UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Fiscal Year Ended December 31, 2018

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period from to

Commission File 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)

31 St. James Avenue, 6th Floor
Boston, MA 02116
(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.
31 St. James Avenue, 6th Floor
Boston, MA 02116
(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 Capital 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 ☐ No ☒

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 ☐ No ☒

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 ☒ No ☐

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) 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. ☒

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 ☐ Accelerated Filer ☐ Non-accelerated Filer ☒ Smaller Reporting Company ☒ Emerging Growth Company ☒

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

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

As of June 30, 2018, 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 $9.8 million, based on the closing price of the registrant's common stock on June 29, 2018.

As of March 1, 2019, there were 18,069,476 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2019 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.

2018 ANNUAL REPORT ON FORM 10-K

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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 timing and anticipated completion of the merger with Salarius Pharmaceuticals, LLC;
- the expected benefits and growth potential of HOTSHOT;
- our ability to obtain funding for our operations if the merger is not completed;
- our ability to expand the sales of our consumer product;
- the size and growth potential of the markets for our consumer product and our drug product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our consumer product;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are, or become, available;
- our plans to resume development of our drug product candidates;
- 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 was previously focused on developing innovative and proprietary treatments for muscle cramps, spasms and spasticity associated with severe neurological conditions. In June 2018, we announced that we were ending our ongoing Phase 2 clinical trials of our lead drug product candidate, FLX-787, in patients with motor neuron disease, or MND, primarily with amyotrophic lateral sclerosis, or ALS, and in patients with Charcot-Marie-Tooth disease, or CMT, due to oral tolerability concerns observed in both studies. The wind-down of the activities associated with these studies was completed in the third quarter of 2018.

In 2016, we launched our consumer product, HOTSHOT®, to prevent and treat exercise-associated muscle cramps, or EAMCs. We continue to market and sell HOTSHOT to endurance athletes who drink it before, during and after exercise to prevent and treat exercise associated muscle cramps, or EAMCs.

In June 2018, we initiated a process to explore a range of strategic alternatives for enhancing stockholder value, including the potential sale or merger of the company. Wedbush PacGrow was engaged to act as our strategic financial advisor at that time. We also announced the restructuring of the organization to reduce our cost structure. In connection with the restructuring plan, we reduced our workforce by approximately 60%, with the reduction completed as of September 30, 2018.

Following an extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on January 3, 2019, we entered into a merger agreement with Salarius Pharmaceuticals, LLC, or Salarius, under which the privately held Salarius will merge with a wholly owned subsidiary of Flex Pharma. If the merger is completed, the business of Salarius will continue as the business of the combined organization.

We expect to devote significant time and resources to completion of this merger. However, there can be no assurance that such activities will result in the completion of the merger. Further, the completion of the merger may ultimately not deliver the anticipated benefits or enhance shareholder value.

If the merger is not completed, we will reconsider our strategic alternatives. In this case, we consider one of the following courses of action to be the most likely alternatives:

- *Dissolve and liquidate our assets*. If, for any reason, the merger does not close, our Board of Directors will most likely conclude that it is in the best interest of stockholders to dissolve the Company and liquidate our assets. In that event, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims. There would be no assurances as to the amount or timing of available cash remaining to distribute to stockholders after paying our obligations and setting aside funds for reserves.

- *Pursue another strategic transaction*. We may resume the process of evaluating a potential strategic transaction in order to attempt another strategic transaction like the merger.

- *Operate the consumer business.* Although less likely than the alternatives above, our Board of Directors may elect to continue to market and sell HOTSHOT and continue to operate our consumer business.

We cannot predict whether or to what extent we might resume previous level of research and development activities, including clinical trials, or what the related future cash needs would be for any such activities.

Historical Business and Programs

We focused our historical efforts on developing innovative and proprietary treatments for muscle cramps, spasms and spasticity associated with severe neurological conditions and exercise-associated muscle cramps.

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.

At the time we decided to stop our two Phase 2 clinical trials in June 2018, we were developing FLX-787 for severe neurological conditions. We had recently completed a Phase 2 exploratory clinical trial in patients with Multiple Sclerosis, or MS, and were executing two Phase 2 clinical trials, one in MND and one in CMT.

One Phase 2 clinical trial in the United States, referred to as the COMMEND trial, was in patients with MND, primarily with ALS, who suffered from muscle cramps. FLX-787 was 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, referred to as the COMMIT trial, was in patients with CMT who suffered from muscle cramps. We stopped these studies due to oral tolerability concerns observed in both studies. In the COMMEND study, 31% of patients randomized to receive the oral disintegrating tablet, or ODT, formulation at 30 mg, taken three times a day, discontinued before the end of the 4-week treatment period due to oral adverse events. A similar proportion of subjects in the COMMIT study discontinued due to oral adverse events, after being randomized to the 30 mg dose. No patients randomized to the 0.5 mg low-dose control discontinued due to oral adverse events in either study. The wind-down of the activities associated with these studies was completed in the third quarter of 2018.

In addition to developing FLX-787, we also developed and launched our HOTSHOT consumer beverage in 2016. HOTSHOT is our consumer beverage containing a proprietary formulation of TRP activators. The majority of HOTSHOT sales are generated through our branded website and third-party websites. We also sell HOTSHOT to select specialty retailers in geographic areas with strong endurance sports markets and directly to athletic teams at the amateur and professional levels.

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. In connection with the restructuring plan announced in June 2018, we elected to reduce the expenses associated with our consumer business segment while we assessed strategic alternatives for the Company and this 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 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.

FLX-787

FLX-787 is a single molecule, chemically synthesized, dual TRP V1/A1 ion channel activator. We originally tested FLX-787 using our electrically-induced human cramp model and we later tested FLX-787 in nocturnal leg cramps. Following the testing of FLX-787 in nocturnal leg cramps, we decided to focus our FLX-787 development efforts on muscle cramps, spasms and spasticity related to severe neurological conditions, including MS, ALS and CMT.

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 our past trials were designed to evaluate a number of different endpoints. We conducted exploratory Phase 2 clinical trials in Australia in MS and ALS that were designed as trials to determine the effect of FLX-787 across a broad range of potential endpoints with no pre-specified primary endpoint. Prior to their stoppage, our Phase 2 clinical trials in the United States in patients with MND and CMT were designed to measure changes in cramp frequency as the primary endpoint along with several secondary endpoints. Change in cramp frequency was chosen 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.

MS Clinical Trial. In March 2018, we announced topline data from our exploratory Phase 2 clinical trial of FLEX-787 in MS patients with frequent muscle cramps/spasms and spasticity. FLX-787 at a dose of 19 mg, taken orally twice daily, in a liquid formulation, was evaluated in a randomized, double-blinded, placebo-controlled, cross over trial in 57 MS patients. In the evaluation of FLX-787 for its impact on MS patients' cramps/spasms and spasticity, pre-specified analyses of the parallel portion of the study showed a statistically significant 27.3% reduction in the frequency of cramps/spasms compared to with control (p=0.001); a 1.4 day increase in cramp/spasm-free days per 14 day period compared with control (p=0.046); clinician rated improvement in spasticity with FLX-787 treatment significantly better than control (p=0.010); and treating physicians reported that 7 of 28 (25%) patients on FLX-787 had "Much Improved" or "Very Much Improved" spasticity versus 0 of 26 (0%) on control based on the Clinical Global Impression of Change in Spasticity.

In addition, in the evaluation of FLX-787 from data that included both cross-over periods in the intent-to-treat population, the pre-specified analysis of Clinical Global Impression of Change in the patient's spasticity showed statistically significant greater improvement with FLX-787 relative to control (p=0.043), while no statistically significant improvement was seen in cramp/spasm frequency, NRS or clinical spasticity scales.

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,

primary lateral sclerosis, 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. 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.

Motor Neuron Disease and ALS Clinical Trial. In August 2017, we announced the initiation of the COMMEND trial, a Phase 2 clinical trial in the United States. The COMMEND trial was designed to evaluate FLX-787 in patients with MND, focused on ALS, who suffer from cramps. This randomized, controlled, double-blinded, parallel design trial included a 28-day run-in period to establish a baseline in cramp frequency. Patients were then 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. We stopped this trial in June 2018 due to oral tolerability issues observed in this study and the COMMIT trial.

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 muscle 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.

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 was a randomized, controlled, double-blinded, parallel design trial included a run-in period to establish a baseline in cramp frequency. Patients then were randomized to 30 mg of FLX-787, formulated as an ODT, administered three times a day or to a control, for 28 days. We stopped this trial in June 2018 due to oral tolerability issues observed in this study and the COMMEND trial.

HOTSHOT

In June 2016, we launched our consumer product, HOTSHOT, which is currently our only source of revenue. 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. We have primarily marketed HOTSHOT to endurance athletes who drink it before, during and after exercise to prevent and treat EAMCs.

On January 22, 2018, we disclosed that we hired an investment banking firm to help us explore strategic alternatives for our consumer business segment. In connection with the restructuring plan announced in June 2018, we elected to reduce the expenses associated with our consumer business segment while we assessed strategic alternatives for the Company and this segment.

Exercise-Associated Muscle Cramps (EAMC)

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.

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, to develop a more appealing consumer product. HOTSHOT includes organic ingredients and is priced at a premium to many existing sports beverages.

HOTSHOT for Relief from Muscle Soreness and Muscle Pain

In addition to helping to prevent and treat muscle cramps, HOTSHOT has also shown potential benefits for relief from muscle soreness and muscle pain.

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.

In 2017, we completed an in-home use study in which 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.

HOTSHOT Brand Strategy

HOTSHOT has historically been marketed primarily to endurance athletes that participate in high endurance sports, such as triathlons, marathons and cycling events and suffer from muscle cramps. In early 2018, we began expanding our sales and marketing efforts to also promote HOTSHOT's ability to provide relief from muscle pain and muscle soreness in endurance and non-endurance athletes. However, in connection with the restructuring activities in June 2018, we reduced our expenses associated with the consumer business segment which has limited our marketing and promotion of HOTSHOT's benefits.

We historically increased 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. Our current efforts to promote HOTSHOT are primarily focused on email campaigns, social media promotion and product sampling.

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. The majority of our sales and marketing efforts have been focused on geographic areas with strong endurance sports markets, including Los Angeles, San Francisco, Boulder, Boston, Chicago and New York. In each of these locations, we built brand awareness by attending endurance sports events and distributing HOTSHOT to leading specialty retailers, such as cycling, running and triathlon stores.

Intellectual Property

The goal of our intellectual property efforts 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 intellectual property approach has been to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our 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. 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 an issued U.S. utility patent application and one granted European patent directed to compositions and methods of using those compositions for preventing, treating or ameliorating

muscle cramping. The issued U.S. patent is scheduled to expire in July 2031 and the granted patent in Europe will have a statutory expiration in July 2031.

We also own additional patent applications directed at various aspects of our prior work including influencing neuromuscular activity by stimulating a TRP channel in the nerve ending of a sensory neuron. In connection with the restructuring actions taken in June 2018, we decided to no longer support these applications.

We also own one design patent application directed to one of our HOTSHOT bottles. The international design patent application was granted in September 2016. The current status of the designations are Australia (granted), Canada (pending), Europe (pending), South Africa (granted), and the United States (granted). The statutory expiration of the design patents will vary based on jurisdiction. The United States design patent will expire in October 2033, subject to the payment of maintenance fees.

While we seek broad coverage for our patents, there is always a risk that an alteration to the composition of matter or formulation of our 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 product.

Our wholly owned subsidiary that holds our consumer business, 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. Outside the U.S., ownership of the HOTSHOT trademark is split between Flex Innovation and the Company. Flex Innovation owns an International Registration for the HOTSHOT trademark and applications or registrations for the HOTSHOT trademark in Australia, China, the European Union, Iran, Israel, Japan, Mexico, New Zealand, Norway, 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, the Company is 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.

In January 2019, the Founders entered into a royalty agreement with Flex Innovation, which replaces the royalty agreement described above related to the sale of over the counter, non-prescription and/or nutritional supplement products. Under the terms of the agreement, Flex Innovation is now the party obligated to pay the Founders a royalty on all over the counter, non-prescription and/or nutritional supplement products sold by Flex Innovation that are marketed to stop, prevent, relieve or otherwise treat muscle cramps, muscle soreness, or aid in muscle recovery. The product must also include at least one ion channel activator, as defined in the agreement. The royalty is payable on sales, as defined, over twenty years with a 2% royalty for the first ten years and a 1% royalty for the next ten years.

Manufacturing

We do not currently have our own manufacturing facilities and we do not intend to establish our own manufacturing facilities. 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 able to identify and establish relationships with qualified additional or back-up suppliers and manufacturers.

