders' original extract formulation of TRP activators. We tested several different formulations of the active ingredients from this extract formulation to refine the taste while ensuring continued efficacy in treating and preventing muscle cramps. We also added emulsifiers and flavoring agents, in order to develop a more appealing consumer product. HOTSHOT includes organic ingredients and is priced at a premium to many existing sports beverages.

Muscle Soreness and Muscle Pain

Background. Post exercise muscle soreness or muscle pain, sometimes referred to as delayed onset muscle soreness, is believed to be a result of microscopic damage to muscle fibers involved with exercise and the resulting inflammation and swelling. Potential remedies to reduce muscle soreness and muscle pain vary from stretching the sore muscles, to ice pack application, massage, acupressure and oral pain relief agents.

HOTSHOT for Relief from Muscle Soreness and Muscle Pain

In an in-home study that we recently completed, the vast majority of endurance and non-endurance athletes surveyed reported that HOTSHOT reduced muscle soreness and muscle pain when used before or after a workout. The in-home study was conducted among 288 endurance and non-endurance athletes who used HOTSHOT over a two-week period. Of these athletes who used HOTSHOT either before, during or after exercise:

- 84% reported that they felt less muscle soreness;
- 92% reported that they felt less muscle pain; and
- 88% said their next day workouts were better because they felt less muscle soreness

We have started to promote these added benefits, along with the anti-cramping benefits, to endurance and non-endurance athletes in order to attract new customers and to increase use occasions with current customers.

HOTSHOT Brand Strategy

We believe there is a significant opportunity to commercialize an efficacious product that treats and prevents EAMCs as well as provides reported relief from muscles soreness and muscle pain under a culturally relevant lifestyle brand. Our product has been historically marketed primarily to endurance athletes that suffer from muscle cramps and participate in high endurance sports, such as triathlons, marathons and cycling events. We are now expanding our sales and marketing efforts to also promote HOTSHOT's ability to provide reported relief from muscle pain and muscle soreness to endurance as well as non-endurance athletes. Our marketing materials and branded website highlight HOTSHOT's efficacy and the scientific origins of and support for HOTSHOT.

We increase awareness and demand for HOTSHOT through the use of targeted digital, print and social media campaigns, sales and marketing campaigns focused on key geographic areas, including product sampling, and public relations activities. To explain the science behind HOTSHOT, we highlight the importance of an athlete's nerves and muscles working together to prevent and treat muscle cramps.

HOTSHOT Distribution

We use e-commerce strategies to sell online through our direct-to-consumer website and through third-party websites, including a retailer that offers international shipping. We focus our sales and marketing efforts on a limited number of geographic areas with strong endurance sports markets, including Los Angeles, San Francisco, Boulder, Boston, Chicago and New York. In each of these locations, we have built brand awareness by attending endurance sports events and distributing HOTSHOT to leading specialty retailers, such as cycling, running and triathlon stores. We plan to increase our efforts to expand the retail presence of HOTSHOT by targeting more mainstream distribution channels, including larger, national retailers, with an initial focus on building a broader retail presence in select cities.

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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

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 a first family of applications, including two pending U.S. utility patent applications and one granted European patent directed to compositions and methods of using those compositions for preventing, treating or ameliorating muscle cramping. The granted patent in Europe, and a patent based on these applications, if issued in the United States, will have a statutory expiration in July 2031.

We also own a second family of patent applications, including one utility patent application that is pending in the United States, Australia, Brazil, Canada, China, the Eurasian Patent Organization, Europe, Israel, Japan, Korea, Mexico, New Zealand, Singapore and South Africa. This application is directed to methods for preventing and treating various muscle-related conditions and disorders and methods of diagnosing and selecting a patient for treatment. The patent applications also include various uses of TRP activators, formulations, compositions of chemical matter, and enabling technology such as the electrical stimulation technique for inducing muscle cramps.

We also own additional families of applications, including three PCT applications and two provisional patent applications. These applications are directed at various aspects of our work including influencing neuromuscular activity by stimulating a TRP channel in the nerve ending of a sensory neuron. The first PCT application will enter the national phase in April 2018. A patent based on the PCT application, if issued, would have a statutory expiration in October 2036. The second and third PCT applications will enter the national phase in July 2019. A patent based on the PCT applications, if issued, would have a statutory expiration in January 2038. A patent based on the pending provisional applications would, if issued, have a statutory expiration in October or December 2038.

We also own one design patent application directed to the design of one of our HOTSHOT bottles. The international patent application was granted in September 2016, and we are currently awaiting the outcome of the designations in Australia, Canada, Europe, Japan, South America, and the United States. The statutory expiration of the design patents will vary based on jurisdiction. If issued in the United States, the design patent will expire 15 years after the date of grant.

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 product have gone through numerous iterations to optimize their effectiveness, thereby creating trade secrets and proprietary know-how. In particular, the formulation of our consumer product is treated as a trade secret. 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.

We have received trademark protection from the U.S. Patent and Trademark Office, or the USPTO, and several foreign bodies for certain of our marks and will continue to apply for trademark protection with the USPTO and applicable foreign bodies for our brand. 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 are an important element of our ability to successfully market our consumer products.

Our wholly owned subsidiary, Flex Innovation Group LLC, or Flex Innovation, owns all U.S. trademark applications and registrations for marks used (or intended to be used) by us, including the HOTSHOT trademark, with the exception of the pending application for the FLEX PHARMA trademark, which is owned by the Company. Outside the U.S., ownership of the HOTSHOT trademark is split between Flex Innovation and the Company. Flex Innovation owns applications or registrations for the HOTSHOT trademark in Australia, China, the European Union, Iran, Israel, Japan, Mexico, New Zealand, Norway, Philippines, the Russian Federation, Singapore, South Korea, Switzerland, Ukraine, and Vietnam. The Company owns applications or registrations for the HOTSHOT trademark in Argentina, Brazil, Canada, Malaysia, Peru, Qatar, South Africa, Thailand, and the United Arab Emirates.

Royalty Agreement

In connection with the transfer of certain intellectual property to us by certain of our founders, 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.

Manufacturing

We do not currently have our own manufacturing facilities. We intend to continue to use our financial resources to focus on developing our 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 rely on a network of third-party manufacturers to supply materials and produce HOTSHOT. Several contract suppliers provide us with raw materials and our co-packer converts these raw materials into finished goods available for sale. We currently rely, and expect to continue to rely, on a sole source third-party co-packer to produce, bottle and package HOTSHOT and have entered into a production agreement with this co-packer. We rely on a third party as the sole source for certain of the raw materials in HOTSHOT and have entered into a supply agreement with this supplier. There can be no assurance that our sole source third-party manufacturer and suppliers will meet our commercial demands in a timely manner or that we will be to identify and establish relationships with qualified additional or back-up suppliers and manufacturers.

Sales and Marketing

We currently have limited marketing, sales or distribution capabilities, which we established in connection with the launch of HOTSHOT. In order to commercialize 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 the geographic market for the product is limited or the prescriptions for the product will be

written principally by a relatively small number of physicians, we may elect to market and sell the products

ourselves. We do not expect to establish direct sales capabilities until shortly before the products are approved for commercial sale.

We may also 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.

HOTSHOT

We launched HOTSHOT in June 2016 and, to date, our marketing efforts have focused on building brand awareness and usage of HOTSHOT. To drive product trial, we use a variety of sales and marketing strategies, including sponsorships of endurance events, endorsements from endurance athletes, public relations campaigns, print and digital media campaigns, social media advertisements, product sampling and promotional activities at events such as marathons, triathlons, cycling events and obstacle course races.

We use e-commerce strategies to sell online through our direct-to-consumer website and through third-party websites, including a retailer that offers international shipping. We target select geographic areas with strong endurance sports markets, including Los Angeles, San Francisco, Boulder, Boston, Chicago and New York. We focused our sales efforts on these locations to accelerate distribution of our product initially through specialty retailers, such as cycling, running and triathlon stores. We plan to increase our efforts to expand the retail presence of HOTSHOT by targeting more mainstream distribution channels, including larger, national retailers, with an initial focus on building a broader retail presence in select cities.

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 patients suffering from MS spasticity, the current treatments include muscle relaxants, sedatives and Botox injections. Other biotechnology companies are developing drug products to treat MS spasticity that are in various stages of development and GW Pharmaceuticals markets Sativex for spasticity.

The October 2009 American Academy of Neurology ALS Care Guidelines found insufficient data to support or refute any specific interventions for the treatment of muscle cramps, twitches and spasticity in ALS patients. The guidelines did note that in diseases such as MS, effective treatments for similar problems include benzodiazepines, baclofen, dantrolene and tizanidine.

There are no drug products approved by the FDA to treat cramps in patients with CMT. Several symptomatic therapies are used, but data from randomized controlled studies is lacking.

HOTSHOT competes against traditional beverage companies, sports beverage companies and companies developing dietary supplements. We believe the principal elements of competition in the consumer product industry are price, taste, selection, brand recognition, brand loyalty, distribution channel offerings, the effectiveness of the product and discretionary income available to consumers.

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. Conventional foods, 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 Clinical Practices, or GCP, and according to the International Council for Harmonization, or ICH, GCP guidelines, to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a new drug application, or 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 trials.

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

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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 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

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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 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.

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.

Conventional Food Regulation

HOTSHOT is regulated as a conventional food. Food products are subject to extensive regulation in the United States and abroad with respect to their safety, manufacturing, packaging, labeling, advertising and distribution. The manufacture, packaging, labeling, holding, sale, and distribution of foods are also subject to extensive local, state, and foreign government regulation. The Bureau of Customs and Border Patrol, or CBP, a division of the Department of Homeland Security, also regulates shipments containing conventional foods 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. Import 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 requires that substances added to food must either be approved food additives or must be generally recognized as safe, or GRAS, for their intended use. GRAS status can be documented through several means: an

applicable FDA regulation, a notification that is submitted to FDA and to which the agency responds that it has no questions, or through a “self-determination” based on the views of scientific experts that is not submitted to the agency. For ingredients that are the subject of a GRAS “self-determination,” either by us or by our suppliers, there can be no assurance that FDA will agree with the GRAS assessment. Moreover, the agency can and has revised

the status of GRAS ingredients, as it did in June 2015 when FDA revoked the GRAS status of partially hydrogenated oils.

The FDA, a state Attorney General, or others could object to the positioning of our consumer product as a conventional food rather than a dietary supplement. The FDA issued a guidance document in 2014 objecting to the marketing of dietary supplements in the form of conventional beverages. The guidance explains that FDA will consider such factors as the labeling and advertising, product name, product packaging, serving size and recommended daily intake, recommendations and directions for use, marketing practices, and composition when determining whether a product is lawfully marketed as a conventional food. We believe we have designed each of these elements in a way that is appropriate for a conventional food, but cannot rule out the possibility that the FDA or another party could take the position that the product must be regulated as a dietary supplement, requiring changes to the label and potentially to the formulation.

The FDA generally prohibits labeling a food 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 food. Additionally, nutrient content claims, or claims that implicitly or expressly characterize the levels of a nutrient found in a food, may only be made in accordance with FDA regulations. However, other claims, including so-called "structure/function claims," are permitted to be included in labeling for foods without FDA pre-approval. Such statements may describe how a food affects the structure, function or general well-being of the body, or the mechanism of action by which a food may affect the structure, function or well-being of the body, but such statements may not state that a food will reduce the risk or incidence of a disease unless such claim has been reviewed and approved by the FDA as a health claim. Structure/function claims used in labeling must be supported by evidence substantiating that the statement is truthful and not misleading. There can be no assurance, however, that the FDA will not determine that a particular structure/function claim 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.

The regulation of foods may increase or become more restrictive in the future. There can be no assurance that, if more stringent statutes are enacted for foods, 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 food and 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, 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 these type of consumer class action claims target 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). Government regulations in foreign countries may prevent or delay the introduction, or require the reformulation, of certain of our products. We expect that compliance with such foreign governmental regulations will generally be the responsibility of our distributors in those countries and we expect these distributors will be independent contractors that 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, 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 certain products in Europe that are lawfully labeled and sold in the United States.

In the United Kingdom, the principal governing legislation is the Food Safety Act of 1990, or FSA (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 may 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 organizations, 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.

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, then 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 law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. There have been judicial and Congressional challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of

the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been enacted. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, President Trump signed

a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Congress also could consider additional legislation to repeal or replace elements of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, then President Obama 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 2025 unless additional Congressional action is taken. On January 2, 2013, then 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 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 is being phased in over several years. 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.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, at the federal level there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that 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 clinical research, 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.

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 additional 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. 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.

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, individual imprisonment, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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.

Foreign 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 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.

Our Reporting Segments

Effective as of the second quarter of 2016 and in connection with the launch of HOTSHOT, we began operating as two reportable segments: Consumer Operations and Drug Development. We operate in only one geographic area, the United States. See Note 15 to our consolidated audited financial statements included elsewhere in this Annual Report for certain financial information related to our two operating segments, which is incorporated by reference into Item 1 of this Annual Report.

Employees

As of March 2, 2018, we had 20 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

Our Drug Development segment has incurred the majority of our research and development expenses. We incurred $54.1 million of research and development expenses from February 26, 2014 (inception) through December 31, 2017. Our research and development efforts are focused on new product development, including pre-clinical research and clinical trials to develop our drug product candidates.

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 U.S. Securities and Exchange Commission, or 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. Further, a copy of this Annual Report is located at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D. C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov. The information found on our website is not incorporated by reference into this Annual Report or any other report we file with or furnish to the SEC.

## 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 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 as we continue our clinical trials and development of FLX-787 for patients with MS, MND and CMT. 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. Additionally, as we continue to commercialize HOTSHOT, we expect to incur significant costs even if we are unable to generate substantial revenue. As of December 31, 2017, we had cash, cash equivalents and marketable securities of $33.3 million. Based upon our current operating plan, we believe our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital requirements to mid-2019. 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 related to HOTSHOT and changes in regulation. Our future funding requirements will depend on many factors, including but not limited to:

- 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 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 our drug product candidates;
- the impact of our assessment and implementation of strategic alternatives for our consumer business segment; 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 any drug product candidate in our targeted 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. 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. 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;
- seek corporate partners for our drug product candidates 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 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 an accumulated net loss of $111.1 million from February 26, 2014, the date of our inception, to December 31, 2017.

Our losses have resulted principally from expenses incurred in the research and development of our original extract formulation, FLX-787, HOTSHOT and our other drug product candidates and from selling, general and administrative expenses that we have incurred while marketing HOTSHOT and building our business infrastructure.

We expect to incur substantial and increased expenses as we continue our development activities and advance our clinical programs and as we continue to commercialize HOTSHOT. 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 drug products approved for commercialization and to date have generated only limited revenue from the sale of HOTSHOT. The development of biotechnology products is a highly speculative undertaking and involves a substantial degree of risk.

Our activities to evaluate and pursue strategic alternatives may not be successful.

On January 22, 2018, we announced that we had engaged an investment banking firm to assist with the consideration of strategic alternatives for our consumer business segment. We expect to devote significant time and resources to identifying and evaluating strategic alternatives. However, there can be no assurance that our process to identify and evaluate potential strategic alternatives will result in any definitive offer to acquire our consumer business segment or enter into any strategic combination or partnership. If any definitive offer to acquire our consumer business segment or enter into any strategic combination or partnership is received, there can be no assurance as to the terms of any such offer, or that a definitive agreement will be executed or that, if a definitive agreement is executed, the transaction will be consummated. In addition, there can be no assurance that any transaction, involving our Company and/or assets, that is consummated would enhance or allow stockholders to realize stockholder value.

We have generated limited consumer product revenue to date and may never become profitable.

We do not have any drug products approved for marketing and, to date, have generated only approximately $2.3 million in revenue from the sale of HOTSHOT since its launch in the second quarter of 2016. 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. For the foreseeable future, we will have to fund all of our operations and capital expenditures from cash, cash equivalents and marketable securities on hand, licensing fees and grants, if any, strategic alliances and potentially, future equity or debt offerings.

Even if we succeed in developing and commercializing one or more drug product candidates, 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.

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 commercialization of our consumer brand and products is dependent on a number of factors, including:

- the ability to create and maintain brand loyalty from our customers;
- marketing HOTSHOT to endurance athletes and expanding our targeted customers to a broader audience;
- 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.

The number of athletes that suffer from EAMCs, muscle soreness or muscle pain, or the frequency experienced by athletes, may not be as large as we estimate. In addition, consumers may be unwilling to pay for a premium priced consumer product for the treatment and/or prevention of EAMCs and relief from muscle pain and muscle soreness. As a result, we may not be able to attract new customers and generate significant revenue from sales of our consumer product, and we may never achieve profitability.

We may be unable to develop and commercialize any drug product candidate, or substantially increase the sales of HOTSHOT, 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 have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We were formed in February 2014 and, as a result, have a limited operating history upon which to evaluate our business. Prior to the launch of HOTSHOT, our operations had been limited to financing and staffing our company, developing our intellectual property, developing our drug product candidates, conducting proof-of-concept clinical trials and preparing for the launch of our consumer brand and product. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial or obtain marketing approval. We have conducted limited sales and marketing activities necessary for the launch of HOTSHOT. 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 drug products.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), (iii) limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after 2018 and elimination of net operating loss carrybacks, (iv) one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time, and (vi) modifying or repealing many business deductions and credits. Any federal net operating loss incurred in 2018 and in future years may now be carried forward indefinitely pursuant to the Tax Act. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. We will continue to examine the impact the Tax Act may have on our business.

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Risks Related to Clinical Development and Regulatory Approval

We are heavily dependent on the successful development of FLX-787. There is a high risk of failure which would have a material adverse impact on our operations and financial condition.