Sales and Marketing

HOTSHOT

We launched HOTSHOT in June 2016 and our marketing efforts have focused on building brand awareness and usage of HOTSHOT. To drive product trial, we have used 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. Our current efforts to promote HOTSHOT are primarily focused on email campaigns, social media promotion and product sampling.

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 have targeted 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.

Competition

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 or may develop. Any drug candidate that we may 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 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 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 have relied and may 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.

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, if any, 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 and other directives designed to delay the implementation of 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, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and the Centers for Medicare and Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact 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, includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2027 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. 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, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation 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. For example, the Trump

administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. Although these and other proposed measure will require authorization through additional legislation to become effective, 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 have increasingly passed legislation and implemented 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.

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. Failure to comply with such regulations 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, among other things, 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. 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).

The federal false claims laws, including the federal civil False Claims Act, and the federal civil monetary penalties statute prohibit, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the federal 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.

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.

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, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations established uniform federal standards for certain "covered entities" (certain 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 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.

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 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.

Employees

As of March 1, 2019, we had 4 full-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.

Corporate and Other Information

We were incorporated in Delaware in February 2014. Our principal executive office is located at 31 St. James Avenue, 6th Floor, Boston, Massachusetts 02116, 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. 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 Business

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

The consummation of the proposed merger between us and Salarius is subject to a number of closing conditions, including the approval by our stockholders of several merger-related matters and other customary closing conditions. The parties are targeting a closing of the transaction in the first half of 2019, however, there can be no assurance that the proposed merger will be consummated on their desired timeframe, or at all.

If the proposed merger between us and Salarius is not consummated, we may be subject to a number of material risks, and our business and stock price could be adversely affected, as follows:

- we have incurred and expect to continue to incur significant expenses related to the proposed merger with Salarius even if the merger is not consummated;
- we may be required to pay Salarius a termination fee of $350,000 and/or reimburse Salarius' expenses up to a maximum of $200,000, depending on the reason for the termination;
- the market price of our common stock may decline to the extent that the current market price reflects a market assumption that the proposed merger will be completed; and
- we may not pursue an alternate merger transaction if the proposed merger with Salarius is not completed.

If the merger is not completed, our Board of Directors may decide to pursue a dissolution, liquidation or winding-up of the company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation, distribution or winding-up as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the merger will be completed. If the merger is not completed, our board of directors would likely decide to pursue a dissolution, liquidation or winding-up of the company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if we dissolve, liquidate or wind-up, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions to our stockholders. Our commitments and contingent liabilities may include: (i) any pending litigation against us, and other various claims and legal actions arising in the ordinary course of business and (ii) payments to certain employees. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to our dissolution, liquidation or winding-up. If a dissolution, liquidation or winding-up were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of our liquidation, dissolution or winding up.

If we fail to continue to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common stock, the delisting could prevent the closing of the merger and adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

On August 13, 2018, we received a letter from the listing qualifications department of The Nasdaq Stock Market, noting that for the prior 30 consecutive business days the bid price of our common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5450(a)(1). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days, or until February 11, 2019, to regain compliance. In order to regain compliance with the minimum closing bid price rule, the closing bid price of our common stock must be at least $1.00 or higher for a minimum of 10 consecutive business days during the 180-day compliance period. On February 12, 2019, we received a letter from the listing qualifications department of The Nasdaq Stock Market, noting that our transfer from the Nasdaq Global Market to the Nasdaq Capital Market was approved and that we were granted an additional 180 period, or until August 12, 2019, to regain compliance with the minimum closing bid price requirement.

If we do not regain compliance with the minimum closing bid price requirement prior to the expiration of the 180-day compliance period, and if it appears to Nasdaq that we will not be able to cure the deficiency, or if we fail to comply with other listing requirements in the future, Nasdaq will provide us with a written notification that our securities are subject to delisting from Nasdaq. At that time, we may appeal the delisting determination to a Nasdaq hearings panel.

On September 27, 2018, we received a letter from the listing qualifications department of The Nasdaq Stock Market, noting that for the prior 30 consecutive business days the market value of our common stock was below $5 million, the minimum amount required by the continued listing requirements of Nasdaq Listing Rule 5450(b)(1)(C). In accordance with Nasdaq Listing Rule 5810(c)(3)(D), we were provided a period of 180 calendar days, or until March 26, 2019, to regain compliance. In order to regain compliance with the minimum market value rule, the market value of our common stock must meet or exceed $5 million for a minimum of 10 consecutive business days during the 180-day grace period. On November 26, 2018, we received a letter from Nasdaq notifying us that we regained compliance with Nasdaq Listing Rule 5450(b)(1)(C). The letter noted that for the last 10 consecutive business days from the date of the letter, the market value of the our publicly held shares was $5 million or greater.

The failure to maintain our listing on Nasdaq could have an adverse effect on the market price and liquidity of our shares of common stock and reduce our ability to raise additional capital. In addition, if our common stock is delisted from Nasdaq and the trading price remains below $5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a “penny stock” (generally, any equity security not listed on a national securities exchange or quoted on Nasdaq that has a market price of less than $5.00 per share, subject to certain exceptions).

As a result of the closure of our Phase 2 studies and the reductions in our workforce announced in June 2018, we have only four employees remaining as of the date of this filing. If we are unable to retain the remaining employees, our ability to consummate the planned merger transaction may be delayed or seriously jeopardized.

On June 13, 2018, we announced workforce reductions, and current headcount has been reduced to four employees. Our cash conservation activities may yield unintended consequences, such as attrition beyond the planned workforce reductions and reduced employee morale, which may cause the remaining employees to seek alternate employment. Competition among biotechnology companies for qualified employees is intense, and the ability to retain the remaining employees is critical to our ability to effectively manage our business and to consummate the planned merger transaction. Additional attrition could have a material adverse effect on our business and ability to consummate the merger. In addition, as a result of the reduction in our workforce, we face an increased risk of employment litigation.

We are an early-stage company with a limited commercial history and a history of net losses. We expect to incur net losses in the future and may never achieve sustained profitability or even revenue.

We are a biotechnology company that has announced an end to our Phase 2 clinical trials of FLX-787 due to oral tolerability concerns observed in the two studies. We currently have no foreseeable path to significant revenue with our current clinical assets. We have historically incurred substantial net losses. Since inception, we have incurred a significant loss. We incurred an accumulated net loss of $133.0 million from February 26, 2014, the date of our inception, to December 31, 2018. We expect our losses to continue. These losses have had, and will continue to

have, an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our business, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

Our business to date has been almost entirely dependent on the clinical success of FLX-787. With the failure of FLX-787, we have no immediate prospects for significant revenue or profitability.

Due to the early stage nature of our business and our limited marketing activities to date, with the failure of FLX-787 it is not likely we have any immediate prospects for significant revenue or profitability.

The loss of our key members of our executive management team could adversely affect our business.

We cannot make any assurances that any of the key remaining members of our management team will remain with us in the event the merger is not consummated. Accordingly, we may be unable to execute any reasonable salvage strategy or properly execute a liquidation, dissolution or winding up of the company.

Declining general economic or business conditions may have a negative impact on our business.

Continuing concerns over U.S. healthcare reform legislation and energy costs, geopolitical issues, such as the government shutdown or Brexit, the availability and cost of credit in the United States and other countries have in the past and may in the future contribute to increased volatility and diminished expectations for the global economy. These factors, if combined with low business and consumer confidence and high unemployment, could precipitate an economic slowdown and recession. If the economic climate deteriorates, our business, as well as the financial condition of our suppliers and our third-party suppliers, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

We depend on our information technology and telecommunications systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant aspects of our operations. These information technology and telecommunications systems support a variety of functions. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive and liability-creating problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from processing all manner of significant data, conducting research and development activities and managing the administrative aspects of our business.

We are required to comply with laws governing the transmission, security and privacy of health information that require significant compliance costs, and any failure to comply with these laws could result in material criminal and civil penalties.

Under the administrative simplification provisions of the federal Health Insurance Portability and Accountability Act of 1996, (which we refer to as "HIPAA"), the U.S. Department of Health and Human Services has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of Protected Health Information, (which we refer to as "PHI"), used or disclosed by health care providers and other covered entities. Three principal regulations with which we are currently required to comply have been issued in final form under HIPAA: privacy regulations, security regulations and standards for electronic transactions.

The privacy regulations cover the use and disclosure of PHI by health care providers. It also sets forth certain rights that an individual has with respect to his or her PHI maintained by a health care provider, including the right to access or amend certain records containing PHI or to request restrictions on the use or disclosure of PHI. We have also implemented policies, procedures and standards to comply appropriately with the final HIPAA security regulations, which establish requirements for safeguarding the confidentiality, integrity and availability of PHI, which is electronically transmitted or electronically stored. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI. As a result, we are required to

comply with both HIPAA privacy regulations and varying state privacy and security laws. AImost all U.S. states now require notification to affected individuals and state authorities, as well as the media in certain cases, in the event of a breach of the security of personal information (including PHI in a few states), often with significant financial penalties for noncompliance.

The Health Information Technology for Economic and Clinical Health Act, (which we refer to as the "HITECH Act"), enacted pursuant to the American Recovery and Reinvestment Act of 2009, (which we refer to as "ARRA"), made sweeping changes to the health information privacy and security regulations of HIPAA by expanding the scope and application of the statute. These changes include, among other things: (1) establishing an affirmative obligation to provide patient data breach notification in the event of the unauthorized acquisition, access, use or disclosure of unsecured PHI; (2) elaborating upon the standard for "minimum necessary" uses and disclosures of PHI by a covered entity; (3) restricting certain uses of PHI for marketing purposes (by expanding the definition of marketing activities requiring authorization); (4) prohibiting certain sales of PHI; (5) establishing an affirmative obligation to provide an accounting of disclosures made for payment, treatment and health care operations (up to three years made through an electronic health record); (6) requiring covered entities to agree to individuals' requests to restrict disclosure of PHI in certain circumstances; (7) applying the security regulations and certain provisions of the privacy regulations to business associates; and (8) modifying an individuals' right to access PHI in an electronic format. The U.S. Department of Health and Human Services issued modifications to the HIPAA Regulations, effective March 26, 2013, implementing some of these changes including the obligation to provide patient data breach notifications, which subject the company to additional administrative requirements in the United States. With regard to the accounting of disclosures, the HITECH Act provides for removing the exception in the existing HIPAA privacy regulations' accounting of disclosures of PHI requirement for disclosures of PHI for payment, treatment, and health care operations purposes made through an electronic health record (within the past three years). The U.S. Department of Health and Human Services issued proposed regulations to implement this provision of the HITECH Act in May 2011, but those regulations have not been finalized.

The HITECH Act also implemented measures to strengthen enforcement of HIPAA and increased applicable penalties for HIPAA violations. Penalties are now tiered and range from $100 to $50,000 per violation with an annual cap for the same violations of $25,000 to $1,500,000. The Office for Civil Rights of the U.S. Department of Health and Human Services, (which we refer to as the "OCR"), has increased enforcement activities and has recently levied large penalties for violations. In addition, as mandated by the HITECH Act, OCR has begun an audit program to assess compliance by covered entities and their business associates with the HIPAA privacy and security rules and breach notification standards.

We seek to comply with HIPAA privacy regulations and state privacy laws. Given the complexity of HIPAA, the HITECH Act and state privacy restrictions, the possibility that the regulations may change, and the fact that the regulations are subject to changing and potentially conflicting interpretation, our ability to comply with HIPAA, the HITECH Act and state privacy requirements is uncertain, and the costs of compliance are significant. To the extent that we or our third-party billing company submit electronic health care claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and the HITECH Act, payments to us may be delayed or denied. Additionally, the costs of complying with any changes to HIPAA, the HITECH Act and state privacy restrictions may have a negative impact on our operations. We could be subject to criminal penalties and civil sanctions for failing to comply with HIPAA, the HITECH Act and state privacy restrictions, which could result in the incurrence of significant monetary penalties.

If we ever again pursued clinic studies or placed a product or products in the market for use by patients, a host of federal and state healthcare regulations would apply to our business, which would create operational risk and potential liability.

Risks Related to Our Financial Condition

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have generated limited revenue from sales of HOTSHOT and have generated no revenue from any of our drug product candidates. We have incurred net losses in each year since our inception on February 26, 2014, including a consolidated net loss of $21.9 million for the year ended December 31, 2018. As of December 31, 2018, we had an accumulated deficit of approximately $133.0 million. Our prior losses, combined with expected future losses, have had and may continue to have an adverse effect on our stockholders' equity and working capital.

To date, we have financed our operations with net proceeds from the private placement of our preferred stock and our initial public offering. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to generate revenue.

The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of investors, which could cause our stock price to decline.

If the merger is not completed, we would need to raise substantial additional funding to the extent we operate our consumer business or resume our drug development efforts, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our drug development efforts or other operations.

If the merger is not completed, we may require substantial additional capital to fund our research and development and expenses related to our consumer brand and HOTSHOT. We had unrestricted cash and cash equivalents of $9.8 million at December 31, 2018. Our current operating plan assumes limited research and development activities and that we will continue to sell HOTSHOT. In the event that the merger is not completed, we would likely pursue a liquidation, dissolution or winding-up of the company, or may seek to complete an alternate strategic transaction or may elect to continue to market HOTSHOT and operate our consumer business. Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to allow us to fund our current operating plan for at least 12 months from the date the financial statements are issued.

We cannot predict to what extent we will resume drug development activities for FLX-787 or any other drug product candidate. If we resume drug development activities, only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical failure can occur at any stage of clinical development and clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical trials. In addition, data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a drug candidate. Further, even if we complete the development for a drug product candidate and gain marketing approvals from the FDA, and comparable foreign regulatory authorities in a timely manner, we cannot be sure that such drug product candidate will be commercially successful in the pharmaceutical market. If the results of clinical trials, the anticipated or actual timing of marketing approvals, or the market acceptance of any drug product candidate, if approved, do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline. Further, if we resume drug development activities, we will need substantial additional financing to complete the development of FLX-787 or any other drug product candidates we may develop.

We expect to incur losses for the foreseeable future. Our ability to achieve profitability in the future is dependent upon achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of those securities could result in substantial dilution for our current stockholders and the terms may include liquidation or other preferences that adversely affect the rights of our current stockholders, further diminishing current stockholders' ability to realize any value for their stock holdings. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings. There can be no assurances, however, that additional funding will be available on terms acceptable to us, or at all.

Risks Related to Our Consumer Business

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.

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.

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 an 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. 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 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.

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. 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 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.

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

The majority of HOTSHOT inventory is concentrated in one warehouse location. Any significant disruption to the operation of the 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.

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 marketing of HOTSHOT entails an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities. 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 be sure that our insurance will be sufficient to cover our losses. Any losses that are not completely covered by our insurance could have a material adverse effect on our business, financial condition or results of operations, including preventing or limiting the commercialization of drug products and consumer products we develop, alone or with collaborators.

Unfavorable publicity or consumer acceptance of 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. 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 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.

Risks Related to our Intellectual Property

If we are unable to maintain intellectual property protection, our competitive position could be harmed.

Our ability to protect our proprietary discoveries and technologies affects our ability to monetize any of our remaining assets. Currently, we rely on a combination of issued U.S. patents, U.S. and foreign patent applications, copyrights, trademarks and trademark applications, confidentiality or non-disclosure agreements, material transfer agreements, licenses, work-for-hire agreements and invention assignment agreements to protect our intellectual property rights. We also maintain certain company know-how, trade secrets and technological innovations designed to provide us with a competitive advantage in the market place as trade secrets.

To the extent there is any remaining value in any of these intellectual property assets, it may be lost if we are unable to protect our intellectual property.

We may face intellectual property infringement claims that could be time-consuming and costly to defend and could result in our loss of significant rights and the assessment of treble damages.

From time to time we may face intellectual property infringement, misappropriation, or invalidity/non-infringement claims from third parties. Some of these claims may lead to litigation. The outcome of any such litigation can never be guaranteed, and an adverse outcome could affect us negatively. For example, were a third party to succeed on an infringement claim against us, we may be required to pay substantial damages (including up to treble damages if such infringement were found to be willful). Potential damages could easily consume all or most of our remaining cash. In addition, we could face an injunction, barring us from conducting the allegedly infringing activity. The outcome of the litigation could require us to enter into a license agreement which may not be under acceptable, commercially reasonable, or practical terms or we may be precluded from obtaining a license at all.

Finally, we could initiate claims to assert or defend our own intellectual property against third parties. If one or more of our patents were held to be invalid or not infringed, we might not be able to exclude others from offering similar or identical products or services. Any intellectual property litigation, irrespective of whether we are the plaintiff or the defendant, and regardless of the outcome, is expensive and time-consuming, and could divert our management's attention from our business and negatively affect our operating results or financial condition.

Risks Related to Ownership of our Common Stock

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

Our stock price has been and is likely in the future to be volatile. The stock market in general and the market for smaller clinical biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for it. The market price for our common stock may be influenced by many factors, including:

- announcements and market perceptions related to the merger;
- issuances of new equity securities pursuant to a future offering, including issuances of preferred stock or convertible debt;
- the success of competitive products, services or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;

- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of health care payment systems;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of the Company more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, it is governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits our stockholders owning in excess of 15% of the outstanding voting stock from merging or combining with us, subject to limited exceptions. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

If our shares become subject to the penny stock rules, it may be more difficult to sell our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTC Bulletin Board does not meet such requirements. If the price of our common stock remains less than $5.00 and we are not listed on a national securities exchange, our common stock may be deemed a penny stock. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive: (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for common stock, and therefore stockholders may have difficulty selling their shares.

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

Prior to our initial public offering on January 28, 2015, there was no public market for our common stock. The listing of our common stock on The Nasdaq Capital Market does not assure that a meaningful, consistent and liquid trading market exists. Although our common stock is listed on The Nasdaq Capital Market, trading volume in our common stock has been limited and an active trading market for our shares may never develop or be sustained. If an active market for our common stock does not develop, it may be difficult for investors to sell their shares without depressing the market price for the shares or at all.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We maintain a shelf registration statement on Form S-3 with the SEC pursuant to which we may, from time to time, sell up to an aggregate of $125 million of our common stock, preferred stock, debt securities and warrants, although we have limited ability to use our shelf registration statement

on Form S-3. Sales of securities under the registration statement will result in dilution of our stockholders and could cause our stock price to fall.

We are an "emerging growth company," and the reduced disclosure 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 of 2012, (which we refer to as the "JOBS Act") and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in our periodic disclosure reports. In particular, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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.

Since the initial public offering on January 28, 2015, we have incurred significantly increased costs and our management has had to devote substantial time as a result of operating as a public company and our future costs are uncertain.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Capital Market or the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel have had to devote a substantial amount of time to these compliance initiatives since becoming a public company. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made certain activities more time-consuming and costlier.

Because we are still a relatively new public company and in the aftermath of the termination of our clinical studies, we cannot predict or estimate the costs we may incur in the future with respect to these compliance initiatives or the timing of such costs. In addition, 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, (which we refer to as "Section 404"), as an emerging growth company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm in our annual report. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk

that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, if ever, capital appreciation, if any, will be our sole source of gain.

We do not anticipate paying future dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, on the common stock will be our stockholders' sole source of gain for the foreseeable future.

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 is located at a small office facility in Boston, MA, which is used for our corporate and sales and marketing functions. Our lease can be terminated upon one month's notice. We believe that our existing facility is sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings

On June 19, 2018, a putative class action lawsuit was filed against us and certain of our current executive officers in the United States District Court for the Southern District of New York, captioned Teofilina Rumaldo v. Flex Pharma, Inc., et al., Case No. 1:18-cv-05493. The complaint purported to be brought on behalf of stockholders who purchased our common stock between November 6, 2017 and June 12, 2018. The complaint generally alleged that we and certain of our current officers violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934,

as amended, and Rule 10b-5 promulgated thereunder by making allegedly false and misleading statements or omissions regarding our business, operational and compliance policies. Specifically, the complaint alleged that we overstated the viability and approval prospects for our product candidate FLX-787 for the treatment of MND and CMT and, as a result, our public statements were materially false and misleading at all relevant times. This case was voluntarily dismissed, with prejudice, on December 10, 2018.

On March 1, 2019, Nahuel Malzone, a purported stockholder of Flex Pharma, sent us a written demand letter and draft complaint alleging that (1) the Company and the members of its Board of Directors, or the Board, violated Section 14(a) of the Securities Exchange Act of 1934, as amended, the Exchange Act, and Rule 14a-9 promulgated thereunder, by filing a proxy statement, which allegedly failed to disclose and/or misrepresented material information about the proposed merger with Salarius Pharmaceuticals, LLC, and (2) the members of the Board, as control persons of the company, violated Section 20(a) of the Exchange Act in connection with the filing of the allegedly materially deficient proxy statement. Mr. Malzone demanded that we provide certain corrective disclosures to the proxy statement/prospectus/information statement. We are reviewing the demand letter and will respond appropriately.

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 is publicly traded on The Nasdaq Capital Market under the symbol "FLKS."

Holders of Record

As of March 1, 2019, we had approximately 18 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

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.

Proceeds from our initial public offering are being used for general corporate purposes, costs related to the potential merger with Salarius and costs to support the continued marketing and sales of HOTSHOT.

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, 2018, December 31, 2017 and December 31, 2016, and the consolidated balance sheet data as of December 31, 2018 and December 31, 2017 from our audited consolidated financial statements, included elsewhere in this Annual Report. The statements of operations data for the year ended December 31, 2015 and the period from inception (February 26, 2014) to December 31, 2014, and the balance sheet data as of December 31, 2016, 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, 2018	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	$ 826,515	$ 1,260,973	$ 989,918	$ —	$ —
Other revenue	11,627	13,526	20,745	—	—
Total revenue	838,142	1,274,499	1,010,663	—	—
Costs and expenses:					
Cost of product revenue	430,750	506,530	662,747	—	—
Research and development	11,908,294	16,989,911	20,378,161	12,749,379	4,003,911
Selling, general and administrative	10,573,321	18,503,684	19,855,987	16,464,279	4,025,895
Total costs and expenses	22,912,365	36,000,125	40,896,895	29,213,658	8,029,806
Loss from operations	(22,074,223)	(34,725,626)	(39,886,232)	(29,213,658)	(8,029,806)
Interest income, net	152,006	291,964	393,109	72,028	18,946
Net loss attributable to common stockholders	$ (21,922,217)	$ (34,433,662)	$ (39,493,123)	$ (29,141,630)	$ (8,010,860)
Net loss per share attributable to common stockholders — basic and diluted[1]	$ (1.22)	$ (1.99)	$ (2.43)	$ (2.08)	$ (4.57)
Weighted-average number of common shares outstanding — basic and diluted[1]	18,016,841	17,260,626	16,233,985	14,032,916	1,753,024

(1) See Note 2 and Note 15 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, 2018	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	$ 9,829,624	$ 33,315,759	$ 61,074,973	$ 93,651,992	$ 33,854,153
Working capital[(2)]	9,208,296	28,687,467	58,578,074	89,400,216	33,157,388
Total assets	10,389,626	34,992,772	63,214,979	95,069,838	35,611,398
Convertible preferred stock	—	—	—	—	41,031,167
Accumulated deficit	(132,961,275)	(111,079,275)	(76,645,613)	(37,152,490)	(8,010,860)
Total stockholders' equity (deficit)	9,282,756	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, 2018 to the year ended December 31, 2017, and the year ended December 31, 2017 to the year ended December 31, 2016.

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, Flex Pharma, or the Company, are a biotechnology company that was previously focused on developing innovative and proprietary treatments for muscle cramps, spasms and spasticity associated with severe neurological conditions. In June 2018, we announced that we were ending our ongoing Phase 2 clinical trials of our lead drug product candidate, FLX-787, in patients with motor neuron disease, or MND, primarily with amyotrophic lateral sclerosis, or ALS, and in patients with Charcot-Marie-Tooth disease, or CMT, due to oral tolerability concerns observed in both studies. The wind-down of the activities associated with these studies was completed in the third quarter of 2018.

In 2016, we launched our consumer product, HOTSHOT®, to prevent and treat exercise-associated muscle cramps, or EAMCs. We continue to market and sell HOTSHOT to endurance athletes who drink it before, during and after exercise to prevent and treat EAMCs.

In June 2018, we initiated a process to explore a range of strategic alternatives for enhancing stockholder value, including the potential sale or merger of the company. Wedbush PacGrow was engaged to act as our strategic financial advisor at that time. We also announced the restructuring of our organization to reduce our cost structure. In connection with the restructuring plan, we reduced our workforce by approximately 60%, with the reduction complete as of September 30, 2018.

Following an extensive process of evaluating strategic alternatives for the Company, including identifying and reviewing potential candidates for a strategic acquisition or other transaction, on January 3, 2019, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Salarius Pharmaceuticals, LLC, or Salarius, under which the privately held Salarius will merge with a wholly owned subsidiary of the company. If the merger is completed, the business of Salarius will continue as the business of the combined company.