A substantial portion of our efforts and expenditures are devoted to developing FLX-787 and, accordingly, our business depends heavily on the successful development of FLX-787. If FLX-787 does not demonstrate a clinically meaningful benefit in some or all of our current clinical trials, it could have a material adverse impact on our operations and financial condition and we may be forced to raise additional capital. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or sell or license some of our assets. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

We cannot be certain that any drug product candidate we develop will receive regulatory approval or be successfully commercialized.

We are currently testing FLX-787 in clinical trials in patients with MS, MND and CMT. We have also studied FLX-787 and other single molecule TRP agonists in our electrically-induced cramp model. While we understand the physical properties of the TRP activators in our extract formulation and their interaction with the primary sensory neurons in the mouth, throat, esophagus and stomach, we do not know whether it is this interaction that produced the reduction in muscle cramps observed in the studies in our electrically-induced cramp model. One of our studies of FLX-787 in subjects with nocturnal leg cramps did not show a statistically significant effect on the pre-specified endpoints. We will need to determine the most appropriate dosage level and delivery mechanism for any drug product candidate. If we are not able to develop drug product candidates that are safe and effective, 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 a 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 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 are in early stages of development there is a high risk of failure and results of earlier studies and trials may not be predictive of future trial results.

Our early clinical studies of FLX-787 in reducing electrically-induced muscle cramps and the results from our ALS clinical trial conducted in Australia may not be predictive of the results of any current or future clinical trials in MS, MND or CMT, or future clinical trials that we may conduct in other neurological conditions. 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 trials has not been validated and the methods of analyzing the results have not been widely agreed upon. As a result, we cannot be certain that our preclinical studies and clinical trials performed to date are an accurate predictor of the efficacy of product candidates in preventing or reducing muscle cramps and spasms. If our clinical trials do not successfully demonstrate the efficacy of our product candidates for MS, MND or CMT patients, our ability to develop and commercialize our drug product candidates may be limited. Clinical development involves an expensive and time-consuming process with an uncertain outcome and we may never succeed in developing marketable products or generating product revenue.

We are currently conducting an exploratory Phase 2 clinical trial in patients with MS, a Phase 2 clinical trial in patients with MND, including ALS, and a Phase 2 clinical trial in patients with CMT. Future clinical trials that we conduct 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. If the FDA or any ethics committee prevents a trial from beginning or an ongoing trial from continuing, our ability to develop drug products may be delayed.

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 clinical trials 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 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 or formulation 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;
- 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 rely on CROs and clinical trial sites to ensure the

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proper and timely conduct of our clinical trials, and while we will have agreements governing their committed activities, we 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;
- 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;
- 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 the studies of our drug product candidates have reported any treatment related serious adverse events, or SAEs. However, there is no guarantee that subjects in our future clinical trials will not experience SAEs. Any side effects could affect subject recruitment or the ability of enrolled subjects to complete clinical trials or result in potential product liability claims, which may harm our business, financial condition and prospects significantly. Further, if we or others identify undesirable side effects caused by our drug product candidates or consumer products, a number of potentially significant negative consequences could result, including:

- 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 HOTSHOT; 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, could substantially increase the costs of commercializing our product candidates as well as costs associated with HOTSHOT.

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 4 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.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies generally are required to promote their drug products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

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 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 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. 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 trials 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 Council for 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. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, our ongoing clinical trial in MS is being conducted outside of the United States, which makes it more difficult for us to monitor CROs and perform visits of our clinical trial sites. As a result, we 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 and package our supplies for our clinical studies and we intend to rely on third parties to produce commercial supplies of any approved drug product candidate, if marketed. Our commercialization of any of our drug product candidates 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 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 or package the clinical supplies of our product candidates for our planned studies, and we lack the resources and the capability to manufacture on a commercial scale. The facilities used by our contract manufacturers to manufacture and package 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 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. If we were unable to obtain product for our clinical studies 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 manufacturers 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. 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, 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.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product for our clinical studies 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 our drug product candidates. 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 depend on third-party manufacturers and suppliers, including sole source manufacturers and suppliers, for HOTSHOT. We may not be able to maintain these relationships and could experience supply disruptions outside of our control.

We rely on a network of third-party manufacturers to supply materials and produce HOTSHOT. Our supply chain for sourcing raw materials and production is a multi-step endeavor. Third-party contract suppliers provide us with raw materials and our co-packer converts these raw materials into finished goods available for sale. Establishing and managing this supply chain requires a significant financial commitment and the creation and maintenance of numerous third-party contractual relationships. Although we attempt to effectively manage the business relationships with companies in our supply chain, we do not have control over their operations. As a result of our reliance on these third-party manufacturers and suppliers, including a sole source co-packer and sole source suppliers of certain components of HOTSHOT, we could be subject to significant supply disruptions.

We currently rely, and expect to continue to rely, on a sole source third-party co-packer to produce, bottle and package HOTSHOT and have entered into a production agreement with this co-packer. We rely on a third party as the sole source for certain of the raw materials in HOTSHOT and have entered into a supply agreement with this supplier. There can be no assurance any of our sole source third-party manufacturers and suppliers will meet our commercial demands in a timely manner or that we will be to identify and establish relationships with qualified additional or back-up suppliers and manufacturers. Any supply or manufacturing disruptions could disrupt the sales of our consumer product, which could have a material adverse impact on our business.

We are dependent on a limited number of fulfillment and distribution partners. If we are unable to obtain shipments of product from our vendors and deliver merchandise to our customers in a timely and cost-effective manner, our business and results of operations would be harmed.

We cannot control all of the various factors that might affect our timely and cost-effective procurement of products from our vendors and delivery of products to our customers. We use third-party fulfillment partners to fulfill orders of HOTSHOT, including shipping HOTSHOT to and from warehouse and distribution facilities and shipping to customers. We are therefore subject to the risks, including increased fuel costs, security concerns, labor disputes, union organizing activity, and inclement weather, associated with our carriers' ability to provide product fulfillment and delivery services to meet our distribution and shipping needs. Failure to procure and deliver merchandise, either to our fulfillment partners or to our customers, in a timely and accurate manner would harm our reputation, our brand, our business, and our results of operations. In addition, any increase in fulfillment costs and expenses could adversely affect our business and operating results.

We may not be successful in establishing development and commercialization collaborations, which 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 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 our consumer product. 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 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 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

If we are unable to attract and retain customers and do so at an acceptable cost, we will be unable to generate significant revenue for HOTSHOT and achieve profitability.

Since launch, we have promoted HOTSHOT as a product that is scientifically proven to prevent and treat muscle cramps. In a recent in-home study, the vast majority of endurance and non-endurance athletes survey reported that HOTSHOT was effective in helping reduce muscle soreness and muscle pain. We have started to promote these added benefits to endurance athletes and are now promoting the full benefits of HOTSHOT to a larger target market of non-endurance athletes. Promoting and positioning HOTSHOT depends largely on the success of our marketing efforts and our ability to provide consistent, high quality customer experiences. We believe that, because we are a small company with low public brand awareness in a competitive market, achieving significant market awareness may require significant marketing expense. To promote our brand and HOTSHOT, we have incurred, and expect to incur, substantial expense in our marketing efforts both to attract and to retain customers.

Consumer acceptance of HOTSHOT as a product to help prevent and treat muscle cramps and reportedly reduce muscle soreness and reduce muscle pain can be significantly influenced by customer reviews, social media, national media attention, the conduct and statements by athletes using or endorsing a product, other publicity about product use and the discretionary income available to consumers. Our promotional activities may not be effective in building our brand awareness and customer base to the extent necessary to generate sufficient revenue to become profitable. Further, we expect to increase our efforts to sell HOTSHOT to retail locations in select markets. If we are not able to obtain a significant retail presence in the future, we may never generate significant revenue from HOTSHOT.

The success of HOTSHOT also depends, in large part, on our ability to attract visitors to our website and convert them into customers in a cost-effective manner. Search engine and other online marketing initiatives comprise a substantial part of our marketing efforts, and our ability to manage costs associated with these initiatives, or to find other channels to acquire and retain customers cost-effectively. If we are unable to attract customers in a cost-effective manner, we may not become profitable.

Even if we are successful generating brand awareness, we may not build a critical mass of repeat customers that continue to purchase our consumer product. After their initial purchase, consumers may elect not to purchase our product for a variety of different reasons, including its taste, price or effectiveness or the customer's limited need. If consumers do not purchase HOTSHOT repetitively, then we will not generate significant revenue from our consumer product and achieve profitability.

The beverage market is subject to some seasonal variations and we expect the impact of seasonality may be more significant for HOTSHOT than it is for other beverages. Given that our customers' exercise patterns may vary with the seasons, we expect HOTSHOT sales to be generally higher during the warmer months when athletes may be more inclined to exercise. Our business will be harmed if customers cease using HOTSHOT during periods of inactivity and do not begin purchasing HOTSHOT in their next training cycle.

If we cannot compete successfully for market share against other pharmaceutical companies, dietary supplement companies and consumer companies, we may not achieve sufficient product revenue and our business will suffer. HOTSHOT competes against both small and large companies developing and marketing dietary supplement and conventional beverages. We believe the principal elements of competition in the consumer product industry are price, taste, selection, brand recognition, brand loyalty, distribution channel offerings, the effectiveness of the product and discretionary income available to consumers. If our consumer product gains market acceptance, we

are likely to experience increased competition 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.

If one of our drug candidates is approved in the future, 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.

Complying with new and existing government regulations for our consumer products, 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 require the reformulation of our products.

HOTSHOT is regulated as a conventional beverage by the FDA. We believe the prevention and treatment of EAMCs is an appropriate marketing claim for a conventional beverage 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 conventional beverages. The FDA may determine that a particular conventional beverage 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 conventional beverages containing that ingredient. Further, the FDA may believe our consumer product is more appropriate regulated as a dietary supplement and require that we make adjustments to our label, which may materially and adversely affect our marketing efforts.

The FDA or FTC may also determine that certain labeling, advertising and promotional claims, statements or activities with respect to a conventional beverage 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 conventional beverage and subject us to

administrative, civil or criminal penalties.

Under the FDA Food Safety Modernization Act, or FSMA, the FDA may suspend a facility's registration (and revoke 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. FDA also has authority under FSMA to issue a mandatory product recall when a company does not voluntarily recall food that poses a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death, after first being asked to do so by FDA.

The FDA has published final regulations for the seven major rules implementing FSMA. In particular, there are new requirements that affect food manufacturing and food imports. The regulation on Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls requirements for human food establishes new requirements, including supplier verification, for safely manufacturing food for U.S. consumption.

The FDA's Foreign Supplier Verification Programs, or FSVP, requires all "importers" of food into the U.S. to develop supplier verification programs of their foreign suppliers.

The FDA and the 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 conventional beverages and has instituted numerous enforcement actions against dietary supplement and conventional beverage 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 and conventional beverage 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 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 conventional beverages, 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.

The majority of our inventory is primarily concentrated in two warehouse locations operated by our third party logistics partner, which exposes us to the risk of natural disasters or other force majeure events. Losses at either location could materially adversely affect our product distributions, sales and consumer satisfaction.

The inventory of HOTSHOT is primarily concentrated in two warehouse locations. Any significant disruption to the operation of either warehouse location for any reason, such as a power failure, equipment breakdown, workforce disruption, or natural or similar disasters, could materially adversely affect our product distribution, sales and consumer satisfaction.

Our network and communications systems are vulnerable to system interruption and damage, which could limit our ability to operate our business and could have a material adverse effect on our business, financial condition or results of operations.

Our ability to receive and fulfill orders promptly and accurately is critical to our success and largely depends on the efficient and uninterrupted operation of our computer and communications hardware and software systems. We may experience periodic system interruptions that impair the performance of our transaction systems or make our website inaccessible to our customers. These system interruptions may prevent us from efficiently accepting and fulfilling orders, sending out promotional emails and other customer communications in a timely manner, introducing new features on our website, or promptly responding to customers. Frequent or persistent interruptions in our services could cause current or potential customers to believe that our systems are unreliable, which could cause

them to avoid our website, drive them to our competitors, and harm our reputation. To minimize future system interruptions, we must continue to improve our systems and network infrastructure to accommodate increases in website traffic and sales volume. We may be unable to promptly and effectively upgrade and expand our systems and integrate additional functionality into our existing systems. In addition, upgrades to our systems may cause existing systems to fail or operate incorrectly. Any unscheduled interruption in our services could result in fewer orders, additional operating expenses, or reduced customer satisfaction, any of which would harm our business, financial condition and operating results. In addition, the timing and cost of upgrades to our systems and infrastructure may substantially impact the costs of operating our consumer business.

Our systems and operations and those of our partners, suppliers and Internet service providers are vulnerable to damage or interruption from fire, flood, earthquakes, power loss, server failure, telecommunications and Internet service failure, acts of war or terrorism, computer viruses and denial-of-service attacks, physical or electronic break-ins, sabotage, human error and similar events. Any of these events could lead to system interruptions, order fulfillment delays, and loss of critical data for us, our partners, our suppliers, or our Internet service providers, and could prevent us from accepting and fulfilling customer orders. Any significant interruption in the availability or functionality of our website or our customer processing, distribution, or communications systems, for any reason, could seriously harm our business, financial condition, and operating results.

We could be harmed by data loss or other security breaches.

Our servers, and those of our partners, are vulnerable to computer viruses, physical or electronic break-ins and similar disruptions, which could lead to interruptions and delays in our service and operations as well as loss, misuse or theft of data. Any attempts by hackers to disrupt our service or our internal systems or those of our partners, if successful, could harm our business, be expensive to remedy and damage our reputation. Although we have developed systems and processes that are designed to protect customer information and prevent data loss and other security breaches, such measures cannot provide absolute security. In addition, we rely on third-party technology and systems in certain aspects of our businesses, including encryption and authentication technology to securely transmit confidential information. Any significant disruption to our service or internal computer systems could adversely affect our business 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 product candidates, could hinder or prevent our products' commercial success.

Our ability to commercialize our drug product 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 product 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;
- 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. 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. 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 were not effective in preventing or treating muscle cramps or other marketed product attributes or 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, loss, 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. The insurance industry has become more selective in offering certain types of insurance, including product liability, product recall, cybersecurity and property casualty insurance. There can be no assurance that we will be able to obtain or maintain adequate amounts of 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.

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Unfavorable publicity or consumer acceptance of HOTSHOT or of dietary supplements or conventional beverages, 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, social media, scientific research or findings, national media attention, the conduct and statements by athletes endorsing a product, other publicity about product use and discretionary income available to consumers. 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 conventional beverage and dietary supplement industries may limit the number of individuals that believe our consumer products are effective in preventing muscle cramps or providing any other claimed benefit, which may negatively our ability to generate significant sales from our consumer products. For instance, many consumers currently believe that hydration, stretching and sports drinks are sufficient to prevent EAMCs. To successfully market HOTSHOT, 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. There is no guarantee that consumers will be willing to use our consumer product, particularly in light of the fact that HOTSHOT is priced at a premium to many conventional beverages. If consumers are not willing to purchase HOTSHOT, our ability to generate significant revenue from the sale of HOTSHOT may be limited.

Scientific research or publicity could be unfavorable to the dietary supplement and conventional beverage industries 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. Further, we have entered into endorsement agreements with professional athletes and expect to continue to do so in the future. Any misconduct by these athletes or negative statements about our product by these athletes may limit our ability to generate significant consumer product sales.

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.

HOTSHOT is formulated to address the needs of athletes and we expect to formulate our drug product candidates to address the needs of individuals suffering from severe neurological diseases. As a conventional beverage, we market our consumer products only to athletes suffering from EAMCs and not to 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 severe neurological 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 ACA was enacted, which includes measures that have or will 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;
- 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; 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.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. and we expect there will be additional challenges and amendments in the future. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been enacted. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of

a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Congress also could consider additional legislation to repeal or replace elements of the ACA. We cannot predict how the ACA, its possible repeal, or any legislation that may be proposed to replace the ACA will impact our business.

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 2025 unless additional Congressional action is taken. In January 2013, then 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 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. Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, at the federal level there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that healthcare reform measures that have been and 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 clinical research, and 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 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 created additional 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.

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

The federal Open Payments program, created under the Physician Payments Sunshine Act within 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 significant administrative, criminal and civil penalties, damages, fines, individual imprisonment, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 have a material adverse effect on our business and results of operations.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on William McVicar, our President and Chief Executive Officer, Thomas Wessel, our Chief Medical Officer, and John McCabe, our Chief Financial Officer. Although we have employment agreements with Drs. McVicar and Wessel and Mr. McCabe, these agreements do not prevent them from

terminating their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of 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 2, 2018, we had 20 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;
- continuing the commercialization of HOTSHOT;
- assessing strategic alternatives for our consumer business segment;
- 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, sales 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 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.

Risks Related to Intellectual Property

Our proprietary rights may not adequately protect our intellectual property and products, and if we cannot obtain or maintain adequate protection of our intellectual property rights, we may not be able to successfully market our 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 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 HOTSHOT and our drug product candidates 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 any drug product candidates and consumer products we develop and/or commercialize, 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

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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. For instance, we treat the formulation of HOTSHOT as a trade secret. 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 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. 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 include 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. 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.

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 consumer products and/or 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.

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 common 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 are an important element of the success of our consumer brand and products. We have obtained a trademark for the HOTSHOT name and other marks associated with our consumer brand. There can be no assurance 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.

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:

- negative results from, delays in commencing or completing, or terminating our clinical trials;
- inability to obtain additional funding;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- failure to generate significant sales for HOTSHOT;
- an announcement related to the outcome of our review of strategic alternatives for our consumer business segment;
- 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;
- 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;
- 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 conventional beverage 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; and
- changes in the market valuations of similar companies.