We expect to devote significant time and resources to the completion of this merger. However, there can be no assurances that such activities will result in the completion of the merger. Further, the completion of the merger may ultimately not deliver the anticipated benefits or enhance shareholder value.

If the merger is not completed, we will reconsider our strategic alternatives. We consider one of the following courses of action to be the most likely alternatives if the merger is not completed:

- *Dissolve and liquidate our assets.* If, for any reason, the merger does not close, our board of directors will most likely conclude that it is in the best interest of stockholders to dissolve the Company and liquidate our assets. In that event, the Company would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims. There would be no assurances as to the amount or timing of available cash remaining to distribute to stockholders after paying our obligations and setting aside funds for reserves.

- *Pursue another strategic transaction.* We may resume the process of evaluating a potential strategic transaction in order to attempt another strategic transaction like the merger.

- *Operate the consumer business.* Although less likely than the alternatives above, our board of directors may elect to continue to market and sell HOTSHOT and continue to operate our consumer business.

We currently operate as two reportable segments:

- The Consumer Operations segment, which reflects the total revenue and costs and expense 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; previously 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 16 to our condensed consolidated financial statements 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 the foreseeable future. Our net loss and our accumulated deficit was $21.9 million and $133.0 million, respectively, for the year ended December 31, 2018, and as of December 31, 2018. To date, we have financed our operations with net proceeds from the private placement of our preferred stock and our initial public offering. If the merger is not completed, we will need to reassess our strategic options and we may need additional capital to fund our future operations. There can be no assurance that we will be able to secure additional funds or, if such funds are available, whether the terms or conditions will be acceptable to us.

Merger Agreement

After conducting a diligent and extensive process of evaluating strategic alternatives for the company and identifying and reviewing potential candidates for a strategic acquisition or other transaction, which included the careful evaluation and consideration of proposals from interested parties, and following extensive negotiation with Salarius, on January 3, 2019, we, Falcon Acquisition Sub, LLC, or Merger Sub, a wholly owned subsidiary of the Company, and Salarius entered into the Merger Agreement. Pursuant to the Merger Agreement, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Salarius, with Salarius continuing as a wholly owned subsidiary of the Company and the surviving corporation.

The Merger Agreement (i) values the Company at $10.5 million, subject to adjustment, on a dollar-for-dollar basis, based on our net cash balance at the closing of the merger compared to a target net cash of $3.3 million, and (ii) values Salarius at $36.6 million, subject to adjustment, on a dollar-for-dollar basis, based on the sale of Series A Preferred units pursuant to subscription agreements that Salarius entered into prior to the Merger Agreement compared to the target sale of $7.0 million of Series A Preferred units.

At the closing of the merger, each outstanding common unit, profits interest common unit and Series A Preferred unit of Salarius will convert into the right to receive shares of our common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to an anticipated reverse stock split of our common stock) at the conversion ratio formulae described in the Merger Agreement. Under those formulae, immediately following the effective time of the merger, our current stockholders will own approximately 19.9% of the combined company (on a partially-diluted basis, excluding the effect of certain options, the dividend or distribution of rights and Warrants to our current stockholders and the possible issuance of a warrant to Wedbush with a value up to $0.5M as payment for a portion of their fee for the merger) and Salarius' current members will own approximately 80.1% of the combined company (on a partially-diluted basis, excluding the effect of certain options, the dividend or distribution of rights and Warrants to our current stockholders and the possible issuance of a warrant to Wedbush). For

purposes of calculating the conversion ratios, the number of outstanding shares of our common stock immediately before the merger takes into account the dilutive effect of approximately 849,610 shares of our common stock underlying options outstanding as of January 3, 2019 that have an exercise price less than or equal to $1.35 per share of our common stock. Approximately 1,447,426 shares of our common stock that underlie options outstanding as of January 3, 2019 have an exercise price greater than $1.35 per share of our common stock.

In addition, at or prior to the closing of the merger, we will pay a dividend of or distribute one right per share of our common stock to our stockholders of record as of a date and time determined by our board of directors. Each right will entitle such stockholders to receive a warrant to purchase shares of our common stock, or Warrant, six months and one day following the closing date of the merger.

The Warrants will contain customary terms and conditions, provided that the Warrants:

- will have an exercise price per share of our common stock equal to the fair market value of a share of our common stock on the closing date of the merger (such exercise price subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to our common stock);
- will be immediately exercisable upon receipt, which receipt will be six months and one day following the closing date of the merger;
- will be exercisable for five years after receipt;
- will be subject to a cashless exercise, at our option, under certain circumstances; and
- will be exercisable, in the aggregate, with respect to that number of shares of our common stock equal to the Warrant Aggregate Value (as defined in the Merger Agreement) divided by the value (determined using the Black-Scholes-Merton option pricing formula) of a warrant to purchase a share of our common stock on the closing date of the merger.

The Warrant Aggregate Value generally represents the difference between (i) the Company's value and (ii) the value of the Company's common stock that our current stockholders will have in the combined company. Accordingly, the Warrant Aggregate Value will be based in part on our net cash balance at the time of closing of the merger and adjusted for the amount of additional financing consummated by Salarius at or before the closing of the merger, as further described in the Merger Agreement.

Concurrent with the execution of the Merger Agreement, certain of our officers, directors and stockholders holding approximately 0.5% of our outstanding common stock and certain officers, directors and members of Salarius holding approximately 35% of the Salarius membership units have entered into lock-up agreements pursuant to which they accepted certain restrictions on transfers of shares of our common stock for the 90-day period following the closing of the merger.

The Merger Agreement contains certain termination rights for both us and Salarius, and further provides that, upon termination of the Merger Agreement under specified circumstances, either party may be required to pay the other party a termination fee of $0.35 million, or in some circumstances we may be required to reimburse Salarius' expenses up to a maximum of $0.2 million. In addition, in certain specified circumstances, Salarius may be required to pay us a termination fee of $1.0 million.

At the effective time of the merger, our board of directors is expected to consist of seven members, six of whom will initially be designated by Salarius and one of whom will initially be designated by us.

Components of Operating Results

Revenue

We adopted ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, on January 1, 2018 using the modified retrospective method. The primary impact of the adoption of ASC 606 related to the timing of revenue recognized for e-commerce sales, due to e-commerce refund rights. Under ASC 606, we recognize revenue when control of the promised good is transferred to the customer, and it reflects the consideration to which we expect to be entitled to receive in exchange for the good. This has resulted in accelerated revenue recognition for e-commerce sales, as under ASC Topic 605, *Revenue Recognition*, all revenue and related costs were deferred and

recognized once the refund period lapsed. Please refer to Note 3 in the accompanying consolidated financial statements for a discussion of the impact of the adoption of ASC 606 on our consolidated financial statements.

Revenue includes sales of HOTSHOT finished goods to e-commerce customers, specialty retailers and sports teams, including professional and collegiate teams. Revenue also consists of payments made by customers for expedited shipping and handling. Under ASC 605 and through December 31, 2017, revenue was recognized when persuasive evidence of an arrangement existed, delivery of the product occurred, the sales price was fixed or determinable and collectability was reasonably assured. We generally provided refunds to e-commerce customers, upon request, within 30 days of delivery. Under ASC 606 and as of January 1, 2018, revenue is recognized when control of the promised goods is transferred to the customer. Control of the promised goods is transferred upon delivery to the customer. For sales through June 18, 2018, we offered refunds to e-commerce customers, upon request, within 30 days of delivery. For sales subsequent to June 18, 2018, we now offer refunds to e-commerce customers, upon request, within 14 days of delivery.

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 any taxes collected from customers and remitted to governmental authorities.

When purchasing via our branded website, customers may purchase HOTSHOT in packs of 3, 6, 12 or 24 bottles, and are offered a first-time purchase discount for a 3 pack. Prior to 2018, we offered a first-time purchase discount for a 6 pack and we began offering the 3 packs and 24 packs in 2018. 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.

While the Company continues to operate its Consumer Operations segment and sell HOTSHOT, 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.

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 include the costs incurred related to the development and testing of our extract formulation and expenses related to the testing and development of our drug product candidates, including FLX-787, and more recently, costs related to ending our Phase 2 clinical studies in MND and CMT. Research and development costs include salaries and other compensation-related costs, such as stock-based compensation for research and development employees and termination benefits, costs of clinical studies of our extract formulation and drug product candidates, drug substance production costs, formulation and production costs of clinical supply, including FLX-787, to support clinical studies, costs for consultants who we utilized 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 have been 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 that our

research and development expenses will continue to decrease as a result of ending our Phase 2 clinical trials in MND and CMT, and the related drug development efforts, and the reduction of research and development staff. We cannot predict to what extent we will resume drug development activities for FLX-787 or other drug product candidates.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses include 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. These costs include personnel costs, costs related to our marketing, sales and promotional activities, including print and digital media campaigns, public relations activities, field marketing efforts, market research, other sales and promotional activities and costs related to the distribution of HOTSHOT. These distribution costs include shipping and handling costs incurred once the product is in salable condition.

Our selling, general and administrative expenses may increase as we incur costs related to the merger, operate as a public company and continue to sell 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, 2018 Compared to the Year Ended December 31, 2017

The following table sets forth our results of operations for the year ended December 31, 2018 compared to the year ended December 31, 2017.

	Year Ended December 31, 2018	Year Ended December 31, 2017	Change	
			$	%
Net product revenue	$ 826,515	$ 1,260,973	$ (434,458)	(34)%
Other revenue	11,627	13,526	(1,899)	(14)%
Total revenue	838,142	1,274,499	(436,357)	(34)%
Costs and expenses:				
Cost of product revenue	430,750	506,530	(75,780)	(15)%
Research and development	11,908,294	16,989,911	(5,081,617)	(30)%
Selling, general and administrative	10,573,321	18,503,684	(7,930,363)	(43)%
Total costs and expenses	22,912,365	36,000,125	(13,087,760)	(36)%
Loss from operations	(22,074,223)	(34,725,626)	12,651,403	(36)%
Interest income, net	152,006	291,964	(139,958)	(48)%
Net loss	$ (21,922,217)	$ (34,433,662)	$ 12,511,445	(36)%

Revenue

Our Consumer Operations segment generated all of our revenue during the year ended December 31, 2018, totaling $0.8 million, as compared to $1.3 million for the year ended December 31, 2017, through sales of HOTSHOT and expedited shipping and handling purchases. The decrease in revenue of $0.4 million primarily relates to decreased marketing spend and activity during the year ended December 31, 2018 compared to the year ended December 31, 2017, as we reduced our Consumer Operations spending while we have been evaluating strategic alternatives for the segment.

Sales via e-commerce represented approximately 85% of our total revenue for the year ended December 31, 2018 compared to 82% for the year ended December 31, 2017.

During the year ended December 31, 2018, we sold approximately 184,000 bottles of HOTSHOT at an average total revenue per bottle of $4.56, compared to 298,000 bottles at an average total revenue per bottle of $4.28 during the year ended December 31, 2017. The increase in average total revenue per bottle is primarily related to fewer price promotions in 2018 compared to 2017, as well a change to the e-commerce trial pack offer in 2018, resulting in higher revenue per bottle compared to the prior year. The decrease in volume of bottles sold in the comparative periods was primarily due to decreased marketing efforts and resulting demand. In addition, the decrease in the number of bottles sold relates to our adoption of ASC 606, as revenue we deferred in the fourth quarter of 2016 was recognized during the first quarter of 2017 under ASC 605.

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 $0.4 million for the year ended December 31, 2018 compared to $0.5 million for the year ended December 31, 2017. Cost of product revenue during the year ended December 31, 2018 includes the cost of HOTSHOT sold, royalty expense, inventory write-offs of approximately $85,000 related to raw materials that are not expected to be used in future production runs, as well as finished goods inventory no longer expected to be used, 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, 2017 included the cost of HOTSHOT sold, royalty expense, inventory write-offs of $42,000 related to certain raw materials not expected to be used in future production runs and expiring finished goods 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 $11.9 million for the year ended December 31, 2018 compared to $17.0 million for the year ended December 31, 2017. The 30% decrease of $5.1 million was primarily related to:

- $1.9 million decrease in clinical trial costs, primarily related to the decision to end our Phase 2 clinical trials of FLX-787 in MND and CMT, and other supporting studies, in the second quarter of 2018;
- $1.0 million decrease in manufacturing and formulation of drug product to support clinical studies, which ceased during the second and third quarters of 2018 related to the decision to end our Phase 2 trials;
- $0.8 million decrease related to stock-based compensation expense, related primarily to the final vesting of restricted common stock issued to our founders in 2014 during the first quarter of 2018, as well as decrease in headcount compared to the prior year;
- $0.8 million decrease in consulting expenses due to winding down of many of our research and development activities due to ending our Phase 2 clinical trials and our strategic assessment;
- $0.3 million decrease in salary and benefit costs due to decreased headcount from prior year, partially offset by restructuring-related expenses, including termination and retention benefit expenses incurred during 2018;
- $0.2 million decrease in employee travel and recruiting costs related to decreased Drug Development headcount from the prior year; and
- $0.1 million decrease in other expenses, including the allocation of insurance and rent expense to the Drug Development segment, related to decreased headcount from the prior year.

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 $10.6 million for the year ended December 31, 2018 compared to $18.5 million for the year ended December 31, 2017. The 43% decrease of $7.9 million was primarily related to:

- $3.9 million of decreased marketing and consulting costs within our Consumer Operations segment for HOTSHOT due to decreased activity during the strategic assessment;
- $2.3 million decrease related to salaries and benefits, as Consumer Operations and corporate headcount decreased from the prior year, partially offset by restructuring-related expenses, including termination and retention benefit expenses, incurred during 2018;
- $1.4 million decrease in stock-based compensation expense, related primarily to a decrease in headcount compared to the prior year and the final vesting of restricted common stock issued to our founders in 2014 during the first quarter of 2018;
- $0.5 million decrease in employee travel and recruiting costs related to decreased Consumer Operations and corporate headcount from the prior year;
- $0.3 million decrease in consulting due to cash conservation efforts during our strategic assessment;
- $0.3 million decrease in rent, office and other expenses primarily due to the termination expenses associated with the lease of our office in New York, NY in the third quarter of 2017 and decreased headcount;
- $0.2 million decrease in HOTSHOT product sampling within our Consumer Operations segment due to decreased marketing events;
- $0.2 million decrease in distribution cost within our Consumer Operations segment due to decreased sales; and
- $1.2 million increase in legal and professional expenses to supplement our corporate personnel and assist with our strategic assessments.

Loss from Operations

Our consolidated loss from operations for the year ended December 31, 2018 totaled $22.1 million. Of this total, $2.0 million of the operating loss was incurred by our Consumer Operations segment, $11.9 million was incurred by our Drug Development segment and the remaining $8.2 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, 2018. 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 and restructuring-related expenses, as well as consulting costs.

Interest Income, net

Interest income, net, decreased by $0.1 million in the year ended December 31, 2018 compared to the year ended December 31, 2017 as we had lower available cash to invest.

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.

	Year Ended December 31, 2017	Year Ended December 31, 2016	Change	
			$	%
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 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 2016 or ramping down in 2017, 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 former corporate headquarters in Boston, MA.

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 the lease for our office in New York, NY, as well as increase in rent expense due to entering into a new lease agreement for our former corporate headquarters in Boston, MA; 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.

Liquidity and Capital Resources

Overview

Since inception, we have incurred operating losses and we anticipate that we will continue to incur losses for the foreseeable future. To date, we have generated limited revenue from sales of HOTSHOT, and have generated no revenue from any of our drug product candidates.

We cannot predict to what extent we will resume drug development activities for FLX-787 or any other drug product candidates, and we may not be successful in generating significant revenue from HOTSHOT. Our operating plan assumes limited research and development activities and that the Consumer Operations segment will continue to sell HOTSHOT. We expect that our research and development expenses will continue to decrease as a result of ending our Phase 2 clinical trials in MND and CMT and the related drug development efforts, and the reduction of research and development staff. Our selling, general and administrative expenses may increase as we continue our efforts related to the merger, operate as a public company, and continue to sell HOTSHOT. There can be no assurance that we will complete the merger with Salarius. If the merger is not completed, we will reconsider our strategic alternatives which may include a dissolution of the company, pursuit of another strategic transaction or the continued operation of the consumer business. Additional capital may be needed to fund operations but there can be no assurances that additional funding will be available on terms acceptable to us, or at all.

Sources of Liquidity

As of December 31, 2018, we had $9.8 million in cash and cash equivalents, which were held in bank deposit accounts and money market funds. The Company held no marketable securities at December 31, 2018.

In the event that we do not complete the merger, we may pursue a dissolution and liquidation of the Company. If the decision is made to dissolve and liquidate the Company, our common stockholders may lose their entire investment. The amount of assets available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will be needed for commitments and contingent liabilities.

Funding Requirements

Our future funding requirements are difficult to forecast and depend on many factors, including our ability to complete the merger and the timing for completion of the merger or, if the merger is not completed, our ability to identify and consummate another strategic transaction or consider other alternatives such as dissolution of the Company. Depending on the outcome of these alternatives, we may need additional capital to fund our operations. There can be no assurances, however, that additional funding will be available on terms we deem to be acceptable, or at all. 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 the Company's common stock. If the Company incurs 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.

Drug Product Candidates

We cannot predict to what extent we will resume drug development activities for FLX-787 or other drug product candidates. To the extent that we pursue drug development activities in the future, 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 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.

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.

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. In connection with the restructuring plan announced in June 2018, we elected to reduce the expenses associated with our consumer business segment while we assessed strategic alternatives for the Company and this segment. The Company is continuing to assess alternatives for the Consumer Operations segment.

Outlook

Based on our research and development plans, our consumer brand and HOTSHOT expenditure plans and the ending of the Phase 2 clinical trials in MND and CMT and the related drug development work, we expect that our existing cash resources will enable us to fund our costs and expenses, working capital and capital expenditure requirements for at least 12 months from the date the financial statements are issued. We based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than expected.

Cash Flows

	Year Ended December 31, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Net cash (used in) provided by:			
Operating activities	$ (23,598,660)	$ (27,722,198)	$ (32,052,113)
Investing activities	14,124,238	24,489,562	(12,240,880)
Financing activities	118,010	2,632	22,098
Net decrease in cash and cash equivalents	$ (9,356,412)	$ (3,230,004)	$ (44,270,895)

Operating activities

Net cash used in operating activities for the year ended December 31, 2018 was $23.6 million, a decrease of $4.1 million compared to the same period in the prior year. The use of cash for the year ended December 31, 2018 was primarily related to our net loss for the period of $21.9 million, offset by non-cash charges consisting of stock compensation expense of $1.9 million, and depreciation, amortization and accretion on investments, and other non-cash items, which totaled $0.3 million. Cash used in operations was increased by a $3.9 million cash outflow from changes in operating assets and liabilities. This outflow was driven by a decrease in accounts payable, accrued expenses and other current liabilities, and deferred rent, which together totaled $4.7 million. The decrease in accounts payable relates to decreased spending at December 31, 2018 compared to December 31, 2017. The decrease in accrued expenses and other current liabilities relates primarily to decreased clinical activity due to the close out of the MND and CMT Phase 2 clinical trials in third quarter of 2018, and decreases in accrued bonus and accrued vacation due to the terminations related to the corporate restructuring, as well as payment of prior year employee-related accruals, partially offset by the accrual for restructuring-related activities as of December 31, 2018. The decrease in deferred rent is due to terminating the operating lease for the company's former corporate headquarters in December 2018. These outflows were offset by inflows from decreases in prepaid expenses and other current assets of $0.6 million and inventory of $0.2 million. The decrease in prepaid expenses and other

current assets primarily relates to the ending of the Phase 2 clinical trials and decreased spending. The decrease in inventory is primarily related to continued sales of HOTSHOT.

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 December 31, 2016. 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 and 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 former corporate headquarters in Boston, MA through 2019. The decrease in prepaid expenses and other current assets is mainly due to a decrease in interest receivable as we had lower cash to invest in 2017 and the timing of payments for Consumer Operations and corporate expenditures.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2018 compared to the year ended December 31, 2017 decreased $10.4 million, primarily related to a $10.5 million decrease in net purchases and sales of marketable securities. This included a $41.5 million decrease in proceeds from maturities and sales of marketable securities and $31.0 million decrease in purchases of marketable securities as our cash balance available for investment decreased and proceeds from prior investments exceeded purchases of new investments. Property and equipment acquisitions decreased $0.1 million as the Company had no property and equipment purchases in 2018.

Net cash used in 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 and proceeds from prior investments exceeded purchases of new investments. 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.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2018 compared to the year ended December 31, 2017 increased $0.1 million, related to proceeds from exercises for options of common stock. Proceeds from exercises of options for common stock during the years ended December 31, 2018 and December 31, 2017 totaled $118,000 and $2,600, respectively.

Cash provided by financing activities during the years ended December 31, 2017 and December 31, 2016 totaled $2,600 and $22,100, respectively, and related to proceeds from exercises of common stock.

Contractual Obligations

During the fourth quarter of 2018, our lease agreement for an approximate 7,200 square foot facility in Boston, MA was terminated, and we relocated to a small leased facility in Boston, MA, which is used for its corporate and sales and marketing functions. The lease expires upon at least one month’s notice. Future minimum lease payments under this lease are not material.

In connection with our strategic assessment, we entered into retention and severance agreements with certain employees. Based upon the terms of these agreements, we may be required to pay up to $1.9 million in retention, bonuses payable upon a change in control and severance payments. See Note 9 to the accompanying consolidated financial statements for more information on our retention and severance arrangements.

In 2014, we 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, 2018 and December 31, 2017 totaled approximately $17,000 and $25,000, respectively.

Future royalty payments are determinable as it is dependent upon the achievement of the earlier mentioned revenue recognition.

In January 2019, the Founders entered into a royalty agreement with Flex Innovation, which replaces the royalty agreement described above related to the sale of over the counter, non-prescription and/or nutritional supplement products. Under the terms of the agreement, Flex Innovation is now the party obligated to pay the Founder's a royalty on all over the counter, non-prescription and/or nutritional supplement products sold by Flex Innovation that are marketed to stop, prevent, relieve or otherwise treat muscle cramps, muscle soreness, or aid in muscle recovery. The product must also include at least one ion channel activator, as defined in the agreement. The royalty is payable on sales, as defined, over twenty years with a 2% royalty for the first ten years and a 1% royalty for the following ten years.

Net Operating Loss and Research and Development Carryforwards

As of December 31, 2018, we had deferred tax assets of $33.8 million. The net 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 carryforwards. As of December 31, 2018, we have a federal NOL carryforward of $110.9 million available to potentially offset future taxable income and state NOL carryforward of $105.4 million. We also have federal research and development tax credit carryforwards of $1.8 million available to potentially offset future federal income taxes. State research credit carryforwards total approximately $570,000. The pre-2018 federal net operating loss carryforwards expire at various dates through 2037. Federal net operating loss carryforwards generated in 2018 and forward will have an unlimited carryforward period as part of the Tax Cuts and Jobs Act, which was signed into law December 22, 2017. The indefinite lived net operating loss carryforwards as of December 31, 2018 are approximately $19.7 million. Research and development credit carryforwards will expire at various dates through 2038. 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, such as the merger with Salarius, or changes that are outside of our control, the tax benefits related to the net operating loss or research and development carryforwards may be limited or lost.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our 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 includes sales of HOTSHOT finished goods to e-commerce customers, specialty retailers and sports teams, including professional and collegiate teams. Revenue also consists of payments made by customers for expedited shipping and handling. Under ASC 605 and through December 31, 2017, revenue was recognized when persuasive evidence of an arrangement existed, delivery of the product occurred, the sales price was fixed or determinable and collectability was reasonably assured. We generally provided refunds to e-commerce customers, upon request, within 30 days of delivery. Under ASC 606 and as of January 1, 2018, revenue is recognized when control of the promised goods is transferred to the customer. Control of the promised good is transferred upon delivery to the customer, in an amount that reflects the consideration to which we expect to be entitled to in exchange for those goods. For sales through June 18, 2018, we offered refunds to e-commerce customers, upon request, within 30 days of delivery. For sales subsequent to June 18, 2018, we now offer refunds to e-commerce customers, upon request, within 14 days of delivery. 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

We do not expect to grant any additional stock options or shares of restricted stock in the future.

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.

In June 2018, the FASB issued ASU No. 2018-07, Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). This ASU is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within that year. Early adoption is permitted, but not before an entity has adopted ASC 606, and the guidance should be applied using a modified retrospective transition approach. Prior to the adoption of ASU 2018-07, stock-based awards issued to non-employees, including stock options and restricted stock, were recorded at their fair values, and were periodically revalued as the equity instruments vested and were recognized as expense over the related service periods on a straight-line basis. The fair value of options granted to non-employees was measured using the Black-Scholes option pricing model reflecting an expected life that was assumed to be the remaining contractual term of the option. The fair value of stock awards was based upon the fair value of our common stock. We early adopted ASU 2018-07 on July 1, 2018 and revalued our unvested nonemployee awards as of the July 1, 2018 adoption date. The adoption did not have a material impact on the

consolidated financial statements and therefore a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year was not required.