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.

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.

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.

As of March 2, 2018, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned approximately 45.6% 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 you may believe are in your best interest as one of our stockholders or entrench our management and/or the board of directors.

Our common stock is thinly traded and in the future, may continue to be thinly traded, and our stockholders may be unable to sell at or near asking prices or at all if they need to sell their shares to raise money or otherwise desire to liquidate such shares.

To date, we have a low volume of daily trades in our common stock on The Nasdaq Global Market. Our stockholders may be unable to sell their common stock at or near their asking prices or at all, which may result in substantial losses to our stockholders. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline significantly in the event that a large number of our common stock are sold on the market without commensurate demand, as compared to a seasoned issuer that could better absorb those sales without adverse impact on its share price.

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 in 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 $1.07 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 $1.0 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 continue to incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

As a public company, we 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. 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 regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

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.

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. 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.

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 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.

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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters are located at a 7,234 square foot leased facility in Boston, MA, which is used for our corporate, research and development and sales and marketing functions. Our lease expires on August 31, 2019. We believe that our existing facility is 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 began trading on The Nasdaq Global Market on January 29, 2015 under the symbol "FLKS." Prior to that time, there was no public market for our common stock. The following tables sets forth the high and low sales prices per share of our common stock as reported on The Nasdaq Global Market for the periods indicated.

| Year Ended December 31, 2017 | High | Low |
|---|---|---|
| First Quarter | $5.78 | $4.00 |
| Second Quarter | $4.57 | $3.06 |
| Third Quarter | $4.43 | $3.18 |
| Fourth Quarter | $4.34 | $2.74 |

| Year Ended December 31, 2016 | High | Low |
|---|---|---|
| First Quarter | $12.48 | $6.53 |
| Second Quarter | $13.16 | $9.06 |
| Third Quarter | $12.10 | $10.33 |
| Fourth Quarter | $11.73 | $4.67 |

On March 2, 2018, the last reported sale price of our common stock was $4.18.

Holders of Record

As of March 2, 2018, we had approximately 24 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.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities

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We did not purchase any of our registered equity securities during the period covered by this Annual Report.

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.

Item 6. Selected Consolidated Financial Data

The following table sets forth our selected consolidated financial data. We derived the consolidated statement of operations data for each of the years ended December 31, 2017, December 31, 2016 and December 31, 2015, and the consolidated balance sheet data as of December 31, 2017 and December 31, 2016 from our audited consolidated financial statements, included elsewhere in this Annual Report. The statements of operations data for the period from inception (February 26, 2014) to December 31, 2014, and the balance sheet data as of December 31, 2015 and December 21, 2014, are derived from our audited financial statements, which are not included herein. 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. The selected consolidated financial data in this section is not intended to replace our consolidated financial statements and the related notes thereto.

| | Year Ended December 31, 2017 | Year Ended December 31, 2016 | Year Ended December 31, 2015 | Period from February 26, 2014 (Inception) to December 31, 2014 |
|---|---|---|---|---|
| Consolidated Statement of Operations Data: | | | | |
| Net product revenue | $1,260,973 | $989,918 | $— | $— |
| Other revenue | 13,526 | 20,745 | — | — |
| Total revenue | 1,274,499 | 1,010,663 | — | — |
| Costs and expenses: | | | | |
| Cost of product revenue | 506,530 | 662,747 | — | — |
| Research and development | 16,989,911 | 20,378,161 | 12,749,379 | 4,003,911 |
| Selling, general and administrative | 18,503,684 | 19,855,987 | 16,464,279 | 4,025,895 |
| Total costs and expenses | 36,000,125 | 40,896,895 | 29,213,658 | 8,029,806 |
| Loss from operations | (34,725,626) | (39,886,232) | (29,213,658) | (8,029,806) |
| Interest income, net | 291,964 | 393,109 | 72,028 | 18,946 |
| Net loss attributable to common stockholders | $(34,433,662) | $(39,493,123) | $(29,141,630) | $(8,010,860) |

| | | | | |
|---|---|---|---|---|
| Net loss per share attributable to common stockholders — basic and diluted[1] | $(1.99) | $(2.43) | $(2.08) | $(4.57) |
| Weighted-average number of common shares outstanding — basic and diluted[1] | 17,260,626 | 16,233,985 | 14,032,916 | 1,753,024 |

(1) See Note 2 and Note 14 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, 2017 | As of December 31, 2016 | As of December 31, 2015 | As of December 31, 2014 |
|---|---|---|---|---|
| Consolidated Balance Sheet Data: | | | | |
| Cash, cash equivalents and marketable securities | $33,315,759 | $61,074,973 | $93,651,992 | $33,854,153 |
| Working capital[(2)] | 28,687,467 | 58,578,074 | 89,400,216 | 33,157,388 |
| Total assets | 34,992,772 | 63,214,979 | 95,069,838 | 35,611,398 |
| Convertible preferred stock | — | — | — | 41,031,167 |
| Accumulated deficit | (111,079,275) | (76,645,613) | (37,152,490) | (8,010,860) |
| Total stockholders' equity (deficit) | 29,105,888 | 59,317,386 | 92,192,408 | (6,538,340) |

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

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 Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this Annual Report. This discussion and analysis and other parts of this Annual Report 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. You should carefully read the "Risk Factors" section of this Annual Report 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."

Introduction

Our Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, is provided in addition to the accompanying consolidated financial statements and notes to assist readers in understanding our results of operations, financial condition, and cash flows. MD&A is organized as follows:

Overview - A discussion of our business and overall analysis of financial and other highlights in order to provide context for the remainder of MD&A.

Results of Operations - An analysis of our financial results comparing the year ended December 31, 2017 to the year ended December 31, 2016, and the year ended December 31, 2016 to the year ended December 31, 2015.

Liquidity and Capital Resources - An analysis of changes in our consolidated balance sheets and cash flows, and discussion of our financial condition and potential sources of liquidity.

Critical Accounting Policies and Significant Judgments and Estimates - A discussion of critical accounting policies and those that require us to make subjective estimates and judgments.

Overview

We are a biotechnology company that is developing innovative and proprietary treatments for muscle cramps, spasms and spasticity associated with severe neurological conditions and exercise-associated muscle cramps. Our lead drug product candidate, FLX-787, is currently being studied in an exploratory Phase 2 clinical trial in Australia in patients with multiple sclerosis, or MS, and in two Phase 2 clinical trials in the United States. One Phase 2 clinical trial in the United States is in patients with motor neuron disease, or MND, primarily with amyotrophic lateral sclerosis, or ALS, who suffer from muscle cramps. FLX-787 is being developed for ALS under fast track designation which was granted by the Food and Drug Administration, or FDA, in July 2017. The other Phase 2 clinical trial in the United States is in patients with Charcot-Marie-Tooth disease, or CMT, who suffer from muscle cramps. In 2016, we launched our consumer product, HOTSHOT®, to prevent and treat exercise-associated muscle cramps, or EAMCs.

Muscle cramps and spasms are involuntary, often painful, contractions that can last several minutes and, in many instances, result in prolonged soreness. Muscle cramps and spasms are thought to result from hyperexcitable alpha-motor neurons. Spasticity is characterized by the combination of weakness and velocity-dependent resistance to stretch, in the same muscle. This reflex hyperexcitability may be due to lost inhibition in spinal cord circuits.

FLX-787, HOTSHOT and our other drug product candidates are based on a mechanism of action we describe as chemical neurostimulation. We believe chemical neurostimulation to be a process in which a molecule, such as FLX-787, acts topically on the surfaces of the mouth, throat, esophagus and stomach to produce a sensory signal by activating nerves in those tissues. That signal is thought to ultimately result in a beneficial effect. Specifically, our product candidates activate certain receptors known as transient receptor potential, or TRP, ion channels in primary sensory neurons producing a signal believed to inhibit neuronal circuits and thereby reduce hyperexcitability in the neurons that fire muscles. Reduced alpha-motor neuron hyperexcitability in spinal cord circuits is thought to suppress repetitive firing of alpha-motor neurons, thereby preventing or reducing muscle cramps and spasms, and potentially reducing reflex hyperexcitability and therefore spasticity.

HOTSHOT is our consumer beverage containing a proprietary formulation of TRP activators. Historically, we have marketed HOTSHOT to endurance athletes who drink it before, during and after exercise to prevent and treat EAMCs. We recently expanded our efforts to address a larger target market of both endurance and non-endurance

athletes and to promote an additional set of benefits. In a recent in-home study, the vast majority of endurance and non-endurance athletes surveyed reported that HOTSHOT was also effective in helping reduce muscle soreness

and muscle pain. We have started to promote these additional benefits to endurance and non-endurance athletes in order both to attract new consumers and to increase use occasions among current consumers.

Concurrent with our efforts to grow HOTSHOT, on January 22, 2018, we disclosed that we engaged an investment banking firm to assist with the consideration of strategic alternatives for our consumer business segment.

Effective in the second quarter of 2016 and in connection with the launch of HOTSHOT, we began operating as the following two reportable segments:

- the Consumer Operations segment, which reflects the total revenue and costs and expenses for HOTSHOT and our consumer operations; and
- the Drug Development segment, which reflects the costs and expenses related to our efforts to develop innovative and proprietary drug products to treat muscle cramps, spasms and spasticity associated with severe neurological conditions.

We disclose information about our reportable segments based on the way that we organize segments within the Company for making operating decisions and assessing financial performance. See Note 15 to our consolidated financial statements included elsewhere in this Annual Report for certain financial information related to our reportable segments.

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. Our net loss and our accumulated deficit was $34.4 million and $111.1 million, respectively, for the year ended December 31, 2017, and as of December 31, 2017. 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 to continue incurring significant research and development expenses related to the development of our drug product candidates and significant selling, general and administrative expenses as we support our research and development efforts, operate as a public company and continue to commercialize HOTSHOT. As a result, we will need additional capital to fund our future operations.

Components of Operating Results

Revenue

Revenue is comprised of net product revenue and other revenue. Net product revenue includes sales of HOTSHOT finished goods to e-commerce customers, specialty retailers and sports teams. Other revenue consists of payments made by customers for expedited shipping and handling. Revenue is recognized when persuasive evidence of an arrangement exists, delivery of the product has occurred, the sales price is fixed or determinable and collectibility is reasonably assured. As we currently do not have adequate history to accurately estimate refunds, all e-commerce sales, and their related costs, are deferred and revenue is recognized once the refund period lapses. For sales through September 30, 2016, we issued refunds to e-commerce customers, upon request, within 21 days of shipment. When we began selling HOTSHOT on a third-party e-commerce website in October 2016, the refund period and related deferral period increased, as we began offering refunds to e-commerce customers, upon request, within 30 days of delivery, for purchases subsequent to September 30, 2016. Specialty retailers and sports team sales are not offered a right of return or refund and revenue is recognized at the time products are delivered. Discounts provided to customers are accounted for as a reduction of product revenue. Total revenue is presented net of any taxes collected from customers and remitted to governmental authorities.

When purchasing via our branded website, customers may purchase HOTSHOT in packs of 6, 12 bottles or 24 bottles and are offered a first-time purchase discount for a 6 pack. In 2018, we began offering a pack of 3 bottles and began offering the first-time purchase discount on this configuration. We expect that a significant portion of our total revenue will continue to be generated through our branded website. We also sell HOTSHOT via third-party e-commerce websites, including a retailer that offers international shipping. Generally, we realize higher revenue per bottle from our e-commerce sales as opposed to third-party website, sports team and specialty retailer sales. HOTSHOT is generally sold to specialty retailers and sports teams in multi-pack cases.

Future sales of HOTSHOT are expected to vary from quarter to quarter and will be impacted by the number of visitors attracted to our branded website and third-party websites, those that purchase, seasonality and the amount of repeat sales that we are able to generate through e-commerce. Future sales will also be impacted by the amount of revenue that we are able to generate through retail channels. Our inability to generate sufficient revenues could have a material

adverse impact on our consumer operations.

In the future, we may generate revenue from a combination of consumer product sales, drug 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 drug 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 from the sale of our drug 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, obtain regulatory approval for them, or fail to successfully commercialize these drug products, our results of operations and financial position would be materially adversely affected.

Cost of Product Revenue

We outsource the manufacture of HOTSHOT to a co-packer. Cost of product revenue includes the cost of raw materials utilized to produce HOTSHOT, co-packing fees, repacking fees, in-bound freight charges and warehouse and transportation charges incurred to bring the finished goods to salable condition. All other costs incurred after this condition is met are considered selling costs and included in selling, general and administrative expenses.

Cost of product revenue includes write-offs of inventory that becomes obsolete, that has a cost basis in excess of its estimated realizable value, or that exceeds projected sales. The amount of inventory write-offs will vary based upon factors such as inventory levels, production levels, projected sales of HOTSHOT and shelf-lives of our inventory components. If we are not successful in generating sufficient levels of revenue from HOTSHOT or if our other estimates prove to be inaccurate, future inventory write-offs may be required.

Cost of product revenue also includes depreciation expense related to manufacturing equipment purchased to support production, as well as royalty amounts payable to certain of our founders on HOTSHOT sales.

Research and Development Expenses

Our research and development expenses to date include the costs incurred related to the development and testing of our extract formulation for muscle cramps in the United States and expenses related to the testing and development of our drug product candidates, including FLX-787. Research and development costs include salaries and other compensation-related costs, such as stock-based compensation, for research and development employees, costs of clinical studies of our extract formulation and drug product candidates, 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 activities are central to our business model. Drug 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 to continue incurring significant research and development expenses related to the development of our drug product candidates. It is difficult to determine, with certainty, the duration and completion costs of our current or future pre-clinical programs and clinical trials of our drug product candidates.

In addition, the probability of success for each drug product candidate will depend on numerous factors, including competition, product safety and efficacy, patent production, 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 drug product candidates, as well as an assessment of each product candidate's commercial potential.

Research and development expenses also include costs incurred related to our Consumer Operations segment for HOTSHOT, including athlete-based efficacy studies, product formulation work, stability studies and other efforts.

Selling, General and Administrative Expenses

Selling, general and administrative expenses includes 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, accounting fees, insurance costs, costs for consultants who we utilize to supplement our personnel, travel costs and facility and office-related costs not included in research and development expenses.

Selling, general and administrative expenses also include costs related to our Consumer Operations segment for our consumer brand and HOTSHOT. Prior to the launch of HOTSHOT, these costs included personnel costs, brand development costs, market research costs, product design costs, pre-launch activity costs and other external costs.

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Since the launch of HOTSHOT, we continue to incur costs related to personnel and market research, and are also incurring costs related to our print and digital media campaigns, public relations activities and costs related to the distribution of our product. These distribution costs include shipping and handling costs incurred once our product is in salable condition.

Our selling, general and administrative expenses may increase as we support our research and development efforts, operate as public company and continue to commercialize HOTSHOT.

Interest Income, Net

Interest income, net primarily consists of interest income from our cash, cash equivalents and marketable securities, amortization and accretion of investment premiums and realized gains and losses.

Results of Operations

Year Ended December 31, 2017 Compared to the Year Ended December 31, 2016

The following table sets forth our results of operations for the year ended December 31, 2017 compared to the year ended December 31, 2016.

| | | | Change | |
|---|---|---|---|---|
| | Year Ended December 31, 2017 | Year Ended December 31, 2016 | $ | % |
| Net product revenue | $1,260,973 | $989,918 | $271,055 | 27 % |
| Other revenue | 13,526 | 20,745 | (7,219) | (35)% |
| Total revenue | 1,274,499 | 1,010,663 | 263,836 | 26 % |
| Costs and expenses: | | | | |
| Cost of product revenue | 506,530 | 662,747 | (156,217) | (24)% |
| Research and development | 16,989,911 | 20,378,161 | (3,388,250) | (17)% |
| Selling, general and administrative | 18,503,684 | 19,855,987 | (1,352,303) | (7 )% |
| Total costs and expenses | 36,000,125 | 40,896,895 | (4,896,770) | (12)% |
| Loss from operations | (34,725,626 ) | (39,886,232 ) | 5,160,606 | (13)% |
| Interest income, net | 291,964 | 393,109 | (101,145) | (26)% |
| Net loss | $(34,433,662) | $(39,493,123) | $5,059,461 | (13)% |

Revenue

Our Consumer Operations segment generated all of our revenue during the year ended December 31, 2017, totaling $1.3 million, as compared to $1.0 million for the year ended December 31, 2016 through sales of HOTSHOT and expedited shipping and handling purchases. HOTSHOT launched in the second quarter of 2016. Revenue was driven by our HOTSHOT marketing, sales and promotional efforts, including our print and digital media campaigns, public relation efforts, field marketing efforts and other sales and promotional activities.

Sales via e-commerce represented approximately 82% of our total revenue for the year ended December 31, 2017 compared to 92% for the year ended December 31, 2016. E-commerce revenue decreased as a percentage of total revenue in the comparative periods due to an increase in specialty retailer and sports team revenue in 2017.

During the year ended December 31, 2017, we sold approximately 298,000 bottles of HOTSHOT at an average total revenue per bottle of $4.28, compared to 210,000 bottles at an average total revenue per bottle of $4.81 during the year ended December 31, 2016. The decrease in average total revenue per bottle is due to various price promotions that were offered to customers during 2017 to attract new and repeat customers. The increase in the number of bottles sold was a result of HOTSHOT being sold for a full year in 2017, compared to a partial year in 2016.

Cost of Product Revenue

All costs of product revenue are recorded by our Consumer Operations segment and relate to the production and sale of HOTSHOT. Cost of product revenue was $0.5 million for the year ended December 31, 2017 compared to $0.7 million for the year ended December 31, 2016. Cost of product revenue during the year ended December 31, 2017 includes the cost of HOTSHOT sold, royalty expense, inventory write-offs of approximately $42,000 related to certain raw materials that are not expected to be used in future production runs and expiring finished goods, and depreciation expense of approximately $0.1 million related to manufacturing equipment used to support production. Cost of product revenue during the year ended December 31, 2016 included the cost of HOTSHOT sold, royalty expense, inventory write-offs of $0.3 million related to HOTSHOT finished goods that were not expected to be sold and depreciation expense of approximately $0.1 million.

Research and Development Expenses

Our Drug Development segment incurred the majority of our research and development expenses. Research and development expenses were $17.0 million for the year ended December 31, 2017 compared to $20.4 million for the year ended December 31, 2016. The 17% decrease of $3.4 million was primarily related to:

- $1.9 million decrease in clinical activities and related work, primarily related to studies or activities completed in the prior year or ramping down in the current year, such as the submission of our IND, costs related to the identification of our drug product candidate and development of our drug substance, offset by startup, formulation and production costs for our FLX-787 Phase 2 clinical trials in the United States, which commenced in 2017, and other related studies and activities;
- $0.9 million decrease in stock-based compensation expense, related primarily to the revaluation of non-employee awards and option grants at lower valuations than the prior year due to decreased stock price;
- $0.3 million decrease related to salaries and benefits as average headcount for research and development personnel decreased compared to the prior year;
- $0.2 million decrease related to our Consumer Operations segment, related to reduced formulation work for HOTSHOT compared to the prior year;
- $0.2 million decrease in consulting expenses as we increased the use of consultants to assist with our IND efforts, which we began in 2016 and completed in the first quarter of 2017; and
- $0.1 million increase in rent expense due to entering into a new lease agreement in 2017 for our current corporate headquarters.

Selling, General and Administrative Expenses

Selling, general and administrative includes expenses that are incurred by our Consumer Operations segment, as well as corporate and unallocated amounts that do not relate to a reportable segment. Selling, general and administrative expenses were $18.5 million for the year ended December 31, 2017 compared to $19.9 million for the year ended December 31, 2016. The 7% decrease of $1.4 million was primarily related to:

- $1.5 million decrease in stock-based compensation expense, related primarily to the revaluation of non-employee awards and option grants at lower valuations than the prior year due to decreased stock price, as well as a stock option award modification in the prior year;
- $0.8 million decrease related to salaries and benefits, as Consumer Operations and corporate headcount decreased from the prior year;
- $0.3 million decrease in external consulting costs within our Consumer Operations segment due to decreased use of consultants;
- $0.6 million of increased costs within our Consumer Operations segment for HOTSHOT print and digital media campaigns and sponsorship programs, as well as costs related to our branded website;
- $0.4 million increase in consulting expenses to supplement our corporate personnel;
- $0.1 million increase in rent expense due to the termination of our lease agreement for our office in New York, NY, as well as increase in rent expense due to entering into a new lease agreement for our current corporate headquarters; and

- $0.1 million increase related to 12 months of distribution costs for HOTSHOT sales in 2017, as the product launched during the second quarter of 2016.

Loss from Operations

Our consolidated loss from operations for the year ended December 31, 2017 totaled $34.7 million. Of this total, $8.9 million of the operating loss was incurred by our Consumer Operations segment, $16.7 million was incurred by our Drug Development segment and the remaining $9.1 million related to corporate and unallocated costs. The operating loss incurred by the Consumer Operations segment was driven by sales, marketing, promotional and distribution costs related to HOTSHOT, and personnel-related expenses, including stock-based compensation. These costs were slightly offset by the total revenue generated from HOTSHOT sales during the year ended December 31, 2017. The operating loss incurred by the Drug Development segment relates to costs incurred for FLX-787 formulation, production and clinical study costs, other clinical study activities and personnel-related expenses, including stock-based compensation, as well as consulting costs.

Interest Income, net

Interest income, net, decreased by $0.1 million in the year ended December 31, 2017 compared to the year ended December 31, 2016 as we had lower available cash to invest.

Year Ended December 31, 2016 Compared to the Year Ended December 31, 2015

The following table sets forth our results of operations for the year ended December 31, 2016 compared to the year ended December 31, 2015.

| | | | Change | |
|---|---|---|---|---|
| | Year Ended December 31, 2016 | Year Ended December 31, 2015 | $ | % |
| Net product revenue | $989,918 | $— | $989,918 | N/A |
| Other revenue | 20,745 | — | 20,745 | N/A |
| Total revenue | 1,010,663 | — | 1,010,663 | N/A |
| Costs and expenses: | | | | |
| Cost of product revenue | 662,747 | — | 662,747 | N/A |
| Research and development | 20,378,161 | 12,749,379 | 7,628,782 | 60 % |
| Selling, general and administrative | 19,855,987 | 16,464,279 | 3,391,708 | 21 % |
| Total costs and expenses | 40,896,895 | 29,213,658 | 11,683,237 | 40 % |
| Loss from operations | (39,886,232) | (29,213,658) | (10,672,574) | 37 % |
| Interest income, net | 393,109 | 72,028 | 321,081 | 446 % |
| Net loss | $(39,493,123) | $(29,141,630) | $(10,351,493) | 36 % |

Revenue

Our Consumer Operations segment generated all of our revenue through sales of HOTSHOT and purchases of expedited shipping and handling. Revenue totaled $1.0 million for the approximate seven month period from the launch of HOTSHOT in June 2016 to December 31, 2016. Revenue was driven by our HOTSHOT pre-launch and launch efforts, print and digital media campaigns, public relation efforts and other sales and promotional activities. Sales via e-commerce represented approximately 92% of our total revenue for the year ended December 31, 2016. From launch in June of 2016 through December 31, 2016, the Company sold approximately 210,000 bottles of HOTSHOT at an average total revenue per bottle of $4.81. There were no sales during the year ended December 31, 2015.

Cost of Product Revenue

All costs of product revenue are recorded by our Consumer Operations segment and relate to the production and sale of HOTSHOT. Cost of product revenue was $0.7 million for the year ended December 31, 2016, and included

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the cost of HOTSHOT sold, depreciation expense related to manufacturing equipment purchased to support production, royalty expense and inventory write-offs. During the year ended December 31, 2016, inventory write offs totaled approximately $0.3 million, primarily related to HOTSHOT finished goods that were not expected to be sold based upon projected sales, estimated product shelf life, the number of units produced, production level requirements and timing of future production runs. There was no cost of product revenue for the year ended December 31, 2015.

Research and Development Expenses

Our Drug Development segment incurred the majority of our research and development expenses. Research and development expenses were $20.4 million for the year ended December 31, 2016 compared to $12.7 million for the year ended December 31, 2015. The 60% increase of $7.6 million was primarily related to:

- $7.5 million of increased costs related to clinical studies of various formulations of our extract formulation and drug product candidates, including FLX-787, in the United States, increased costs related to clinical studies of FLX-787 outside of the United States, IND-supporting activities for FLX-787, and the manufacture of clinical supply;
- $0.6 million increase in consulting expenses to supplement Drug Development segment personnel due to increased activities;
- $0.2 million increase related to our Consumer Operations segment for research and formulation of HOTSHOT;
- $0.6 million decrease in personnel costs incurred by our Drug Development segment, primarily stock-based compensation expense, related to the to revaluation of non-employee awards and option grants at lower valuations than the prior year due to decreased stock price; and
- $0.1 million decrease in other costs, primarily allocated insurance and office-related expenses.

Selling, General and Administrative Expenses

Selling, general and administrative includes expenses that are incurred by our Consumer Operations segment as well as corporate and unallocated amounts that do not relate to a reportable segment. Selling, general and administrative expenses were $19.9 million for the year ended December 31, 2016 compared to $16.5 million for the year ended December 31, 2015. The 21% increase of $3.4 million was primarily related to:

- $1.0 million of increased personnel costs incurred by our Consumer Operations segment, including salaries and other compensation-related costs such as stock-based compensation, due to hiring additional personnel to support the launch of HOTSHOT, and certain employee termination costs;
- $0.6 million of increased corporate personnel costs, including salaries and other compensation-related costs, related to additional administrative personnel hired to support our growth and increased activities;
- $0.6 million of increased external costs within our Consumer Operations segment related to developing our consumer brand and HOTSHOT, including brand development and strategy costs, and marketing and promotional costs for pre-launch and launch activities, as selling commenced in the second quarter of 2016;
- $0.5 million of increased external consulting costs for our Consumer Operations segment, primarily related to supporting HOTSHOT launch activities;
- $0.3 million increase in stock-based compensation expense, primarily related to employee stock option grants, partially offset by the revaluation of non-employee awards at lower valuations due to decreased stock price;
- $0.2 million increase in legal and professional fees, mainly related to patents and related legal work; and
- $0.2 million increase in other costs, primarily insurance and facility-related fees.

Loss from Operations

Our consolidated loss from operations for the year ended December 31, 2016 totaled $39.9 million. Of this total, $10.0 million of the operating loss was incurred by our Consumer Operations segment, $19.6 million was incurred by our Drug Development segment and the remaining $10.2 million related to corporate and unallocated costs. The operating loss incurred by the Consumer Operations segment was driven by production costs, selling, marketing, promotional and branding costs related to preparing for, and executing, the launch of HOTSHOT, and personnel-related expenses, including stock-based compensation. These costs were slightly offset by the total revenue generated from HOTSHOT sales during the year ended December 31, 2016. The operating loss incurred by the Drug Development segment relates to costs incurred for pre-clinical and clinical activities, personnel-related expenses, including stock-based compensation, and consulting costs.

Interest Income, net

Interest income, net, increased by $0.3 million in the year ended December 31, 2016 compared to the year ended December 31, 2015, as we increased our investments in U.S. government securities and corporate debt from money market accounts and interest rates increased, offset by lower available cash to invest.

Liquidity and Capital Resources

Overview

Since inception, we have incurred operating losses and we anticipate that we will continue to incur losses for at least the next several years. To date, we have generated limited revenue from sales of HOTSHOT, and have generated no revenue from any of our drug product candidates. We may not be successful in generating significant revenue from HOTSHOT. We expect to continue incurring significant research and development expenses related to the development of our drug product candidates as well as selling, general and administrative expenses related to supporting our research and development efforts, operating as a public company and supporting our HOTSHOT commercial efforts. 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, 2017, we had $33.3 million in cash, cash equivalents and marketable securities, which were held in bank deposit accounts, money market funds, U.S. government agency securities, commercial paper and corporate debt securities.

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. During 2014, we issued 15,775,221 shares of series A convertible preferred stock and received aggregate net proceeds of $15.6 million, net of issuance costs, and we issued 14,078,647 shares of series B convertible preferred stock and received aggregate net proceeds of $25.4 million, net of issuance costs. 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 IPO. In our IPO, we sold 5,491,191 shares of common stock (including shares sold pursuant to the exercise of an overallotment option granted to the underwriters) that resulted in net proceeds to us of $79.9 million.

As of December 31, 2017, 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

We expect that we will require additional funding 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 rights to commercialize our drug products to partners, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution activities. We also expect to incur additional costs to support our operations as well as the costs associated with operating as a public company.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms,

if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our

product candidates or sell or license some of our assets. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical costs, third-party research and development costs, legal and other regulatory expenses, marketing, promotion and selling 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.

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:

- receiving regulatory approval to conduct clinical trials;
- successfully enrolling, and completing, clinical trials;
- receiving 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 our drug product candidate, FLX-787, is in the early stage 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 FLX-787.

Consumer Brand and Products

The development and growth of HOTSHOT is uncertain, including the timing and resources needed to support successful commercialization. The success of HOTSHOT depends, in large part, on a growth strategy that establishes distribution and placement of the product, attracts consumers and maintains brand loyalty. Delays or unexpected costs related to HOTSHOT could significantly change the costs and timing of expenses associated with our consumer operations.

Concurrent with our efforts to grow HOTSHOT, on January 22, 2018, we disclosed that we engaged an investment banking firm to assist with the consideration of strategic alternatives for our consumer business segment.

Outlook

Based on our research and development plans, our consumer brand and HOTSHOT expenditure plans and our expectations of timing related to the progress of our clinical programs, we expect that our existing cash resources and marketable securities will enable us to fund our costs and expenses, working capital and capital expenditure requirements to mid-2019. 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, and the timing of progress of these efforts is uncertain.

Cash Flows

| | Year Ended December 31, 2017 | Year Ended December 31, 2016 | Year Ended December 31, 2015 |
|---|---|---|---|
| Net cash (used in) provided by: | | | |
| Operating activities | $(27,722,198) | $(32,051,873) | $(20,746,118) |
| Investing activities | 24,489,562 | (12,240,880) | (27,265,091) |
| Financing activities | 2,632 | 22,098 | 80,843,751 |
| Net (decrease) increase in cash and cash equivalents | $(3,230,004) | $(44,270,655) | $32,832,542 |

Operating activities

Net cash used in operating activities for the year ended December 31, 2017 was $27.7 million, a decrease of $4.3 million compared to the same period in the prior year. The use of cash for the year ended December 31, 2017 was primarily related to our net loss for the period of $34.4 million, offset by non-cash charges consisting of stock compensation expense of $4.2 million, and depreciation, amortization and accretion on investments which totaled $0.3 million. Cash used in operations was also offset by a $2.2 million cash inflow from changes in operating assets and liabilities. This inflow was driven by an increase in accounts payable, accrued expenses and other current liabilities, and deferred rent of $2.0 million, and by a decrease in prepaid expenses and other current and noncurrent assets of $0.2 million. The increases in accounts payable and accrued expenses and other current liabilities relate to the timing of invoices, primarily related to clinical trial startup activities for our FLX-787 Phase 2 clinical trials in the United States. The increase in deferred rent is due to signing a direct lease for our corporate headquarters through 2019. The decrease in prepaid expenses and other current assets is mainly due to a decrease in accrued interest as we had lower cash to invest in the current year and as well as the timing of payments for Consumer Operations and corporate expenditures.

Net cash used in operating activities for the year ended December 31, 2016 was $32.1 million, an increase of $11.3 million compared to December 31, 2015. The use of cash for the year ended December 31, 2016 was primarily related to our net loss for the period of $39.5 million, offset by non-cash charges consisting of stock compensation expense of $6.6 million, and depreciation, amortization and accretion on investments which together totaled $0.3 million. Cash used in operations was also offset by a $0.6 million cash inflow from changes in operating assets and liabilities. This inflow was driven by an increase in accounts payable, accrued expenses and other current liabilities of $1.1 million, offset by an increase in prepaid expenses and other current and noncurrent assets of $0.1 million and an increase in inventory of $0.5 million. The increase in accounts payable, accrued expenses and other current liabilities was primarily due to an increase in clinical trial activity and an increase in compensation-related accruals. The increase in prepaid expenses and other current assets relates to the timing of payments for clinical trials and related activities, and the increase in inventory relates to the launch of HOTSHOT in the second quarter of 2016.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2017 compared to the year ended December 31, 2016, increased $36.7 million, primarily related to a $36.3 million increase in net purchases and sales of marketable securities. This included $30.6 million increase in proceeds from maturities and sales of marketable securities and $5.7 million decrease in purchases of marketable securities as our cash balance available for investment

decreased. Property and equipment acquisitions decreased $0.4 million, which primarily related to prior year activity of manufacturing equipment purchased to produce HOTSHOT and development of our branded website for HOTSHOT.

Net cash used in investing activities for the year ended December 31, 2016 compared to the year ended December 31, 2015, decreased $15.0 million, primarily related to a $15.3 million increase in net purchases and sales of marketable securities. This included $14.6 million increase in proceeds from maturities and sales of marketable securities and $0.7 million decrease in purchases of marketable securities. Property and equipment acquisitions increased $0.3 million, primarily related to purchases of manufacturing equipment used to produce HOTSHOT and the development of our branded website for e-commerce sales.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2017 did not change significantly compared to the year ended December 31, 2016. Cash provided by financing activities during the years ended December 31, 2017 and 2016 totaled $2,600 and $22,100, respectively, and related to proceeds from exercises of common stock.

Net cash provided by financing activities of $80.8 million for the year ended December 31, 2015 was primarily related to net proceeds of $79.9 million from completion of our IPO, and $0.4 million related to proceeds from exercises of common stock.

Contractual Obligations

The following summarizes our significant contractual obligations as of December 31, 2017:

| Contractual Obligations | Total | Less Than 1 Year | 1 - 3 Years |
|---|---|---|---|
| Operating lease obligations[(1)] | $777,655 | $466,593 | $311,062 |
| Total | $777,655 | $466,593 | $311,062 |

(1) Consists of our lease agreement for an approximate 7,200 square foot facility used for administrative, sales and marketing and research and development activities in Boston, Massachusetts. The Boston lease expires in August 31, 2019, and has a letter of credit in support of this lease in the amount of $126,595. On July 25, 2017, in conjunction with transitioning our consumer operations to Boston, we terminated our lease in New York, New York, which had been used to support our Consumer Operations segment sales and marketing personnel. As of the termination date, we had no remaining contractual obligations under that lease.

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 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 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 are 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). Royalty amounts earned by the founders during the twelve months ended December 31, 2017 and December 31, 2016 totaled approximately $25,000 and $20,000, respectively. Future royalty payments are not included in the table above as the amount of these payments is not determinable as it is dependent upon the achievement of the earlier mentioned revenue recognition.