We recorded total non-cash stock-based compensation expense to employees and non-employees of $1.9 million for the year ended December 31, 2018, $4.2 million for the year ended December 31, 2017 and $6.6 million for the year ended December 31, 2016. At December 31, 2018, we had $2.2 million of total unrecognized compensation cost related to non-vested equity awards. Total unrecognized compensation cost will be adjusted for future changes in employee and non-employee forfeitures, if any. We expect to recognize the unrecognized compensation over a remaining weighted-average period of 2.74 years.

The intrinsic value of all outstanding vested and unvested options as of December 31, 2018 was zero.

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.
- ***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, 2018	Year ended December 31, 2017	Year ended December 31, 2016
Expected volatility	81.56% to 82.41%	73.87% to 81.04%	71.01% to 74.20%
Risk-free interest rate	2.45% to 2.91%	1.83% to 2.40%	1.23% to 2.40%
Expected term	5.3 - 10 years	5.3 - 9.5 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, or ASU No. 2016-09, 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.

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, 2018, we had cash and cash equivalents of $9.8 million. 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 subject to interest rate risk and may fall in value if market interest rates increase. As of December 31, 2018, our cash was only invested in money market funds, and we did not have any marketable securities. Therefore, we have minimal market risk related to 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-32 of this Annual Report.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file under the 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, 2018. 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, 2018, 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

Not applicable.

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 2019 Annual Meeting of Stockholders. If such proxy statement is not filed on or before April 30, 2019, the information called for by this item will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

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 2019 Annual Meeting of Stockholders. If such proxy statement is not filed on or before April 30, 2019, the information called for by this item will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

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 2019 Annual Meeting of Stockholders. If such proxy statement is not filed on or before April 30, 2019, the information called for by this item will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

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 2019 Annual Meeting of Stockholders. If such proxy statement is not filed on or before April 30, 2019, the information called for by this item will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

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 2019 Annual Meeting of Stockholders. If such proxy statement is not filed on or before April 30, 2019, the information called for by this item will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

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.

			Incorporated by reference herein	
Number		Description	Form	Date Filed with SEC
2.1		Agreement and Plan of Merger dated January 3, 2019 by and among the Registrant, Falcon Acquisition Sub, LLC and Salarius Pharmaceuticals, LLC.	Current Report on Form 8-K (File No. 001-36812)	January 4, 2019
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	+	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
10.8	+	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
10.9	+	Separation Agreement, effective as of June 26, 2018, by and between the Registrant and Thomas Wessel	Quarterly Report on Form 10-Q (File No. 001-36812)	August 1, 2018
10.10	+	Advisor Agreement, dated June 26, 2018, by and between the Registrant and Thomas Wessel	Quarterly Report on Form 10-Q (File No. 001-36812)	August 1, 2018
10.11		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

Number		Description	Incorporated by reference herein	
			Form	Date Filed with SEC
10.12		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
10.13		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
10.14		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
10.15		Lease Agreement, dated January 27, 2017, between the Registrant and BP Prucenter Acquisition LLC	Current Report on Form 8-K (File No. 001-36812), as amended.	February 2, 2017
10.16		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
10.17	+	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
10.18	+	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
10.19	+	Amendment to Executive Employment Agreement, effective as of June 20, 2018, by and between the Registrant and John McCabe	Quarterly Report on Form 10-Q (File No. 001-36812)	August 1, 2018
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	Quarterly Report on Form 10-Q (File No. 001-36812)	November 6, 2017
10.24	+	Amendment to Executive Employment Agreement, effective as of June 20, 2018, by and between the Registrant and William McVicar	Quarterly Report on Form 10-Q (File No. 001-36812)	August 1, 2018
10.25	†	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
10.26	†	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		
23.1		Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm		
24.1		Power of Attorney is made to the signature page hereto		

Number		Description	Incorporated by reference herein	
			Form	Date Filed with SEC
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		
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.		

+ 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, 2018 and 2017, for the year ended December 31, 2018, 2017 and 2016

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors 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, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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 6, 2019

FLEX PHARMA, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 9,829,624	$ 19,186,036
Restricted cash	126,595	—
Marketable securities	—	14,129,723
Accounts receivable	9,939	10,385
Inventory	186,920	431,891
Prepaid expenses and other current assets	162,088	777,102
Total current assets	10,315,166	34,535,137
Property and equipment, net	74,460	331,040
Restricted cash	—	126,595
Total assets	$ 10,389,626	$ 34,992,772
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 342,530	$ 2,004,440
Accrued expenses and other current liabilities	764,340	3,712,221
Deferred revenue	—	72,188
Deferred rent, current portion	—	58,821
Total current liabilities	1,106,870	5,847,670
Deferred rent, net of current portion	—	39,214
Total liabilities	1,106,870	5,886,884
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2018 and December 31, 2017; none issued or outstanding at December 31, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at December 31, 2018 and December 31, 2017, 18,069,476 and 17,972,166 shares issued at December 31, 2018 and December 31, 2017, respectively, and 18,067,392 and 17,797,178 shares outstanding at December 31, 2018 and December 31, 2017, respectively	1,807	1,780
Additional paid-in capital	142,242,224	140,184,630
Accumulated other comprehensive loss	—	(1,247)
Accumulated deficit	(132,961,275)	(111,079,275)
Total stockholders' equity	9,282,756	29,105,888
Total liabilities and stockholders' equity	$ 10,389,626	$ 34,992,772

See accompanying notes to consolidated financial statements.

FLEX PHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Net product revenue	$ 826,515	$ 1,260,973	$ 989,918
Other revenue	11,627	13,526	20,745
Total revenue	838,142	1,274,499	1,010,663
Costs and expenses:			
Cost of product revenue	430,750	506,530	662,747
Research and development	11,908,294	16,989,911	20,378,161
Selling, general and administrative	10,573,321	18,503,684	19,855,987
Total costs and expenses	22,912,365	36,000,125	40,896,895
Loss from operations	(22,074,223)	(34,725,626)	(39,886,232)
Interest income, net	152,006	291,964	393,109
Net loss	$ (21,922,217)	$ (34,433,662)	$ (39,493,123)
Net loss attributable to common stockholders	$ (21,922,217)	$ (34,433,662)	$ (39,493,123)
Net loss per share attributable to common stockholders — basic and diluted	$ (1.22)	$ (1.99)	$ (2.43)
Weighted-average number of common shares outstanding — basic and diluted	18,016,841	17,260,626	16,233,985

See accompanying notes to consolidated financial statements.

FLEX PHARMA, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Net loss	$ (21,922,217)	$ (34,433,662)	$ (39,493,123)
Other comprehensive gain:			
Change in net unrealized gains on available-for-sale securities	1,247	367	23,040
Comprehensive loss	$ (21,920,970)	$ (34,433,295)	$ (39,470,083)

See accompanying notes to consolidated financial statements.

FLEX PHARMA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2015	—	$ —	15,741,618	$ 1,574	$ 129,367,978	$ (24,654)	$ (37,152,490)	$ 92,192,408
Vesting of restricted common stock	—	—	1,023,664	102	(102)	—	—	—
Issuance of common stock from option exercises	—	—	8,516	2	22,096	—	—	22,098
Stock-based compensation expense	—	—	—	—	6,572,963	—	—	6,572,963
Unrealized gain on available-for-sale securities	—	—	—	—	—	23,040	—	23,040
Net loss	—	—	—	—	—	—	(39,493,123)	(39,493,123)
Balance at December 31, 2016	—	$ —	16,773,798	$ 1,678	$ 135,962,935	$ (1,614)	$ (76,645,613)	$ 59,317,386
Vesting of restricted common stock	—	—	1,021,804	102	(102)	—	—	—
Issuance of common stock from option exercises	—	—	1,576	—	2,632	—	—	2,632
Stock-based compensation expense	—	—	—	—	4,219,165	—	—	4,219,165
Unrealized gain on available-for-sale securities	—	—	—	—	—	367	—	367
Net loss	—	—	—	—	—	—	(34,433,662)	(34,433,662)
Balance at December 31, 2017	—	$ —	17,797,178	$ 1,780	$ 140,184,630	$ (1,247)	$ (111,079,275)	$ 29,105,888
Vesting of restricted common stock	—	—	172,904	17	(17)	—	—	—
Issuance of common stock from option exercises	—	—	97,310	10	118,000	—	—	118,010
Stock-based compensation expense	—	—	—	—	1,939,611	—	—	1,939,611
Unrealized gain on available-for-sale securities	—	—	—	—	—	1,247	—	1,247
Adjustment related to adoption of new accounting pronouncement using the modified retrospective transition method (Note 2)	—	—	—	—	—	—	40,217	40,217
Net loss	—	—	—	—	—	—	(21,922,217)	(21,922,217)
Balance at December 31, 2018	—	$ —	18,067,392	$ 1,807	$ 142,242,224	$ —	$ (132,961,275)	$ 9,282,756

See accompanying notes to consolidated financial statements

FLEX PHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Operating activities			
Net loss	$ (21,922,217)	$ (34,433,662)	$ (39,493,123)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	228,158	324,548	277,231
Stock-based compensation expense	1,939,611	4,219,165	6,572,963
Amortization and accretion on investments	11,537	(68,139)	16,161
Other non-cash items	20,310	1,781	3,434
Changes in operating assets and liabilities:			
Accounts receivable	7,206	1,796	(12,181)
Inventory	227,979	22,241	(454,132)
Prepaid expenses and other current assets	600,121	148,881	(17,409)
Other assets	—	64,800	(64,800)
Accounts payable	(1,661,910)	819,357	309,437
Accrued expenses and other current liabilities	(2,951,420)	1,124,648	746,879
Deferred revenue	—	(16,156)	88,344
Deferred rent	(98,035)	68,542	(9,475)
Other long term liabilities	—	—	(15,442)
Net cash used in operating activities	(23,598,660)	(27,722,198)	(32,052,113)
Investing activities			
Purchases of marketable securities	(1,997,751)	(32,987,697)	(38,682,081)
Proceeds from maturities and sales of marketable securities	16,117,184	57,585,413	26,995,324
Purchases of property and equipment	—	(113,498)	(559,378)
Proceeds from sales of property and equipment	4,805	5,344	5,255
Net cash provided by (used in) investing activities	14,124,238	24,489,562	(12,240,880)
Financing activities			
Proceeds from exercise of common stock	118,010	2,632	22,098
Net cash provided by financing activities	118,010	2,632	22,098
Net decrease in cash, cash equivalents and restricted cash	(9,356,412)	(3,230,004)	(44,270,895)
Cash, cash equivalents and restricted cash at beginning of period	19,312,631	22,542,635	66,813,530
Cash, cash equivalents and restricted cash at end of period	$ 9,956,219	$ 19,312,631	$ 22,542,635
Supplemental cash flow information			
Property and equipment purchases included in accounts payable	$ —	$ —	$ 7,100

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 was previously focused on developing innovative and proprietary treatments for muscle cramps, spasms and spasticity associated with severe neurological conditions. In June 2018, the Company announced that it was ending the Company's ongoing Phase 2 clinical trials of the Company's lead drug product candidate, FLX-787, in patients with motor neuron disease, or MND, primarily with amyotrophic lateral sclerosis, or ALS, and in patients with Charcot-Marie-Tooth disease, or CMT, due to oral tolerability concerns observed in both studies. The wind-down of the activities associated with these studies was completed in the third quarter of 2018.

In 2016, the Company launched its consumer product, HOTSHOT®, to prevent and treat exercise-associated muscle cramps, or EAMCs. The Company continues to market and sell HOTSHOT to endurance athletes who drink it before, during and after exercise to prevent and treat EAMCs.

In June 2018, the Company initiated a process to explore a range of strategic alternatives for enhancing stockholder value, including the potential sale or merger of the Company. Wedbush PacGrow was engaged to act as its strategic financial advisor at that time. The Company also announced the restructuring of its organization to reduce the Company's cost structure. In connection with the restructuring plan, the Company reduced its workforce by approximately 60%, with the reduction completed as of September 30, 2018.

Following an extensive process of evaluating strategic alternatives for the Company, including identifying and reviewing potential candidates for a strategic acquisition or other transaction, on January 3, 2019, the Company entered into an Agreement and Plan of Merger, or the Merger Agreement, with Salarius Pharmaceuticals, LLC, or Salarius, under which the privately-held Salarius will merge with a wholly-owned subsidiary of the Company. If the merger is completed, the business of Salarius will continue as the business of the combined company.

The Company operates as two reportable segments, Consumer Operations and Drug Development. See Note 16 for additional discussion and information on the Company's reportable segments.