Net Operating Loss and Research and Development Carryforwards

As of December 31, 2017, we had deferred tax assets of $28.5 million and deferred tax liabilities of approximately $4,000. 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 and state net operating loss, or NOL, tax carryforward. As of December 31, 2017, we have a federal NOL carryforward of $91.2 million available to

potentially offset future taxable income and state NOL carryforward of $90.4 million. We also have federal research and development tax credit carryforwards of $1.6 million available to potentially offset future

federal income taxes. State research credit carryforwards total approximately $428,000. The federal net operating loss carryforwards and research and development tax credit carryforwards expire at various dates through 2037. 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 net operating loss or research and development credit 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 net operating loss or research and development credit carryforwards 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 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 net operating loss or research and development carryforwards may be limited or lost.

On December 22, 2017, the Tax Cuts and Jobs Act tax was signed into law. This legislation makes significant changes in U.S. tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from the current rate of 35% to 21%. As a result of the enacted law, we were required to revalue deferred tax assets and liabilities at the enacted rate. This revaluation resulted in a decrease in net deferred tax assets of $12.6 million and a corresponding reduction in the valuation allowance against these assets. There is no impact to income tax expense. The other provisions of the Tax Cuts and Jobs Act did not have a material impact on our 2017 consolidated financial statements.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118, or SAB 118, which allows the recording of provisional amounts related to the revaluation of deferred tax assets and liabilities during a measurement period not to extend beyond one year of the enactment date. The ultimate accounting may differ from these provisional amounts due to, among other things, additional analysis, changes in interpretations and assumptions we have made, additional regulatory guidance that may be issued, and actions we may take as a result of the 2017 Tax Act. We expect to complete the final accounting within the measurement period.

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 consolidated 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 consolidated 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 Annual Report on Form 10-K, we believe the following are the critical accounting policies used in the preparation of our consolidated 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 and prepaid expenses as actual costs become known.

Inventory

Inventory consists of costs related to the production of HOTSHOT, which is produced for us by a co-packer. Beginning in the first quarter of 2016, we began capitalizing inventory costs associated with HOTSHOT when it was determined that the inventory had a probable future economic benefit. Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. We periodically analyze our inventory levels, and write down inventory that has become obsolete, that has a cost basis in excess of its estimated realizable value or that exceeds projected sales.

Revenue

Revenue is comprised of net product revenue and other revenue. Net product revenue includes sales of HOTSHOT finished goods to e-commerce customers, specialty retailers and sports teams. Other revenue consists of customer purchases of expedited shipping and handling. Total revenue is recognized when persuasive evidence of an arrangement exists, delivery of the product has occurred, the sales price is fixed or determinable and collectibility is reasonably assured. For sales through September 30, 2016, we issued refunds to e-commerce customers, upon request, within 21 days of shipment. In October 2016, we began offering refunds to e-commerce customers, upon request, within 30 days of delivery, for purchases subsequent to September 30, 2016. As we do not currently have adequate history to accurately estimate refunds, all e-commerce sales, and their related costs, are deferred and revenue is recognized once the refund period lapses. For specialty retailer and sports team sales, total revenue is recognized at the time products are delivered to customers. We do not offer a right of return or refund to specialty retailers or sports teams.

Discounts provided to customers are accounted for as a reduction of product revenue.

Total revenue is presented net of taxes collected from customers and remitted to governmental authorities.

Stock-Based Compensation

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. 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, 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 compensation expense related to awards to employees with performance conditions is recognized based on grant date fair value over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

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 $4.2 million for the year ended December 31, 2017, $6.6 million for the year ended December 31, 2016 and $6.6 million for the year ended December 31, 2015. At December 31, 2017, we had $4.5 million 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. We expect to recognize the unrecognized compensation over a remaining weighted-average period of 2.26 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, 2017 was approximately $0.8 million, of which approximately $0.7 million 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.

Performance-based stock option grants

Performance-based vesting criteria for stock options primarily relate to specific revenue targets at certain milestone dates. Stock-based compensation expense associated with performance-based stock options is recognized if the performance condition is considered probable of achievement using management's best estimates. As of December 31, 2017, there were no performance-based stock options outstanding.

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 IPO in February 2015, we estimated the fair value of our common stock, as discussed below. As a result of the completion of our IPO, our common stock is now valued by reference to the publicly-traded closing price of our common stock on the date of grant.
- 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 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.

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

| | Year ended December 31, 2017 | Year ended December 31, 2016 | Year ended December 31, 2015 |
|---|---|---|---|
| Expected volatility | 73.87% to 81.04% | 71.01% to 74.20% | 72.98% to 74.94% |
| Risk-free interest rate | 1.83% to 2.40% | 1.23% to 2.40% | 1.62% to 2.49% |
| Expected term | 5.3 - 9.5 years | 5.3 - 10 years | 5.3 - 10 years |
| Expected dividend yield | 0% | 0% | 0% |

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

Prior to adoption of ASU No. 2016-09 Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, stock-based compensation expense was recognized net of estimated forfeitures, such that expense was recognized only for share-based awards that were expected to vest. A forfeiture rate was estimated annually and revised, if necessary, in subsequent periods if actual forfeitures differed from initial estimates. Upon adoption of ASU No. 2016-09 on January 1, 2017, we no longer apply a forfeiture rate and instead account for

forfeitures as they occur. We recorded the difference in forfeiture estimate as a cumulative adjustment to retained earnings in the first quarter of 2017.

Prior to the completion of our IPO, 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 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 was based on 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 following the completion of our IPO. 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.

We have taken advantage of reduced reporting burdens in this Annual Report on Form 10-K.

We may take advantage of these exemptions for up to five years following the completion of our IPO, or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual 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, 2017, we had cash, cash equivalents and marketable securities of $33.3 million. We invest in a variety of financial instruments, principally money market funds, U.S. government agency securities, commercial paper and investment-grade corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Available for sale securities that we invest in are primarily subject to interest rate risk and may fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-30 of this Annual Report.

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

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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 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 our chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of the end of the period covered by this Annual Report, we carried out an evaluation, under the supervision and with the participation of our management, including the chief executive officer and the chief financial 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 chief financial 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 periods presented.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control—Integrated Framework (2013). Based on our assessment, our management believes that, as of December 31, 2017, our internal control over financial reporting is effective.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

The term of Christoph Westphal, M.D., Ph.D., as a member of the Company's Board of Directors was scheduled to expire at the 2018 Annual Meeting of Stockholders. On March 5, 2018, Dr. Westphal notified the Company that he was resigning from the Board of Directors, effective March 7, 2018. Dr. Westphal's resignation did not result from any disagreements with the Company.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to the information set forth in the sections titled “Proposal 1 - Election of Directors,” "Information Regarding the Board of Directors and Corporate Governance," “Executive Officers” and "Section 16(a) Beneficial Ownership Reporting Compliance" in our proxy statement for our 2018 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by this item is incorporated by reference to the information set forth in the sections titled “Executive and Director Compensation” and “Information Regarding the Board of Directors and Corporate Governance - Compensation Committee Interlocks and Insider Participation” in our proxy statement for our 2018 Annual Meeting of Stockholders.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance Under Equity Compensation Plans” in our proxy statement for our 2018 Annual Meeting of Stockholders.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled “Transactions with Related Persons” and “Information Regarding the Board of Directors and Corporate Governance” in our proxy statement for our 2018 Annual Meeting of Stockholders.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference to the information set forth in the section titled “Independent Registered Public Accounting Firm Fees" contained in Proposal 2 in our proxy statement for our 2018 Annual Meeting of Stockholders.

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:



Financial Statement Schedules

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

Exhibits

The exhibits listed below are filed as part of this Form 10-K other than Exhibit 32.1, which shall be deemed furnished.

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| | | | Incorporated by reference herein | |
|---|---|---|---|---|
| Number | | Description | Form | Date Filed with SEC |
| 3.1 | | Amended and Restated Certificate of Incorporation of the Registrant | Current Report on Form 8-K (File No. 001-36812) | February 9, 2015 |
| 3.2 | | Amended and Restated Bylaws of the Registrant | Current Report on Form 8-K (File No. 001-36812) | February 9, 2015 |
| 4.1 | | Form of Common Stock Certificate of the Registrant | Registration Statement on Form S-1 (File No. 333-201276), as amended. | January 13, 2015 |
| 4.2 | | Amended and Restated Investors' Rights Agreement, dated July 23, 2014, by and among the Registrant and certain of its stockholders | Registration Statement on Form S-1 (File No. 333-201276), as amended. | December 29, 2014 |
| 10.1 | + | Form of Indemnity Agreement by and between the Registrant and its directors and officers | Registration Statement on Form S-1 (File No. 333-201276), as amended. | January 13, 2015 |
| 10.2 | + | Flex Pharma, Inc. 2014 Equity Incentive Plan, as amended, and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder | Registration Statement on Form S-1 (File No. 333-201276), as amended. | December 29, 2014 |
| 10.3 | + | Flex Pharma, Inc. 2015 Equity Incentive Plan | Registration Statement on Form S-1 (File No. 333-201276), as amended. | January 13, 2015 |
| 10.4 | + | Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice under the Flex Pharma, Inc. 2015 Equity Incentive Plan | Annual Report on Form 10-K (File No. 001-36812) | March 24, 2015 |
| 10.5 | + | Flex Pharma, Inc. 2015 Employee Stock Purchase Plan | Registration Statement on Form S-1 (File No. 333-201276), as amended. | January 13, 2015 |
| 10.6 | + | Flex Pharma, Inc. Non-Employee Director Compensation Policy, as revised | Annual Report on Form 10-K (File No. 001-36812) | March 8, 2017 |
| 10.7 | + | Executive Employment Agreement, dated as of May 27, 2015, by and between the Registrant and Christoph Westphal | Current Report on Form 8-K (File No. 001-36812) | June 2, 2015 |
| 10.8 | + | Offer Letter, dated December 23, 2014, by and between the Registrant and Thomas Wessel | Annual Report on Form 10-K (File No. 001-36812) | March 8, 2016 |
| 10.9 | + | Amendment to Offer Letter, dated May 27, 2015, by and between the Registrant and Thomas Wessel | Annual Report on Form 10-K (File No. 001-36812) | March 8, 2016 |

| | | | |
|---|---|---|---|
| 10.10 | Royalty Agreement, dated March 20, 2014, by and between the Registrant, Bruce Bean, Donald MacKinnon, Roderick MacKinnon and Christoph Westphal | Registration Statement on Form S-1 (File No. 333-201276), as amended. | December 29, 2014 |
| 10.11 | Founders Agreement, dated February 25, 2014, by and among Bruce Bean, Donald MacKinnon, Roderick MacKinnon and Christoph Westphal, as adopted by the Registrant on February 27, 2014, as amended | Registration Statement on Form S-1 (File No. 333-201276), as amended. | December 29, 2014 |
| 10.12 | Technology Assignment Agreement, dated March 20, 2014, by and between the Registrant, Catalyst Research, LLC, Bruce Bean, Donald MacKinnon and Roderick MacKinnon | Registration Statement on Form S-1 (File No. 333-201276), as amended. | December 29, 2014 |
| 10.13 | Patent Assignment Agreement, dated March 20, 2014, by and between the Registrant, Bruce Bean, Donald MacKinnon and Roderick MacKinnon | Registration Statement on Form S-1 (File No. 333-201276), as amended. | December 29, 2014 |
| 10.14 | Lease Agreement, dated January 27, 2017, between the Registrant and BP Prucenter Acquisition LLC | Current Report on Form 8-K (Filed No. 001-36812), as amended. | February 2, 2017 |

| Number | | Description | Incorporated by reference herein Form | Date Filed with SEC |
|---|---|---|---|---|
| 10.15 | | License Agreement, dated May 1, 2014, by and between the Registrant and ECLDS, LLC, as amended | Current Report on Form 10-Q (File No. 001-36812) | August 3, 2016 |
| 10.16 | + | Executive Employment Agreement, dated as of May 27, 2015, by and between the Registrant and John McCabe | Current Report on Form 8-K (File No. 001-36812) | June 2, 2015 |
| 10.17 | + | Amendment to Executive Employment Agreement dated December 14, 2016 between John McCabe and the Registrant | Current Report on Form 8-K (File No. 001-36812) | December 15, 2016 |
| 10.18 | + | Executive Employment Agreement, dated as of July 15, 2015, by and between the Registrant and Katharine Lindemann | Current Report on Form 8-K (File No. 001-36812) | September 9, 2015 |
| 10.19 | + | Executive Employment Agreement, dated as of May 27, 2015, by and between the Registrant and Robert Hadfield | Annual Report on Form 10-K (File No. 001-36812) | March 8, 2016 |
| 10.20 | + | Executive Employment Agreement, dated as of May 27, 2015, by and between the Registrant and Elizabeth Woo | Annual Report on Form 10-K (File No. 001-36812) | March 8, 2016 |
| 10.21 | + | Executive Employment Agreement, dated as of April 5, 2017, by and between the Registrant and William McVicar | Current Report on Form 8-K (File No. 001-36812) | April 5, 2017 |
| 10.22 | + | Amendment to Executive Employment Agreement, dated as of July 6, 2017, by and between the Registrant and William McVicar | Current Report on Form 8-K (File No. 001-36812) | July 11, 2017 |
| 10.23 | + | Amended and Restated Executive Employment Agreement, dated as of August 1, 2017, by and between the Registrant and William McVicar | Annual Report on Form 10-Q (File No. 001-36812) | November 6, 2017 |
| 10.24 | † | Production Agreement with Aseptic Solutions USA, LLC and Flex Innovation Group LLC | Quarterly Report on Form 10-Q (File No. 001-36812) | May 4, 2016 |
| 10.25 | † | Supply Agreement dated May 9, 2016 by and between Trilogy Essential Ingredients Inc. and Flex Innovation Group LLC | Quarterly Report on Form 10-Q (File No. 001-36812) | August 3, 2016 |
| 21.1 | | Subsidiaries of the Registrant | Annual Report on Form 10-K (File No. 001-36812) | March 8, 2016 |
| 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 and Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350 |
| 101.INS | * | XBRL Instance Document |
| 101.SCH | * | XBRL Taxonomy Extension Schema Document |

| Number | Description | Incorporated by reference herein Form | Date Filed with SEC |
|---|---|---|---|
| 101.CAL | * XBRL Taxonomy Extension Calculation Linkbase Document | | |
| 101.DEF | * XBRL Taxonomy Extension Definition Linkbase Document | | |
| 101.LAB | * XBRL Taxonomy Extension Label Linkbase Document | | |
| 101.PRE | * XBRL Taxonomy Extension Presentation Linkbase Document. | | |

* Filed herewith.
+ Indicates management contract or compensatory plan.
† Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC.
# Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Flex Pharma, Inc.
Index to Consolidated Financial Statements
As of December 31, 2017 and 2016, for the year ended December 31, 2017, for the year ended December 31, 2016 and for the year ended December 31, 2015

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of
Flex Pharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Flex Pharma, Inc. (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

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

Boston, Massachusetts
March 7, 2018

FLEX PHARMA, INC.
CONSOLIDATED BALANCE SHEETS

| | December 31, 2017 | December 31, 2016 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $19,186,036 | $22,416,040 |
| Marketable securities | 14,129,723 | 38,658,933 |
| Accounts receivable | 10,385 | 12,181 |
| Inventory | 431,891 | 454,132 |
| Prepaid expenses and other current assets | 777,102 | 925,983 |
| Total current assets | 34,535,137 | 62,467,269 |
| Property and equipment, net | 331,040 | 556,315 |
| Other assets | — | 64,800 |
| Restricted cash | 126,595 | 126,595 |
| Total assets | $34,992,772 | $63,214,979 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | $2,004,440 | $1,192,183 |
| Accrued expenses and other current liabilities | 3,712,221 | 2,587,573 |
| Deferred revenue | 72,188 | 88,344 |
| Deferred rent, current portion | 58,821 | 21,095 |
| Total current liabilities | 5,847,670 | 3,889,195 |
| Deferred rent, net of current portion | 39,214 | 8,398 |
| Total liabilities | 5,886,884 | 3,897,593 |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2017 and December 31, 2016; none issued or outstanding at December 31, 2017 and December 31, 2016 | — | — |
| Common stock, $0.0001 par value; 100,000,000 shares authorized at December 31, 2017 and December 31, 2016, 17,972,166 and 17,970,590 shares issued at December 31, 2017 and December 31, 2016, respectively, and 17,797,178 and 16,773,798 shares outstanding at December 31, 2017 and December 31, 2016, respectively | 1,780 | 1,678 |
| Additional paid-in capital | 140,184,630 | 135,962,935 |
| Accumulated other comprehensive loss | (1,247) | (1,614) |
| Accumulated deficit | (111,079,275) | (76,645,613) |
| Total stockholders' equity | 29,105,888 | 59,317,386 |
| Total liabilities and stockholders' equity | $34,992,772 | $63,214,979 |

See accompanying notes to consolidated financial statements.

FLEX PHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

| | Year Ended December 31, 2017 | Year Ended December 31, 2016 | Year Ended December 31, 2015 |
|---|---|---|---|
| Net product revenue | $1,260,973 | $989,918 | $— |
| Other revenue | 13,526 | 20,745 | — |
| Total revenue | 1,274,499 | 1,010,663 | — |
| Costs and expenses: | | | |
| Cost of product revenue | 506,530 | 662,747 | — |
| Research and development | 16,989,911 | 20,378,161 | 12,749,379 |
| Selling, general and administrative | 18,503,684 | 19,855,987 | 16,464,279 |
| Total costs and expenses | 36,000,125 | 40,896,895 | 29,213,658 |
| Loss from operations | (34,725,626) | (39,886,232) | (29,213,658) |
| Interest income, net | 291,964 | 393,109 | 72,028 |
| Net loss | $(34,433,662) | $(39,493,123) | $(29,141,630) |
| Net loss attributable to common stockholders | $(34,433,662) | $(39,493,123) | $(29,141,630) |
| Net loss per share attributable to common stockholders — basic and diluted | $(1.99) | $(2.43) | $(2.08) |
| Weighted-average number of common shares outstanding — basic and diluted | 17,260,626 | 16,233,985 | 14,032,916 |

See accompanying notes to consolidated financial statements.