Liquidity

The Company has incurred an accumulated deficit of $132,961,275 from February 26, 2014 (inception) through December 31, 2018. The Company had cash and cash equivalents of $9,829,624 at December 31, 2018. The Company's operating plan assumes limited research and development activities and that the Consumer Operations segment will continue to sell HOTSHOT.

In the event that the Company does not complete the merger with Salarius, the Company (i) may elect to pursue a dissolution and liquidation of the Company, (ii) pursue another strategic transaction or (iii) may continue to market HOTSHOT and operate its consumer business. If the Company dissolves and liquidates, the Company's common stockholders may lose their entire investment. The amount of assets available for distribution to the Company's stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will be needed for commitments and contingent liabilities.

Based on the Company's operating plan, the Company believes that its existing cash and cash equivalents 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.

The Company cannot predict the outcome of the merger or whether and to what extent it will resume drug development activities for FLX-787 or other drug product candidates and to what extent it will promote and sell HOTSHOT or other consumer products in the future. Accordingly, it is difficult to predict future cash needs. Management does expect the Company to incur losses for the foreseeable future. The Company's ability to achieve profitability in the future is dependent upon 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. If the Company raises funds through the sale of equity or convertible debt securities, the issuance of those securities could result in substantial dilution of the stockholders' ownership in the

Company. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

2. Summary of significant accounting policies

Basis of presentation and use of estimates

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States GAAP 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.

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, Flex Innovation Group LLC, a Delaware limited liability company which contains the Company's consumer-related operations, and Falcon Acquisition Sub, LLC, a Delaware limited liability company established for purposes of the merger. 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.

In addition, the inventory of HOTSHOT is concentrated in one warehouse location. Any significant disruption to the operation of the warehouse location for any reason, such as a power failure, equipment breakdown, workforce disruption, or natural or similar disasters, could materially adversely affect the Company's product distribution and sales.

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, and management, view the Company's operations and manage its business as two operating segments, Drug Development and Consumer Operations (see Note 16). The Company operates in one geographic segment, the United States.

Concentrations of credit risk and off-balance sheet risk

Cash and cash equivalents are financial instruments that potentially subject the Company to concentrations of credit risk. The Company held no marketable securities as of December 31, 2018. The Company's cash and cash equivalents 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 bottled finished goods to e-commerce customers, specialty retailers and sports teams, including professional and collegiate teams. Other revenue consists of payments made by customers for expedited shipping and handling. On January 1, 2018, the Company adopted ASU No. 2014-09, *Revenue from Contracts with Customers* ("*ASC 606*"), using the modified retrospective method applied to contracts not yet completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and are reported in accordance with the Company's historical accounting under ASC Topic 605, *Revenue Recognition* ("*ASC 605*").

Under ASC 605 and through December 31, 2017, revenue was recognized when persuasive evidence of an arrangement existed, delivery of the product occurred, the sales price was fixed or determinable and collectability was reasonably assured. The Company generally provided refunds to e-commerce customers, upon request, within 30 days of delivery. As the Company did not have adequate history to accurately estimate refunds, all e-commerce sales, and their related costs, were deferred and revenue was recognized once the refund period lapsed. This deferral represents total deferred revenue presented on the Company's consolidated balance sheet at December 31, 2017. For specialty retailers and sports teams, the Company did not offer a right of return or refund and revenue was recognized at the time products were delivered to customers. Discounts provided to customers were accounted for as a reduction of product revenue.

Upon the adoption of ASC 606 on January 1, 2018, revenue is recognized when control of the promised goods is transferred to the customer, upon delivery to the customer, in an amount that reflects the consideration to which the Company expects to be entitled to in exchange for those goods. See Note 3 for further discussion of revenue.

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 collectability is reasonably assured. Receivables are evaluated for collectability 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, 2018 and December 31, 2017.

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

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, 2018 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 $822,000, $3,566,000 and $2,936,000 for the years ended December 31, 2018, December 31, 2017 and December 31, 2016, respectively.

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 $98,000, $261,000 and $170,000 for the years ended December 31, 2018, December 31, 2017 and December 31, 2016, respectively.

Restructuring-related costs

The Company records employee termination costs in accordance with ASC Topic 712, *Compensation - Nonretirement and Postemployment Benefits* ("ASC 712"), if the termination benefits are paid as part of an ongoing benefit arrangement, which includes benefits provided as part of the Company's established severance policy or as part of an executive employment agreement. The Company accrues employee termination costs associated with an on-going benefit arrangement if the obligation is attributable to prior services rendered, the rights to the benefits have vested, the payment is probable, and the Company can reasonably estimate the liability. The Company accounts for employee termination benefits that represent a one-time benefit in accordance with ASC Topic 420, *Exit or Disposal Cost Obligations* ("ASC 420"). Upon communication of the termination to the employee, the Company expenses these costs over the employee's future service period, if any.

Restructuring-related costs are recorded within research and development expenses and selling, general and administrative expenses on the Company's consolidated statement of operations. Liabilities associated with the Company's restructuring activities are recorded as a component of accrued expenses and other current liabilities on its consolidated balance sheet. See Note 9 for additional information on the Company's current restructuring plan.

Property and equipment

Property and equipment are 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, 2018.

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 have primarily included 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.

In July 2018, the Company adopted ASU 2018-07, *Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. Prior to the adoption of ASU 2018-07, the Company accounted 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 were 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 were recognized as services were provided, which was generally the vesting period, on a straight-line basis. The unvested portion of the awards was subject to re-measurement over the vesting period. Following the adoption of ASU 2018-07, the Company accounts for stock granted to non-employees in accordance with ASC 718 in the same manner as employee awards described above. The adoption did not have a material impact on the condensed consolidated financial statements and therefore a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year was not required.

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 the public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. The Company computes historical volatility data using the volatility for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. Due to the lack of Company specific historical option activity, the Company has estimated the expected term of its employee stock options using the "simplified" method, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term for non-employee awards is the remaining contractual term of the option. The risk-free interest rates are based

on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid and does not expect to pay dividends in the foreseeable future.

The Company does not apply a forfeiture rate to stock-based compensation expense and 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, 2018 and December 31, 2017, 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, 2018, December 31, 2017 and December 31, 2016, 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, 2018, December 31, 2017 and December 31, 2016.

Recent accounting pronouncements

In May 2014, the FASB issued ASC 606 which supersedes the revenue recognition requirements in ASC 605 and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted ASC 606 as of January 1, 2018 using the modified retrospective transition method. See Note 3 for further details.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). 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. In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*. This ASU is intended to clarify, or correct unintended application of the guidance outlined in ASU No. 2016-02. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*. This ASU is intended to address comparative reporting requirements for initial adoption. The guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those years. Based on the Company's evaluation of the effect of this standard, the Company does not expect the adoption of this guidance to have a material effect on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 2016-15 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 Company retrospectively adopted ASU No. 2016 in the first quarter of 2018, retrospectively, which did not impact the Company's condensed consolidated financial statements or disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows* ("ASU 2016-18"). ASU 2016-18 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 are no longer 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. The Company adopted ASU No. 2016-18 in the first quarter of 2018, retrospectively, resulting in a change to the presentation of restricted cash on the condensed consolidated statement of cash flows.

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of such amounts in the condensed consolidated statements of cash flows:

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 9,829,624	$ 19,186,036
Restricted cash	126,595	126,595
Cash, cash equivalents and restricted cash shown on the condensed consolidated statement of cash flows	$ 9,956,219	$ 19,312,631

In May 2017, the FASB issued ASU No. 2017-09, *Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), to provide clarity and reduce diversity in practice, cost and complexity when applying the guidance of Topic 718. The guidance is effective for fiscal years beginning after December 15, 2017 and interim periods within those years. Early adoption is permitted, and the guidance should be applied prospectively. The Company adopted ASU 2017-09 in the first quarter of 2018, which did not impact the Company's condensed consolidated financial statements or disclosures.

In June 2018, the FASB issued ASU 2018-07. This ASU is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within that year. Early adoption is permitted, but not before an entity has adopted ASC 606, and the guidance should be applied using a modified retrospective transition approach. The Company early adopted ASU 2018-07 on July 1, 2018 and revalued its unvested nonemployee awards as of the July 1, 2018 adoption date. The

adoption did not have a material impact on the condensed consolidated financial statements and therefore a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year was not required.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). This ASU modifies the disclosure requirements on fair value measurements in Topic 820, *Fair Value Measurement*. The guidance is effective for annual reporting periods beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2018-13 on its consolidated financial statements and 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.

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 19).

3. Revenue from contracts with customers

Adoption of ASC Topic 606, "Revenue from Contracts with Customers"

On January 1, 2018, the Company adopted ASC 606 using the modified retrospective method applied to contracts not yet completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and are reported in accordance with the Company's historical accounting under ASC 605.

The primary impact of the adoption of ASC 606 related to the timing of revenue recognized for e-commerce sales, due to e-commerce refund rights. Under ASC 606, the Company recognizes revenue when control of the promised good is transferred to the customer and reflects the consideration to which the Company expects to be entitled to receive in exchange for the good. This has resulted in accelerated revenue recognition for e-commerce sales, as under ASC 605, all revenue and related costs were deferred and recognized once the refund period lapsed.

The cumulative effect of applying the new guidance to all contracts that were not completed as of January 1, 2018 was recorded as an adjustment to accumulated deficit of approximately $40,000 as of the adoption date, which was primarily the result of reducing deferred revenue by approximately $70,000 and deferred cost of product revenue and selling fees by approximately $30,000, that were recorded on the consolidated balance sheet at December 31, 2017. The Company would have recognized approximately $44,000 of additional total revenue during the twelve months ended December 31, 2018, respectively, if the Company had continued to recognize revenue under ASC 605.

The adoption of ASC 606 did not impact income taxes, as the Company fully reserves its net deferred tax assets. Therefore, the change to the Company's net deferred tax asset position due to adoption was offset by a corresponding change to the valuation allowance.

Revenue recognition

Revenue includes sales of HOTSHOT bottled finished goods to e-commerce customers, specialty retailers and sports teams, including professional and collegiate teams. Revenue also consists of payments made by customers for expedited shipping and handling.

The Company expenses fulfillment costs as incurred because the amortization period would be less than one year in accordance with the ASC 606 practical expedient.

In accordance with ASC 606, the Company applies the following steps to recognize revenue for the sale of bottled finished goods that reflects the consideration to which the Company expects to be entitled to receive in exchange for the promised goods:

1. *Identify the contract with a customer*

A contract with a customer exists when the Company enters into an enforceable contract with a customer. The contract is based on either the acceptance of standard terms and conditions on the websites for e-commerce customers, or the execution of terms and conditions contracts with specialty retailers and sports teams. These contracts define each party's rights, payment terms and other contractual terms and conditions of the sale. The Company applies judgment in determining the customer's ability and intention to pay, which is based on a variety of factors including the customer's historical payment experience and, in some circumstances, published credit and financial information pertaining to the customer.

2. Identify the performance obligations in the contract

Performance obligations promised in a contract are identified based on the goods that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract, whereby the transfer of the goods is separately identifiable from other promises in the contract. The Company has concluded the sale of bottled finished goods and related shipping and handling are accounted for as a single performance obligation.

3. Determine the transaction price

The transaction price is determined based on the consideration to which the Company will be entitled to receive in exchange for transferring goods to the customer. For sales through June 18, 2018, the Company offered refunds to e-commerce customers, upon request, within 30 days of delivery. For sales subsequent to June 18, 2018, the Company now offers refunds to e-commerce customers, upon request, within 14 days of delivery. The Company estimates the amount of potential refunds at each reporting period using a portfolio approach of historical data, adjusted for changes in expected customer experience, including seasonality and changes in economic factors, as necessary. 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 an element of the transaction price and as a reduction to revenue, and were approximately $38,000, $278,000, $135,000 and for the twelve months ended December 31, 2018, December 31, 2017, and December 31, 2016, respectively.

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

4. Determine the satisfaction of performance obligation

Revenue is recognized when control of the bottled finished goods is transferred to the customer. Control of the bottled finished goods is transferred at a point in time, upon delivery to the customer. The period of time between the satisfaction of the performance obligation and when payment is due from the customer is not significant.

Concentrations of credit risk

The Company had no customers that represented greater than 10% of total revenue during the twelve months ended December 31, 2018, December 31, 2017, or December 31, 2016. The vast majority of revenue was generated from sales within the United States.

4. Restricted cash

As of December 31, 2018 and December 31, 2017, the Company had $126,595 of restricted cash in the form of a letter of credit. The Company maintained this letter of credit as a security deposit on the lease of its former corporate headquarters in Boston, Massachusetts that was set to expire on August 31, 2019. The Company terminated this lease on December 13, 2018 (see Note 10). The letter of credit was released, and the cash became unrestricted on January 4, 2019.