FLEX PHARMA, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

| | Year Ended December 31, 2017 | Year Ended December 31, 2016 | Year Ended December 31, 2015 |
|---|---|---|---|
| Net Loss | $(34,433,662) | $(39,493,123) | $(29,141,630) |
| Other Comprehensive gain (loss): | | | |
| Unrealized gain (loss) on available-for-sale securities | 367 | 23,040 | (24,654) |
| Comprehensive loss | $(34,433,295) | $(39,470,083) | $(29,166,284) |

See accompanying notes to consolidated financial statements.

FLEX PHARMA, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

| | Series A Convertible Preferred Stock | | Series B Convertible Preferred Stock | | Preferred Stock | Common Stock | | Additional Paid-In Capital | Accumula Other Compreh |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Shares | Amount | | Loss |
| Balance at December 31, 2014 | 15,775,221 | $15,637,032 | 14,078,647 | $25,394,135 | — | $ — 2,215,711 | $221 | $1,472,299 | $— |
| Conversion of Series A convertible preferred stock to common stock | (15,775,221) | (15,637,032 ) | — | — | — | — | 3,683,637 | 368 | 15,636,664 | — |
| Conversion of Series B convertible preferred stock to common stock | — | — | (14,078,647) | (25,394,135 ) | — | — | 3,287,471 | 329 | 25,393,806 | — |
| IPO proceeds, net of offering costs of $7,998,871 | — | — | — | — | — | — | 5,491,191 | 549 | 79,859,636 | — |
| Vesting of restricted common stock | — | — | — | — | — | — | 1,016,328 | 102 | (102 | ) — |
| Issuance of common stock from option exercises | — | — | — | — | — | — | 47,280 | 5 | 408,316 | — |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | 6,597,359 | — |
| Unrealized loss on available-for-sale securities | — | — | — | — | — | — | — | — | — | (24,654 |
| Net loss | — | — | — | — | — | — | — | — | — | — |
| Balance at December 31, 2015 | — | $— | — | $— | — | $ — 15,741,618 | $1,574 | $129,367,978 | $(24,654 |
| Vesting of restricted common stock | — | — | — | — | — | — | 1,023,664 | 102 | (102 | ) — |
| Issuance of common stock from option exercises | — | — | — | — | — | — | 8,516 | 2 | 22,096 | — |
| | — | — | — | — | — | — | — | — | 6,572,963 | — |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Stock-based compensation expense | | | | | | | | |
| Unrealized gain on available-for-sale securities | — | — | — | — | — | — | — | 23,040 |
| Net loss | — | — | — | — | — | — | — | — |
| Balance at December 31, 2016 | — | $— | — | $— | ~~$ 1~~6,773,798 | $1,678 | $135,962,935 | $(1,614 |
| Vesting of restricted common stock | — | — | — | — | —1,021,804 | 102 | (102 ) | — |
| Issuance of common stock from option exercises | — | — | — | — | —1,576 | — | 2,632 | — |
| Stock-based compensation expense | — | — | — | — | — | — | 4,219,165 | — |
| Unrealized gain on available-for-sale securities | | | | | — | — | — | 367 |
| Net loss | — | — | — | — | — | — | — | — |
| Balance at December 31, 2017 | — | $— | — | $— | ~~$ 1~~7,797,178 | $1,780 | $140,184,630 | $(1,247 |

See accompanying notes to consolidated financial statements

FLEX PHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Year Ended December 31, 2017 | Year Ended December 31, 2016 | Year Ended December 31, 2015 |
|---|---|---|---|
| Operating activities | | | |
| Net loss | $(34,433,662) | $(39,493,123) | $(29,141,630) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation expense | 324,548 | 277,231 | 49,881 |
| Stock-based compensation expense | 4,219,165 | 6,572,963 | 6,597,359 |
| Amortization and accretion on investments | (68,139) | 16,161 | 9,523 |
| Other non-cash items | 1,781 | 3,434 | 4,123 |
| Changes in operating assets and liabilities: | | | |
| Restricted cash | — | 240 | (27) |
| Accounts receivable | 1,796 | (12,181) | — |
| Inventory | 22,241 | (454,132) | — |
| Prepaid expenses and other current assets | 148,881 | (17,409) | (538,178) |
| Other assets | 64,800 | (64,800) | 100,103 |
| Accounts payable | 819,357 | 309,437 | 621,393 |
| Accrued expenses and other current liabilities | 1,124,648 | 746,879 | 1,570,216 |
| Deferred revenue | (16,156) | 88,344 | — |
| Deferred rent | 68,542 | (9,475) | (18,881) |
| Other long term liabilities | — | (15,442) | — |
| Net cash used in operating activities | (27,722,198) | (32,051,873) | (20,746,118) |
| Investing activities | | | |
| Purchases of marketable securities | (32,987,697) | (38,682,081) | (39,397,769) |
| Proceeds from maturities and sales of marketable securities | 57,585,413 | 26,995,324 | 12,398,295 |
| Purchases of property and equipment | (113,498) | (559,378) | (265,617) |
| Proceeds from sales of property and equipment | 5,344 | 5,255 | — |
| Net cash provided by (used in) investing activities | 24,489,562 | (12,240,880) | (27,265,091) |
| Financing activities | | | |
| Proceeds from initial public offering, net of offering costs | — | — | 80,435,430 |
| Proceeds from exercise of common stock | 2,632 | 22,098 | 8,321 |
| Proceeds from early exercise of common stock | — | — | 400,000 |
| Net cash provided by financing activities | 2,632 | 22,098 | 80,843,751 |
| Net (decrease) increase in cash and cash equivalents | (3,230,004) | (44,270,655) | 32,832,542 |
| Cash and cash equivalents at beginning of period | 22,416,040 | 66,686,695 | 33,854,153 |
| Cash and cash equivalents at end of period | $19,186,036 | $22,416,040 | $66,686,695 |
| Supplemental cash flow information | | | |
| Property and equipment purchases included in accounts payable and accrued expense | $— | $7,100 | $106,680 |
| IPO issuance costs paid in cash through December 31, 2014 | $— | $— | $575,245 |

See accompanying notes to consolidated financial statements.

FLEX PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
1. Organization and operations
The Company
Flex Pharma, Inc. (the "Company") is a biotechnology company that is developing innovative and proprietary treatments for muscle cramps, spasms and spasticity associated with severe neurological conditions and exercise-associated muscle cramps. The Company's lead drug product candidate, FLX-787, is currently being studied in an exploratory Phase 2 clinical trial in Australia in patients with multiple sclerosis, or MS, and in two Phase 2 clinical trials in the United States. One Phase 2 clinical trial in the United States is in patients with motor neuron disease, or MND, primarily with amyotrophic lateral sclerosis, or ALS, who suffer from muscle cramps. FLX-787 is being developed for ALS under fast track designation which was granted by the Food and Drug Administration in July 2017. The other Phase 2 clinical trial in the United States is in patients with Charcot-Marie-Tooth disease, or CMT, who suffer from muscle cramps. In 2016, the Company launched its consumer product, HOTSHOT®, to prevent and treat exercise-associated muscle cramps.
FLX-787, HOTSHOT and the Company's other drug product candidates are based on a mechanism of action the Company describes as chemical neurostimulation. The Company believes chemical neurostimulation to be a process in which a molecule, such as FLX-787, acts topically on the surfaces of the mouth, throat, esophagus and stomach to produce a sensory signal by activating nerves in those tissues. That signal is thought to ultimately result in a beneficial effect. Specifically, the Company's product candidates activate certain receptors known as transient receptor potential ion channels in primary sensory neurons producing a signal believed to inhibit neuronal circuits and thereby reduce hyperexcitability in the neurons that fire muscles. Reduced alpha-motor neuron hyperexcitability in spinal cord circuits is thought to suppress repetitive firing of alpha-motor neurons, thereby preventing or reducing muscle cramps and spasms, and potentially reducing reflex hyperexcitability and therefore spasticity.
The Company operates as two reportable segments, Consumer Operations and Drug Development. See Note 15 for additional discussion and information on the Company's reportable segments.
The Company is subject to risks common to companies in the biotechnology and consumer products industries, including, but not limited to, risks of failure of pre-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 and development by competitors of alternative products.
In February 2015, the Company sold 5,491,191 shares of common stock (inclusive of 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) through an underwritten initial public offering ("IPO") at a price of $16.00 per share. The aggregate net proceeds received by the Company from the offering were approximately $79,900,000, after deducting underwriting discounts and commissions and offering expenses payable by the Company of approximately $8,000,000 (See Note 2).
Liquidity
The Company has incurred an accumulated deficit of $111,079,275 from February 26, 2014 (inception) through December 31, 2017, and will require substantial additional capital to fund its research and development and expenses related to its consumer brand and HOTSHOT. The Company had cash, cash equivalents and marketable securities of $33,315,759 at December 31, 2017. The Company's operating plan assumes: (1) the efforts of the Company's Drug Development segment are focused on the support and completion of current clinical trials; (2) reduced spending, compared to the prior year, by the Consumer Operations segment, including reduced marketing spend; and (3) limited headcount additions and corporate expenditures. Based on the Company's implemented operating plan, the Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to allow the Company to fund its current operating plan for at least 12 months from the date the financial statements are issued. 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 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. If the Company is unable to raise additional capital in sufficient amounts or on acceptable terms, the Company may have to significantly delay, scale back or discontinue the development or commercialization of one or more of it’s drug product candidates or sell or license assets in the Drug Development and Consumer Operations segments.

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 inventory write-offs, 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.

Prior to the Company's IPO, the Company utilized 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 included estimates and assumptions that required the Company's judgment. These estimates and assumptions included 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 have resulted in different fair values of common stock at each valuation date and may have materially affected the financial statements.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries: TK Pharma, Inc., a Massachusetts Securities Corporation, and Flex Innovation Group LLC, a Delaware limited liability company, which contains the Company's consumer-related operations. All significant intercompany balances and transactions have been eliminated in consolidation.

Concentration of risk

The Company outsources the manufacture of HOTSHOT to a single co-packer that produces bottled finished goods. The Company also sources certain raw materials from sole suppliers. A disruption in the supply of materials or the production of finished goods could significantly impact the Company's revenues in the future as alternative sources of raw materials and co-packing may not be available at commercially reasonable rates or within a reasonably short period of time.

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 two operating

segments, Drug Development and Consumer Operations (see Note 15). The Company operates in one geographic segment, the United States.

Concentrations of credit risk and off-balance sheet risk

Cash, cash equivalents and marketable securities are financial instruments that potentially subject the Company to concentrations of credit risk. The Company's cash, cash equivalents and marketable securities are held in accounts at financial institutions that management believes are 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.

Revenue

Revenue is comprised of net product revenue and other revenue. Net product revenue includes sales of HOTSHOT finished goods to e-commerce customers, specialty retailers and sports teams. Other revenue consists of payments made by customers for expedited shipping and handling, which the Company began offering during the third quarter of 2016. Revenue is recognized when persuasive evidence of an arrangement exists, delivery of the product has occurred, the sales price is fixed or determinable and collectibility is reasonably assured. For sales through September 30, 2016, the Company issued refunds to e-commerce customers, upon request, within 21 days of shipment. When the Company began selling HOTSHOT on a third-party e-commerce website in October 2016, the refund period and related deferral period increased, as the Company began offering refunds to e-commerce customers, upon request, within 30 days of delivery, for purchases subsequent to September 30, 2016. As the Company currently does not have adequate history to accurately estimate refunds, all e-commerce sales, and their related costs, are deferred and revenue is recognized once the refund period lapses. This deferral represents total deferred revenue presented on the Company's consolidated balance sheet. For specialty retailers and sports teams, the Company does not offer a right of return or refund and revenue is recognized at the time products are delivered to customers.

Discounts provided to customers are accounted for as a reduction of product revenue, and were approximately $278,000 and $135,000 for the years ended December 31, 2017 and December 31, 2016, respectively. There were no such discounts in 2015 as the Company had not yet launched HOTSHOT.

Net product revenue and other revenue are presented net of taxes collected from customers and remitted to governmental authorities.

The Company had no customers that represented greater than 10% of total revenue during the year ended December 31, 2017 or during the year ended December 31, 2016. All revenue was generated from sales within the United States.

Accounts receivable and allowance for doubtful accounts

Accounts receivable are stated at their carrying values, net of any allowances for doubtful accounts. Accounts receivable consist primarily of amounts due from specialty retailers and sports teams, for which collectibility is reasonably assured. Receivables are evaluated for collectibility on a regular basis and an allowance for doubtful accounts is recorded, if necessary. No allowance for doubtful accounts was deemed necessary at December 31, 2017 and December 31, 2016.

Cost of product revenue

Cost of product revenue includes the cost of raw materials utilized to produce HOTSHOT, co-packing fees, repacking fees, in-bound freight charges and warehouse and transportation costs incurred to bring HOTSHOT finished goods to salable condition. All other costs incurred after this condition is met are considered selling costs and included in selling, general and administrative expenses. Cost of product revenue also includes write-offs for inventory that has become obsolete, has a cost basis in excess of its estimated realizable value, or exceeds projected sales, as well as depreciation expense related to manufacturing equipment purchased to support production and royalty amounts payable to certain of the Company's founders on HOTSHOT sales.

Inventory

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

The Company launched HOTSHOT in the second quarter of 2016 and began capitalizing inventory costs associated with HOTSHOT in the first quarter of 2016, when it was determined that the inventory costs had probable future economic benefit. Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out ("FIFO") basis.

The Company outsources the manufacture of HOTSHOT to a co-packer. Inventory at December 31, 2017 includes raw materials available for future production runs, as well as finished goods.

The Company periodically analyzes its inventory levels and writes down inventory that has become obsolete, has a cost basis in excess of its estimated realizable value, or exceeds projected sales. Estimates of excess inventory consider factors such as inventory levels, production requirements, projected sales and the estimated shelf-lives of inventory components. Inventory write-offs are recorded as a component of cost of product revenue.

Advertising expense

Advertising expense consists of media and production costs related to print and digital advertising. All advertising is expensed as incurred. Total advertising expenses are included in selling, general and administrative and were approximately $3,566,000 and $2,936,000 for the years ended December 31, 2017 and December 31, 2016, respectively. There were no such costs in 2015 as the Company had not yet launched HOTSHOT.

Shipping and handling costs

Shipping and handling costs related to the movement of inventory to the Company's co-packer and from the co-packer to the Company's third-party warehousing and fulfillment partners is capitalized as inventory and expensed as a cost of product revenue when revenue is recognized. Shipping and handling costs to move finished goods from the Company's warehousing and third-party fulfillment partners to customer locations are included in selling, general and administrative expense in the consolidated statement of operations, and were approximately $261,000 and $170,000 for the years ended December 31, 2017 and December 31, 2016, respectively. There were no such costs in 2015 as the Company had not yet launched HOTSHOT.

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, once assets are placed in service, 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 |
| Manufacturing equipment | 3 years |
| Website development costs | 1-2 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, 2017.

Research and development expense

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 insurance, 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 based on their grant date fair values. Compensation expense related to awards to employees with service conditions 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. Compensation expense related to awards to employees with performance conditions is recognized based on grant date fair value over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date. 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 significant trading history for the Company's common stock, it has 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.

Prior to adoption of ASU No. 2016-09 Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, share-based compensation expense was recognized net of estimated forfeitures, such that expense was recognized only for share-based awards that were expected to vest. A forfeiture rate was estimated annually and revised, if necessary, in subsequent periods if actual forfeitures differed from initial estimates. Upon

adoption of ASU No. 2016-09 on January 1, 2017, the Company no longer applies a forfeiture rate and instead accounts for forfeitures as they occur.

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, 2017 and December 31, 2016, the Company did 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 years ended December 31, 2017, December 31, 2016 and December 31, 2015, the Company has excluded the effects of all potentially dilutive shares from the weighted-average number of common shares outstanding as their inclusion in the computation for each period would be anti-dilutive due to the net loss per share incurred by the Company.

Comprehensive loss

Comprehensive loss is the change in equity of a company during a period from transactions and other events and circumstances, excluding transactions resulting from investments by owners and distributions to owners. Comprehensive loss includes net loss and the change in accumulated other comprehensive loss for the period. Accumulated other comprehensive loss consisted entirely of unrealized gains and losses on available-for-sale marketable securities for the years ended December 31, 2017, December 31, 2016 and December 31, 2015. See the consolidated statements of comprehensive loss for relevant disclosures.

The following tables summarize the changes in accumulated other comprehensive loss during the years ended December 31, 2017, December 31, 2016 and December 31, 2015.

| | |
|---|---|
| Balance as of December 31, 2016 | $(1,614) |
| Other comprehensive gain | 367 |
| Balance as of December 31, 2017 | $(1,247) |

| | |
|---|---|
| Balance as of December 31, 2015 | $(24,654) |
| Other comprehensive gain | 23,040 |
| Balance as of December 31, 2016 | $(1,614 ) |

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

| | |
|---|---|
| Balance as of December 31, 2014 | $— |
| Other comprehensive loss | (24,654) |
| Balance as of December 31, 2015 | $(24,654) |

Recent accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The ASU provides for a single comprehensive model for use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2016 with no early adoption permitted. In July 2015, the FASB deferred the effective date of this accounting update to annual periods beginning after December 15, 2017, along with an option to permit early adoption as of the original effective date. The Company is required to adopt the standard in the ASU using one of two acceptable methods: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers, Principal versus Agent Considerations (Reporting Revenue Gross versus Net), clarifying the implementation guidance on principal versus agent considerations. Specifically, an entity is required to determine whether the nature of a promise is to provide the specified good or service itself (that is, the entity is a principal) or to arrange for the good or service to be provided to the customer by the other party (that is, the entity is an agent). The determination influences the timing and amount of revenue recognition. The effective date and transition requirements for ASU No. 2016-08 are the same as the effective date and transition requirements for ASU No. 2014-09.

The Company has evaluated the adoption impact of the guidance related to the Company's sales of HOTSHOT. Based on evaluation of the Company's revenue streams, the Company has determined that the timing of recognition for e-commerce sales will change by an immaterial amount, due to e-commerce refund rights. Through December 31, 2017 and prior to adoption of the new standard, since the Company does not have an adequate history to accurately estimate refunds, all e-commerce sales and related costs have been deferred and recognized once the refund period lapses. Under the new standard, the Company will estimate the amount of potential refunds and may recognize revenue related to some of these sales earlier if it is probable that a significant revenue reversal will not occur. Adoption will not have a significant impact on revenue recognition for the company's specialty retail or sports team channels, as no right of refund or return exists.

The guidance is not expected to have a material impact to the consolidated statements of operations or balance sheets in any prior or prospective reporting period. The Company has finalized its accounting policy, and has designed and implemented necessary changes to processes and controls to allow for proper recognition, presentation and disclosure upon adoption effective in the beginning of fiscal year 2018.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330). This ASU simplifies the measurement of inventory by requiring certain inventory to be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016 and for interim periods therein. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The Company adopted this ASU as of March 31, 2017, which did not have a material impact on its condensed consolidated financial statements

In February 2016, the FASB issued ASU No. 2016-02, Leases. The ASU requires lessees to recognize the assets and liabilities on their balance sheet for the rights and obligations created by most leases and continue to recognize expenses on their income statements over the lease term. It will also require disclosures designed to give financial

statement users information on the amount, timing, and uncertainty of cash flows arising from leases. The guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted. While the Company is currently evaluating the effect this standard will have on its consolidated financial statements and timing of adoption, the Company expects that upon adoption, it will recognize

right-of-use assets and lease liabilities and those amounts could be material. The Company is still assessing the expected impact on our consolidated statements of operations and cash flows.

In March 2016, the FASB issued ASU No. 2016-09, Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This ASU simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. The Company adopted the new standard on January 1, 2017 and has elected to account for forfeitures as they occur. The change was applied on a modified retrospective basis with a cumulative effect adjustment to increase retained earnings by approximately $2,000, as of January 1, 2017. In addition, upon adoption of the new standard, the Company has additional deferred tax assets related to tax deductions from excess tax benefits related to the exercise of stock options. As a result, the deferred tax assets associated with net operating losses increased by approximately $42,000 in the first quarter of 2017. The amounts are offset by a corresponding increase in the valuation allowance. As such, there is no net effect on the Company’s consolidated statements of operations for the twelve months ended December 31, 2017.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The update amends the guidance in ASU 230 Statement of Cash Flows, and clarifies how entities should classify certain cash receipts and cash payments on the statement of cash flows with the objective of reducing the existing diversity in practice related to eight specific cash flow issues. The amendments in this update are effective for fiscal years beginning after December 15, 2017, and interim periods within those years. Early adoption is permitted. The Company does not expect the adoption of ASU 2016-15 to have a material impact on its consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows, which amends ASU Topic 230. This update requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities will no longer be required to present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. When cash, cash equivalents, restricted cash and restricted cash equivalents are presented in more than one line item on the balance sheet, the new guidance requires a reconciliation of the totals in the statement of cash flows to the related captions in the balance sheet. Entities will also have to disclose the nature of their restricted cash and restricted cash equivalent balances. The guidance is effective for fiscal years beginning after December 15, 2017 and interim periods within those years. Early adoption is permitted. Entities are required to apply the guidance retrospectively. The new guidance will change the presentation of restricted cash in the Company's consolidated financial statements in the first quarter of 2018.

In May 2017, the FASB issued ASU 2017-09, Stock Compensation (Topic 718): Scope of Modification Accounting, to provide clarity and reduce diversity in practice, cost and complexity when applying the guidance in Topic 718. The guidance is effective for fiscal years beginning after December 15, 2017 and interim periods within those years. Early adoption is permitted. The Company does not expect the adoption of this guidance to have a material effect on its consolidated financial statements and related 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 consolidated financial position or results of operations upon adoption.

Initial public offering

On February 3, 2015, the Company completed its IPO, whereby the Company sold 5,491,191 shares of its common stock (inclusive of 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 IPO) at a price of $16.00 per share. The shares began trading on The Nasdaq Global Market on January 29, 2015. The aggregate net proceeds received by the Company from the IPO were approximately $79,900,000, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. Upon the closing of the IPO, all outstanding

shares of convertible preferred stock converted into 6,971,108 shares of common stock. Additionally, the Company is now authorized to issue 100,000,000 shares of common stock.

Deferred IPO issuance costs, which primarily consisted of direct incremental legal and accounting fees related to the Company's IPO, were capitalized at December 31, 2014. Upon the closing of the IPO in February 2015, IPO issuance costs of $1,848,737, as well as underwriting discounts and commissions of $6,150,134, were offset against the IPO proceeds within additional paid-in capital.

Reverse stock split

In January 2015, the Company effected a one-for-4.2825 reverse stock split of its then 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 consolidated financial statements and notes to consolidated 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.

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 (see Note 18).

3. Restricted cash

As of December 31, 2017 and December 31, 2016, the Company had $126,595 of restricted cash 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 (see Note 9).

4. Fair value measurements

The Company records cash equivalents and marketable securities at fair value. ASC Topic 820, Fair Value Measurements and Disclosures established a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company’s own assumptions (unobservable inputs). The hierarchy consists of three levels:

Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 – Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, directly or indirectly, for substantially the full term of the asset or liability.

Level 3 – Unobservable inputs that reflect the Company’s own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

The following table summarizes the cash equivalents and marketable securities measured at fair value on a recurring basis as of December 31, 2017 and December 31, 2016:

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

| | Level 1 | Level 2 | Level 3 | Balance at December 31, 2017 |
|---|---|---|---|---|
| Cash equivalents | $5,046,205 | $— | $ — | $5,046,205 |
| Marketable securities: | | | | |
| U.S. government agency securities | — | 8,986,259 | — | 8,986,259 |
| Commercial paper | — | 4,440,689 | — | 4,440,689 |
| Corporate debt securities | — | 702,775 | — | 702,775 |
| | $5,046,205 | $14,129,723 | $ — | $19,175,928 |

| | Level 1 | Level 2 | Level 3 | Balance at December 31, 2016 |
|---|---|---|---|---|
| Cash equivalents | $11,681,074 | $— | $ — | $11,681,074 |
| Marketable securities: | | | | |
| U.S. government agency securities | — | 31,059,491 | — | 31,059,491 |
| Commercial paper | — | 6,081,202 | — | 6,081,202 |
| Corporate debt securities | — | 1,518,240 | — | 1,518,240 |
| | $11,681,074 | $38,658,933 | $ — | $50,340,007 |

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. The majority of the Company's cash equivalents consist of money market funds that are valued based on publicly available quoted market prices for identical securities as of December 31, 2017. After completing its validation procedures, the Company did not adjust or override any fair value carrying amounts of as of December 31, 2017.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair values at December 31, 2017 and 2016, due to their short-term nature.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the year ended December 31, 2017 or during the year ended December 31, 2016. The Company had no financial assets or liabilities that were classified as Level 3 at any point during the year ended December 31, 2017 or during the year ended December 31, 2016.

5. Cash equivalents and marketable securities

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. Cash equivalents as of December 31, 2017 and December 31, 2016 consisted of money market funds.

Marketable securities as of December 31, 2017 and December 31, 2016 consisted of corporate debt securities, commercial paper and U.S. government agency securities. Management determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company classifies its marketable securities as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities. Marketable securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity and a component of total comprehensive income (loss) in the consolidated statement of comprehensive income (loss), until realized. Realized

gains and losses are included in investment income on a specific-identification basis. There

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were no realized gains on marketable securities during the year ended December 31, 2017, and there were immaterial realized gains on marketable securities during the year ended December 31, 2016.

The Company reviews marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statement of operations if the Company has experienced a credit loss, has the intent to sell the marketable security, or if it is more likely than not that the Company will be required to sell the marketable security before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to the end of the period.

Marketable securities at December 31, 2017 and December 31, 2016 consisted of the following:

| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| As of December 31, 2017 | | | | |
| Current (due within 1 year): | | | | |
| U.S. government agency securities | $8,987,254 | $ 38 | $ (1,033) | $8,986,259 |
| Commercial paper | 4,440,689 | — | — | 4,440,689 |
| Corporate debt securities | 703,027 | — | (252) | 702,775 |
| Total | $14,130,970 | $ 38 | $ (1,285) | $14,129,723 |

| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| As of December 31, 2016 | | | | |
| Current (due within 1 year): | | | | |
| U.S. government agency securities | $31,060,710 | $ 2,912 | $ (4,131) | $31,059,491 |
| Commercial paper | 6,081,202 | — | — | 6,081,202 |
| Corporate debt securities | 1,518,635 | — | (395) | 1,518,240 |
| Total | $38,660,547 | $ 2,912 | $ (4,526) | $38,658,933 |

The Company held six securities that were in an unrealized loss position at both December 31, 2017 and December 31, 2016, all of which were in a continuous loss position for less than 12 months. The aggregate fair value of securities in an unrealized loss position was $8,191,315 and $16,519,620 at December 31, 2017 and December 31, 2016, respectively. There were no individual securities that were in a significant unrealized loss position as of December 31, 2017 or December 31, 2016. The Company evaluated its securities for other-than-temporary impairment and considered the decline in market value for the securities to be primarily attributable to current economic and market conditions. The Company has the intent and ability to hold such securities until recovery. Based on this analysis, these marketable securities were not considered to be other-than-temporarily impaired as of December 31, 2017.

At December 31, 2017 and December 31, 2016, all investments held by the Company were classified as current. Investments classified as current have maturities of less than one year. Investments classified as noncurrent are those that (i) have a maturity greater than one year and (ii) management does not intend to liquidate within the next year, although these funds are available for use and therefore classified as available-for-sale.

6. Inventory

The Company began capitalizing inventory as of March 31, 2016, when it was determined that the inventory had a probable future economic benefit. Inventory has been recorded at cost as of December 31, 2017 and December 31,

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2016. Costs capitalized at December 31, 2017 and December 31, 2016 relate to HOTSHOT finished goods, as well as raw materials available to be used for future production runs.
The following table presents inventory:

| | December 31, 2017 | December 31, 2016 |
|---|---|---|
| Raw materials | $17,411 | $19,888 |
| Finished goods | 414,480 | 434,244 |
| Total inventory | $431,891 | $454,132 |

In the second quarter of 2017, the Company completed a production run of HOTSHOT. From the second to fourth quarter of 2017, the Company wrote off materials purchased for production that were not expected to be used in future production runs, as well as expiring finished goods. In 2016, the Company wrote off raw materials purchased for production runs of HOTSHOT that were not expected to be used in future production runs, as well as finished goods not expected to be sold based upon projected sales, estimated product shelf life, the number of units produced and production level requirements.
Write-offs totaled approximately $42,000 and $282,000 for the years ended December 31, 2017 and December 31, 2016, respectively, and are included in cost of product revenue in the accompanying consolidated statement of operations.
The cost of product revenue related to deferred revenue is capitalized and recorded as cost of product revenue at the time the revenue is recognized.
7. Property and equipment, net
Property and equipment, net consists of the following:

| | December 31, 2017 | December 31, 2016 |
|---|---|---|
| Manufacturing equipment | $421,999 | $421,999 |
| Computers and computer equipment | 311,847 | 276,263 |
| Website development costs | 177,886 | 159,836 |
| Laboratory equipment | 13,368 | 13,368 |
| Capital in progress | 28,823 | 7,863 |
| Total property and equipment | 953,923 | 879,329 |
| Accumulated depreciation | (622,883 ) | (323,014 ) |
| Property and equipment, net | $331,040 | $556,315 |

Capital in progress consists of assets acquired but not yet placed into service. At December 31, 2017 capital in progress consisted of computers and computer equipment, and at December 31, 2016 capital in progress consisted of computers and website development costs.

Depreciation expense was $324,548, $277,231 and $49,881 for the years ended December 31, 2017, December 31, 2016, and December 31, 2015, respectively.

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

8. Accrued expenses and other current liabilities
Accrued expenses and other current liabilities consist of the following:

| | December 31, 2017 | December 31, 2016 |
|---|---|---|
| Research and development costs | $2,502,400 | $938,665 |
| Payroll and employee-related costs | 874,246 | 1,453,665 |
| Professional fees | 227,980 | 153,219 |
| Consumer product-related costs | 107,595 | 42,024 |
| Total | $3,712,221 | $2,587,573 |

9. Commitments and contingencies
Lease commitments
On April 29, 2014, the Company leased office space in Boston, Massachusetts that was scheduled to expire on August 31, 2017. In January 2017, the Company signed a lease to extend the use of the same office space from September 1, 2017 to August 31, 2019.
Additionally, on October 21, 2014, the Company leased office space in New York, New York under an operating lease that was originally scheduled to expire on October 31, 2018. In March 2017, the Company commenced a plan to transition its consumer operations from New York to Boston. In connection with this transition, the Company terminated its New York office operating lease and was released from any further obligations in July 2017.
As of December 31, 2017, the minimum future lease payments under the Company's Boston operating lease was as follows:

| | |
|---|---|
| 2018 | $466,593 |
| 2019 | 311,062 |
| Total minimum lease payments | $777,655 |

Rent expense is being recognized on a straight-line basis. The Company recorded approximately $522,000, $337,000 and $253,000 of rent expense for the twelve months ended December 31, 2017, December 31, 2016 and December 31, 2015, respectively.
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. The Company began incurring royalty expense upon commencement of HOTSHOT sales during the second quarter of 2016. The Company recorded approximately $25,000 and $20,000 of royalty expense during the twelve months ended December 31, 2017 and December 31, 2016, respectively. Royalty amounts owed to the founders as of December 31, 2017 and December 31, 2016 were approximately $3,000 and $4,000. No royalty amounts were owed to the founders as of December 31, 2015.
Litigation

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities as of December 31, 2017.

10. 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 was 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 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 was 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. As of December 31, 2017, there were no shares of Series A convertible preferred stock or Series B convertible preferred stock authorized.

On February 3, 2015, the Company filed an amended and restated certificate of incorporation (the “Restated Certificate”) with the Secretary of State of the State of Delaware in connection with the closing of the Company’s IPO. As of December 31, 2017, under the Restated Certificate, the Company is authorized to issue 10,000,000 shares of preferred stock ("Preferred Stock") with a par value of $0.0001 per share. The Company has not issued any shares of Preferred Stock as of December 31, 2017.

11. Common stock

As of December 31, 2017, the Company had authorized 100,000,000 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. The Company does not intend to declare dividends for the foreseeable future.

Restricted common stock to founders

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 5,251,075 shares of restricted common stock outstanding as of December 31, 2017. Unvested restricted common stock awards to non-employees are re-measured at each vest date and each financial reporting date.

The following is a summary of restricted common stock activity:

| | Number of Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Unvested at December 31, 2016 | 1,185,958 | $ 0.10 |
| Issued | — | — |
| Vested | (1,016,304) | 0.10 |
| Forfeited | — | — |
| Unvested at December 31, 2017 | 169,654 | $ 0.10 |

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The total fair value of shares vested during the twelve months ended 2017, 2016 and 2015 was approximately $3,840,000, $9,646,000 and $15,616,000 respectively.

Restricted common stock to consultants

There were no shares of restricted common stock granted to non-employee consultants and advisors during 2017 or 2015. During 2016, the Company granted a total of 18,194 of shares of restricted common stock to non-employee consultants and advisors. Such shares are not accounted for as outstanding until they vest. There were 12,860 shares of restricted common stock issued to consultants outstanding as of December 31, 2017. Unvested restricted common stock awards to non-employees are re-measured at each vest date and each financial reporting date.

The following is a summary of restricted common stock activity:

| | Number of Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Unvested at December 31, 2016 | 10,834 | $ 9.72 |
| Issued | — | — |
| Vested | (5,500 ) | 8.95 |
| Forfeited | — | — |
| Unvested at December 31, 2017 | 5,334 | $ 10.51 |

The total fair value of shares vested during the twelve months ended 2017 and 2016 was approximately $22,000 and $71,000, respectively. No shares were issued to consultants during the twelve months ended December 31, 2015.

Employee stock purchase plan

In 2015, the Company's Board of Directors adopted, and the Company's stockholders approved, the 2015 Employee Stock Purchase Plan (the "ESPP"). As of the December 31, 2017, no shares of common stock have been purchased under the ESPP.

Shares reserved for future issuance

The Company has reserved the following number of shares of common stock for future issuance:

| | As of December 31, | |
|---|---|---|
| | 2017 | 2016 |
| Stock-based compensation awards | 3,439,820 | 2,722,573 |
| Vesting of restricted common stock | 174,988 | 1,196,792 |
| Employee stock purchase plan | 534,274 | 354,569 |
| Total | 4,149,082 | 4,273,934 |

12. Stock-based compensation

In March 2014, the Company adopted the Flex Pharma, Inc. 2014 Equity Incentive Plan (the "2014 Plan"), under which it had the ability to grant incentive stock options ("ISOs"), non-qualified stock options, restricted stock awards,

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restricted stock units and stock appreciation rights to purchase up to 116,754 shares of common stock. In April 2014, the Company amended the 2014 Plan to reserve for the issuance of up to 1,451,087 shares of common stock pursuant to equity awards. In September 2014, the Company further amended the 2014 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, were determined by the board of directors, subject to the provisions of the 2014 Plan. For options granted under the 2014 Plan, the exercise price equaled the fair market value of the common stock as determined by the board of directors on the date of grant. No further awards will be granted under the 2014 Plan.

In January 2015, the Company's board of directors adopted, and the Company's stockholders approved, the 2015 Equity Incentive Plan (the "2015 Plan"), which became effective immediately prior to the closing of the Company's IPO. The 2015 Plan provides for the grant of 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 may be granted to the Company's employees, including officers, and to non-employee directors and consultants. As of December 31, 2017, there were 859,329 shares remaining available for the grant of stock awards under the 2015 Plan.

There were no stock options issued to non-employee consultants or members of the Scientific Advisory Board during 2017. During 2016 and 2015, the Company granted a total of 14,670 and 10,507, respectively, of stock options to non-employee consultants and members of its Scientific Advisory Board. 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 year ended December 31, 2017, December 31, 2016 and December 31, 2015 was approximately $201,000, $370,000 and $517,000, respectively.

The Company has awarded stock options to its employees, directors, advisors and consultants, pursuant to the plans described above. Stock options subsequent to the completion of the Company's IPO are granted with an exercise price equal to the closing market price of the Company's common stock on the date of grant. Stock options generally vest over one to four years and have a contractual term of ten years. Stock options are valued using the Black-Scholes option pricing model and compensation cost is recognized based on the resulting value over the service period. Unvested awards to non-employees are re-measured at each vest date and at each financial reporting date. The following table summarizes stock option activity for employees and non-employees for the twelve months ended December 31, 2017:

| | Shares | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2016 | 2,156,250 | $ 8.66 | 7.94 | $1,605,684 |
| Granted | 1,059,500 | 4.20 | | |
| Exercised | (1,576) | 1.67 | | |
| Forfeited | (418,642) | 8.87 | | |
| Expired | (215,041) | 10.51 | | |
| Outstanding at December 31, 2017 | 2,580,491 | $ 6.65 | 7.55 | $803,600 |
| Exercisable at December 31, 2017 | 1,404,844 | $ 7.21 | 6.56 | $692,232 |
| Vested or expected to vest at December 31, 2017 | 2,580,491 | $ 6.65 | 7.55 | $803,600 |

During 2017, 2016 and 2015, the Company granted stock options to purchase an aggregate of 1,059,500, 763,320, and 994,748 shares of its common stock, respectively. The weighted-average grant date fair value of option awards granted during 2017, 2016 and 2015 were $2.80, $6.35, and $8.55, respectively.

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The number of stock options exercised during 2017, 2016 and 2015 were 1,576, 8,516, and 47,280, respectively. The weighted-average exercise price of options exercised during 2017, 2016 and 2015 was $1.67, $2.59, and $8.63, respectively. The total intrinsic value of options exercised during 2017, 2016 and 2015 was $2,606, $64,302, and $149,386, respectively. 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 regarding the fair value of the underlying Common Stock on each measurement date:

| | Year Ended December 31, 2017 | Year Ended December 31, 2016 | Year Ended December 31, 2015 |
|---|---|---|---|
| Expected volatility | 73.87% to 81.04% | 71.01% to 74.20% | 72.98% to 74.94% |
| Risk-free interest rate | 1.83% to 2.40% | 1.23% to 2.40% | 1.62% to 2.49% |
| Expected term | 5.3 - 9.5 years | 5.3 - 10 years | 5.3 - 10 years |
| Expected dividend yield | 0 % | 0 % | 0 % |

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 consolidated statements of operations and comprehensive loss as follows:

| | Year Ended December 31, 2017 | Year Ended December 31, 2016 | Year Ended December 31, 2015 |
|---|---|---|---|
| Research and development | $1,545,737 | $2,435,565 | $3,192,063 |
| Selling, general and administrative | 2,673,428 | 4,137,398 | 3,405,296 |
| Total | $4,219,165 | $6,572,963 | $6,597,359 |

Selling, general and administrative expense for the year ended December 31, 2016 included $285,000 related to stock options that were modified in connection with an employee termination agreement.

As of December 31, 2017, there was approximately $4,533,000 of total unrecognized compensation cost related to unvested 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 2.26 years.

13. Income taxes

For the years ended December 31, 2017, December 31, 2016 and December 31, 2015, the Company did not record a current or deferred income tax provision or benefit. The Company's losses before income taxes for the periods presented consisted solely of domestic losses.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act tax reform legislation. This legislation makes significant changes in U.S. tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from the current rate of 35% to 21%. As a result of

the enacted law, the Company was required to revalue deferred tax assets and liabilities at the enacted rate. This revaluation resulted in a decrease in net deferred tax assets of $12,600,000 and a corresponding reduction in the valuation allowance against these assets. There is no impact to income tax expense. The other provisions of the Tax Cuts and Jobs Act did not have a material impact on the 2017 consolidated financial statements.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118, or SAB 118, to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed, including computations, in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act. The Company has recognized the provisional tax impacts related to the revaluation of the deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. The ultimate impact may differ from these provisional amounts due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the Tax Reform Act. The accounting is expected to be complete when the 2017 U.S. corporate income tax return is filed in 2018.

The following table presents a reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to the effective income tax rate as reflected in the consolidated financial statements:

| | Year Ended December 31, 2017 | Year Ended December 31, 2016 | Year Ended December 31, 2015 |
|---|---|---|---|
| Federal income tax expense at statutory rate | 35.0 % | 35.0 % | 35.0 % |
| State income tax, net of federal benefit | 5.0 % | 5.0 % | 3.4 % |
| Permanent differences | (0.7 )% | 0.0 % | (0.2 )% |
| Stock-based compensation | (1.9 )% | (2.6 )% | (6.3 )% |
| Research credits | 2.2 % | 1.9 % | 1.8 % |
| Other, net | (1.3 )% | (0.1 )% | 0.4 % |
| Payroll Tax Credit Election | (0.7 )% | 0.0 % | 0.0 % |
| Change in valuation allowance | (1.1 )% | (39.2 )% | (34.1 )% |
| Deferred rate change | (36.5 )% | 0.0 % | 0.0 % |
| Effective tax rate | 0.0 % | 0.0 % | 0.0 % |

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Deferred income tax assets and liabilities are determined based upon temporary differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.
The following table presents the significant components of the Company's deferred tax assets and liabilities:

| | December 31, 2017 | December 31, 2016 |
|---|---|---|
| Deferred tax assets: | | |
| U.S. and state net operating loss carryforwards | $24,744,841 | $24,322,172 |
| Accruals and other temporary differences | 202,301 | 529,462 |
| Amortization | 35,783 | 32,171 |
| Stock-based compensation | 1,591,131 | 1,847,441 |
| Tax credit carryforward | 1,964,189 | 1,423,292 |
| Total deferred tax assets | 28,538,245 | 28,154,538 |
| Less valuation allowance | (28,533,755) | (28,127,611) |
| Deferred tax assets | 4,490 | 26,927 |
| Deferred tax liabilities: | | |
| Stock-based compensation | (4,490) | (23,316) |
| Depreciation | — | (3,611) |
| Accruals and other temporary differences | — | — |
| Deferred tax liabilities | (4,490) | (26,927) |
| Net deferred tax assets | $— | $— |

As of December 31, 2017, the Company has U.S. federal net operating loss carryforwards of approximately $91,200,000 and U.S. state net operating loss carryforwards of approximately $90,400,000 ($7,100,000 tax affected), which are available to reduce future taxable income. The Company also had federal research and development tax credit carryforwards of approximately $1,600,000 and state research and development tax credit carryforwards of approximately $428,000, which may be used to offset future tax liabilities.
The Company adopted ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, for the quarter ended March 31, 2017. As a result of adoption, the deferred tax assets associated net operating losses increased by approximately $42,000. These amounts were offset by a corresponding increase in the valuation allowance. The adoption of ASU 2016-09 had no impact to the Company’s consolidated statement of operations, balance sheet, or retained earnings.
The Company's federal and state operating loss carryforwards and tax credit carryforwards will expire at various dates through 2037. 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 has 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 has not conducted an assessment to determine whether there may have been a Section 382 or 383 ownership changes.

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ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After considerations of all the evidence, both positive and negative, the Company continues to maintain a valuation allowance for the full amount of the 2017 deferred tax asset because it is more likely than not that the deferred tax asset will not be realized. The valuation allowance increased by approximately $406,000 from December 31, 2016 to December 31, 2017, primarily due to an increase in net operating losses.

The Company has no unrecognized tax benefits. Interest and penalty charges, if any, related to uncertain tax positions would be classified as income tax expenses in the accompanying consolidated statement of operations. At December 31, 2017 and 2016, the Company had no accrued interest or penalties related to uncertain tax positions.

Under the Protecting Americans from Tax Hikes Act, enacted in December 2015, certain qualified small businesses may elect to apply up to $250,000 of its federal research and development tax credit against the Social Security portion of its payroll tax liability. The Company elected the $250,000 credit on its 2016 tax return and utilized approximately $22,000 of the credit as a decrease to its payroll tax expense in 2017.

14. Net loss per share

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.

Because the Company has reported net losses for the periods 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 for the periods indicated, because including them would have had an anti-dilutive impact:

| | Year Ended December 31, 2017 | Year Ended December 31, 2016 | Year Ended December 31, 2015 |
|---|---|---|---|
| Options to purchase common stock | 2,580,491 | 2,156,250 | 1,824,973 |
| Unvested restricted common stock | 174,988 | 1,196,792 | 2,202,262 |
| Total | 2,755,479 | 3,353,042 | 4,027,235 |

15. Segment Information

Effective as of the second quarter of 2016 and in connection with the launch of HOTSHOT, the Company operates as two reportable segments:

- The Consumer Operations segment, which reflects the total revenue and costs and expenses related to HOTSHOT and the Company's consumer operations.
- The Drug Development segment, which reflects the costs and expenses related to the Company's efforts to develop innovative and proprietary drug products to treat muscle cramps, spasms and spasticity associated with severe neurological conditions.

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

The Company discloses information about its reportable segments based on the way that the Company's Chief Operating Decision Maker, who the Company has identified as the Chief Executive Officer, and management, organizes segments within the Company for making operating decisions and assessing financial performance. The Company evaluates the performance of its reportable segments based on revenue and operating income or loss. The accounting policies of the segments are the same as those described herein as well as those described in Note 2. Corporate and unallocated amounts that do not relate to a reportable segment have been allocated to "Corporate". No asset information has been provided for the Company's reportable segments as management does not measure or allocate such assets on a reportable segment basis.

Information for the Company's reportable segments for the years ended December 31, 2017, December 31, 2016, and December 31, 2015 are as follows:

| Year Ended December 31, 2017 | Consumer Operations | Drug Development | Corporate | Consolidated |
|---|---|---|---|---|
| Total revenue | $1,274,499 | — | — | $1,274,499 |
| Loss from operations | $8,877,330 | 16,715,752 | 9,132,544 | $34,725,626 |
| Interest income, net | $— | — | 291,964 | $291,964 |
| Year Ended December 31, 2016 | Consumer Operations | Drug Development | Corporate | Consolidated |
| Total revenue | $1,010,663 | — | — | $1,010,663 |
| Loss from operations | $10,023,137 | 19,620,338 | 10,242,757 | $39,886,232 |
| Interest income, net | $— | — | 393,109 | $393,109 |
| Year Ended December 31, 2015 | Consumer Operations | Drug Development | Corporate | Consolidated |
| Total revenue | $— | — | — | $— |
| Loss from operations | $7,892,584 | 12,224,692 | 9,096,382 | $29,213,658 |
| Interest income, net | $— | — | 72,028 | $72,028 |

16. Related parties

Royalty agreement

In 2014, the Company entered into a royalty agreement with certain of the Company's founders under which these founders are paid a royalty of 2%, in the aggregate, of gross sales of any product sold by the Company or by any of the Company's licensees for use in the treatment of any neuromuscular disorder, and that uses, incorporates or embodies, or is made using, any of the Company's intellectual property, including any know-how.

Upon the launch of HOTSHOT in the second quarter of 2016, the Company's founders began earning royalties under this agreement. Royalty amounts earned by the founders during the years ended December 31, 2017 and December 31, 2016 totaled approximately $25,000 and $20,000, respectively, including approximately $3,000 and$4,000 not yet paid as of year end, respectively. There were no such amounts earned during the year ended December 31, 2015. Royalty expense is recorded in cost of product revenue in the consolidated statement of operations.

License agreement

For the period from May 2014 through July 2016, the Company licensed a portion of its office space to ECLDS, LLC, which was controlled by the Company's former Chief Executive Officer. In October 2015, the license agreement was assigned by ECLDS, LLC to a third party, that was not owned by the Company's former Chief Executive Officer, but for which a business relationship existed. In July 2016, the license agreement terminated.

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Under the terms of the license, the entity charged the same rental rate as that was charged to the Company. During the years ended December 31, 2016 and December 31, 2015, the Company received approximately $32,000, and $61,000, respectively, in license fees from the aforementioned related party, and such amounts received have been recorded as a reduction to rent expense.

17. Quarterly financial information (unaudited)

| | First Quarter Ended March 31, 2017 | Second Quarter Ended June 30, 2017 | Third Quarter Ended September 30, 2017 | Fourth Quarter Ended December 31, 2017 |
|---|---|---|---|---|
| Net product revenue | $240,292 | $330,688 | $407,241 | $282,752 |
| Other revenue | 2,255 | 4,835 | 6,360 | 76 |
| Total revenue | 242,547 | 335,523 | 413,601 | 282,828 |
| Costs and expenses: | | | | |
| Cost of product revenue | 79,106 | 145,325 | 148,756 | 133,343 |
| Research and development | 3,914,974 | 4,076,220 | 4,739,360 | 4,259,357 |
| Selling, general and administrative | 4,594,716 | 4,990,943 | 4,934,937 | 3,983,088 |
| Total costs and expenses | 8,588,796 | 9,212,488 | 9,823,053 | 8,375,788 |
| Loss from operations | (8,346,249) | (8,876,965) | (9,409,452) | (8,092,960) |
| Interest income, net | 77,854 | 72,342 | 77,339 | 64,429 |
| Net loss | $(8,268,395) | $(8,804,623) | $(9,332,113) | $(8,028,531) |
| Net loss per share attributable to common stockholders — basic and diluted | $(0.49) | $(0.51) | $(0.54) | $(0.46) |
| Weighted-average number of common shares outstanding — basic and diluted | 16,873,512 | 17,130,264 | 17,386,249 | 17,642,646 |

| | First Quarter Ended March 31, 2016 | Second Quarter Ended June 30, 2016 | Third Quarter Ended September 30, 2016 | Fourth Quarter Ended December 31, 2016 |
|---|---|---|---|---|
| Net product revenue | $— | $112,685 | $586,134 | $291,099 |
| Other revenue | — | — | 12,940 | 7,805 |
| Total revenue | — | 112,685 | 599,074 | 298,904 |
| Costs and expenses: | | | | |
| Cost of product revenue | 197,020 | 110,931 | 221,090 | 133,706 |
| Research and development | 4,387,079 | 6,094,921 | 5,665,357 | 4,230,804 |
| Selling, general and administrative | 5,111,695 | 5,377,784 | 5,447,847 | 3,918,661 |
| Total costs and expenses | 9,695,794 | 11,583,636 | 11,334,294 | 8,283,171 |
| Loss from operations | (9,695,794) | (11,470,951) | (10,735,220) | (7,984,267) |
| Interest income, net | 103,333 | 107,818 | 97,726 | 84,232 |
| Net loss | $(9,592,461) | $(11,363,133) | $(10,637,494) | $(7,900,035) |
| | $(0.61) | $(0.71) | $(0.65) | $(0.48) |

| | | | | |
|---|---|---|---|---|
| Net loss per share attributable to common stockholders — basic and diluted | | | | |
| Weighted-average number of common shares outstanding — basic and diluted | 15,843,532 | 16,105,555 | 16,361,617 | 16,619,596 |

18. Subsequent events

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

The Company has completed an evaluation of all subsequent events after the balance sheet date of December 31, 2017 through the date these consolidated financial statements were issued. The Company concluded that no subsequent events have occurred that require disclosure.

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/ William McVicar
William McVicar, 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 William McVicar, 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/ William McVicar<br>William McVicar, Ph.D. | President, Chief Executive Officer, Member of the Board of Directors (Principal Executive Officer) | March 7, 2018 |
| /s/ John McCabe<br>John McCabe | Chief Financial Officer (Principal Financial and Accounting Officer) | March 7, 2018 |
| /s/ Jeffrey Capello<br>Jeffrey Capello | Member of the Board of Directors | March 7, 2018 |
| /s/ Peter Barton Hutt<br>Peter Barton Hutt | Member of the Board of Directors | March 7, 2018 |
| /s/ Marc Kozin<br>Marc Kozin | Member of the Board of Directors | March 7, 2018 |
| /s/ Roderick MacKinnon<br>Roderick MacKinnon, M.D. | Member of the Board of Directors | March 7, 2018 |
| /s/ Stuart Randle | Member of the Board of Directors | March 7, 2018 |

| | | |
|---|---|---|
| Stuart Randle | | |
| /s/ Michelle Stacy<br>Michelle Stacy | Member of the Board of Directors | March 7, 2018 |
| /s/ Roger Tung<br>Roger Tung | Member of the Board of Directors | March 7, 2018 |
| /s/ Christoph Westphal<br>Christoph Westphal, M.D., Ph.D. | Member of the Board of Directors | March 7, 2018 |