5. 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, 2018 and December 31, 2017:

	Level 1	Level 2	Level 3	Balance at December 31, 2018
Cash equivalents	$ 2,333,771	$ —	$ —	$ 2,333,771
	$ 2,333,771	$ —	$ —	$ 2,333,771

	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

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 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, 2018. After completing its validation procedures, the Company did not adjust or override any fair value carrying amounts of as of December 31, 2018.

The carrying amounts reflected in the consolidated balance sheets for cash, restricted cash, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair values at December 31, 2018 and 2017, 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, 2018 or during the year ended December 31, 2017. The Company had no financial assets or liabilities that were classified as Level 3 at any point during the year ended December 31, 2018 or during the year ended December 31, 2017.

6. 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, 2018 and December 31, 2017 consisted of money market funds.

The Company held no marketable securities as of December 31, 2018. Marketable securities as of December 31, 2017 consisted of U.S. government agency securities, commercial paper and corporate debt 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 were no realized gains on marketable securities during the years ended December 31, 2018 or December 31, 2017.

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.

The Company held no marketable securities at December 31, 2018. Marketable securities at December 31, 2017 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

At December 31, 2017, the Company held six debt securities that were in an unrealized loss position, all of which had been 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 at and December 31, 2017. There were no individual securities that were in a significant unrealized loss position as of December 31, 2017. 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 economic and market conditions. The Company had 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, 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.

7. Inventory

Inventory has been recorded at cost as of December 31, 2018 and December 31, 2017. Costs capitalized at December 31, 2018 and December 31, 2017 relate to HOTSHOT finished goods and raw materials available to be used for future production runs.

The following table presents inventory:

	December 31, 2018	December 31, 2017
Raw materials	$ 7,247	$ 17,411
Finished goods	179,673	414,480
Total inventory	$ 186,920	$ 431,891

In the second quarter of 2018, the Company wrote off raw materials that are not expected to be used in future production runs, as well as finished goods inventory no longer expected to be used. In 2017, the Company wrote off raw materials not expected to be used in future production runs and expiring finished goods not anticipated to be sold. 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 $85,000, $42,000 and $282,000 for the years ended December 31, 2018, December 31, 2017 and December 31, 2016, respectively, and are included in cost of product revenue in the accompanying consolidated statement of operations.

8. Property and equipment, net

Property and equipment, net consists of the following:

	December 31, 2018	December 31, 2017
Manufacturing equipment	$ 421,999	$ 421,999
Computers and computer equipment	275,670	311,847
Website development costs	177,886	177,886
Laboratory equipment	—	13,368
Capital in progress	—	28,823
Total property and equipment	875,555	953,923
Accumulated depreciation	(801,095)	(622,883)
Property and equipment, net	$ 74,460	$ 331,040

Capital in progress consists of assets acquired but not yet placed into service. There was no capital in progress at December 31, 2018. At December 31, 2017 capital in progress consisted of computers and computer equipment.

Depreciation expense was $228,158, $324,548 and $277,231 for the years ended December 31, 2018, December 31, 2017, and December 31, 2016, respectively.

In 2018, the Company disposed of computer and computer equipment, laboratory equipment and capital in progress that was sold or no longer in use. Property and equipment disposals, net, for the year ended December 31, 2018 totaled $28,422. The Company received proceeds of $4,805 related to these disposals, resulting in a loss of $23,617, included in research and development expense and selling, general and administrative expense in the accompanying consolidated statement of operations. Disposals in prior years were immaterial.

9. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31, 2018	December 31, 2017
Payroll and employee-related costs	$ 417,997	$ 874,246
Professional fees	269,544	227,980
Restructuring-related costs	68,593	—
Consumer product-related costs	5,360	107,595
Research and development costs	2,846	2,502,400
Total	$ 764,340	$ 3,712,221

Restructuring-related costs

In June 2018, the Company's Board of Directors ("Board") approved a corporate restructuring plan to reduce the Company's cost structure. In connection with the corporate restructuring plan, the Company reduced its workforce by approximately 60%, with the reduction completed as of September 30, 2018.

Also, in June 2018, the Board approved employee retention arrangements and certain increased severance payments related to the corporate restructuring plan, to incentivize certain employees to remain with the Company through a potential sale or merger. As of December 31, 2018, the Company had paid $205,000 in retention bonuses and had paid or accrued approximately $186,000 in severance benefits associated with these arrangements. As of December 31, 2018, cash retention benefits totaling approximately $1,006,000 will be payable to the remaining employees and certain former employees who continue to provide service as consultants, upon the occurrence of a change in control event, including a sale or merger of the Company. Of this total, $603,000 relates to amounts payable to certain employees and former employees who continue to provide service as consultants only upon a change in control event, and $403,000 relates to amounts payable upon a change in control event or at certain timepoints through early 2019 if the individuals are employed by the Company and in good standing at the date of payment, even if a change in control event has not occurred. Upon a change in control event and termination without cause, the remaining employees will be eligible for up to approximately $928,000, in the aggregate, of severance benefits.

During the year ended December 31, 2018, the Company recognized expense for restructuring-related activities of approximately $1,366,000 which is comprised of approximately $1,037,000 recorded as termination benefits under ongoing benefit arrangements for terminated employees, approximately $100,000 as one-time termination benefit costs for terminated employees, approximately $214,000 in retention benefits for retained employees and approximately $15,000 of other restructuring related costs, including consulting and legal fees. There are currently no assurances a change in control event will take place. The Company does not consider the payment of severance benefits for retained employees or the payment of retention benefits only payable upon a change in control to be probable for accounting purposes as of December 31, 2018. On January 3, 2019, the Company entered into a Merger Agreement with Salarius. Unless and until the Company's shareholders have approved this specific transaction, the Company's probability assessment regarding a change in control event is not expected to change.

The Company expects to incur between approximately $1,769,000 and $3,354,000 in total costs for its restructuring-related activities, including approximately $1,366,000 that was recorded during 2018, included in the table below and $403,000 related to the annual bonus program that was recorded during 2018, included in payroll and employee-related costs. Based on the Company's current probability assessment regarding a change in control event and termination of retained employees, there are no anticipated charges in 2019. The range noted above includes approximately $603,000 related to retention benefits only payable upon a change in control event and $928,000 of severance benefits only payable upon a change in control event and termination under certain circumstances.

The following table outlines the Company's restructuring activities during the year ended December 31, 2018:

Accrued restructuring balance as of December 31, 2017	$	—
Charges:		
Employee termination benefits		1,136,388
Employee retention benefits		214,417
Other		14,995
Payments		(1,297,207)
Accrued restructuring balance as of December 31, 2018	$	68,593

The Company's accrued restructuring balance as of December 31, 2018 is included as a component of accrued expenses and other current liabilities on the Company's condensed consolidated balance sheet as of December 31, 2018. For the twelve months ended December 31, 2018, approximately $968,000 of the restructuring-related charges are included in research and development expenses and approximately $398,000 are included in selling, general and administrative expenses in the Company's condensed consolidated statement of operations.

For the twelve months ended December 31, 2018, approximately $81,000 of the restructuring-related charges were incurred by the Company's Consumer Operations segment, approximately $968,000 were incurred by the Company's Drug Development segment and the remaining charges of approximately $317,000 related to corporate costs. In total, the Company may incur restructuring-related charges of up to approximately $113,000 and $1,036,000 within the Company's Consumer Operations and Drug Development segments, respectively. The Company may incur up to $2,205,000 of corporate costs that do not relate to a reportable segment.

10. Commitments and contingencies

Lease commitments

On April 29, 2014, the Company leased office space in Boston, Massachusetts for its former corporate headquarters. The lease for this office space was scheduled to expire on August 31, 2019 but was terminated on December 13, 2018. The company has no remaining obligations under this lease agreement as of December 31, 2018.

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.

In November 2018, the Company leased space at a smaller office facility in Boston, Massachusetts. This lease expires upon at least one month's notice, resulting in minimum future lease payments of $2,350.

Rent expense is being recognized on a straight-line basis. The Company recorded approximately $351,000, $522,000 and $337,000 of rent expense for the twelve months ended December 31, 2018, December 31, 2017 and December 31, 2016, respectively.

Royalty agreement

In March 2014, the Company entered into a royalty agreement with certain of its founders, or collectively the 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 $17,000, $25,000 and $20,000 of royalty expense during the twelve months ended December 31, 2018, December 31, 2017 and December 31, 2016, respectively. Royalty amounts owed to the Founders as of December 31, 2018, December 31, 2017 and December 31, 2016 were approximately $3,000, $3,000 and $4,000, respectively.

In January 2019, the Founders entered into a royalty agreement with Flex Innovation Group LLC, which, in part, replaces the royalty agreement with Flex Pharma, Inc., described above, related to the sale of over the counter, non-prescription and/or nutritional supplement products. The royalty is payable over twenty years from the date of the agreement, with a 2% royalty due on product sales, as defined in the agreement, for the first ten years and a 1% royalty due for the following ten years.

Litigation

On March 1, 2019, a written demand was made on the Company by a purported shareholder requesting that additional information, including financial projections and valuation analyses, be made in the Company's Registration Statement on Form S-4 relating to the proposed merger with Salarius. The demand stated, among other thing, that, if such disclosures are not made within a reasonable period of time, the shareholder intends to file a securities class action lawsuit in federal court. The Company will review the demand letter and respond appropriately.

The Company does not have contingency reserves established for any litigation liabilities as of December 31, 2018.

11. Preferred stock

As of December 31, 2018, 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, 2018.

12. Common stock

As of December 31, 2018, 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% vested ratably over four years, during which time the Company had the right to repurchase the unvested shares held by a recipient if the relationship between such recipient and the Company ceased. Such shares were not accounted for as outstanding until they vested. Unvested restricted common stock awards to non-employees were re-measured at each vest date and each financial reporting date. All restricted common stock sold to the founders of the Company had vested as of December 31, 2018 and is no longer eligible for repurchase.

The following is a summary of restricted common stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2017	169,654	$ 0.10
Issued	—	—
Vested	(169,654)	0.10
Forfeited	—	—
Unvested at December 31, 2018	—	$ —

The total fair value of shares vested during the twelve months ended 2018, 2017 and 2016 was approximately $725,000, $3,840,000 and $9,646,000 respectively.

Restricted common stock to consultants

There were no shares of restricted common stock granted to non-employee consultants and advisors during 2018 or 2017. 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 16,110 shares of restricted common stock issued to consultants outstanding as of December 31, 2018. Prior to July 1, 2018, unvested restricted common stock awards to non-employees were re-measured at each vest date and each financial reporting date. On July 1, 2018, the Company adopted ASU 2018-07 using a modified retrospective transition approach. As a result, the Company permanently revalued all unvested stock awards granted to non-employees as of July 1, 2018. The adoption-date fair value did not materially change from the fair value as of June 30, 2018 and therefore, a cumulative-effect adjustment was not required.

The following is a summary of restricted common stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2017	5,334	$ 10.51
Issued	—	—
Vested	(3,250)	10.16
Forfeited	—	—
Unvested at December 31, 2018	2,084	$ 11.05

The total fair value of shares vested during the twelve months ended 2018, 2017 and 2016 was approximately $9,000, $22,000 and $71,000 respectively.

Employee stock purchase plan

As of the December 31, 2018, no shares of common stock have been purchased under the 2015 Employee Stock Purchase Plan (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,	
	2018	2017
Stock-based compensation awards	4,061,397	3,439,820
Vesting of restricted common stock	2,084	174,988
Employee stock purchase plan	713,996	534,274
Total	4,777,477	4,149,082

13. 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, restricted stock units and stock appreciation rights. 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, 2018, there were 1,740,416 shares remaining available for the grant of stock awards under the 2015 Plan.

During 2018 and 2016, the Company granted a total of 30,000 and 14,670, respectively, of stock options to non-employee consultants. There were no stock options issued to non-employee consultants during 2017. 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, 2018, December 31, 2017 and December 31, 2016 was approximately $124,000, $201,000 and $370,000, 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. Prior to July 1, 2018, unvested awards to non-employees were re-measured at each vest date and at each financial reporting date. On July 1, 2018, the Company adopted ASU 2018-07 using a modified retrospective transition approach. As a result, the Company permanently revalued all unvested stock options granted to non-employees as of July 1, 2018. The adoption-date fair value did not materially change from the fair value as of June 30, 2018 and therefore, a cumulative-effect adjustment was not required.

The following table summarizes stock option activity for employees and non-employees for the twelve months ended December 31, 2018:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	2,580,491	$ 6.65	7.55	$ 803,600
Granted	1,517,544	2.74		
Exercised	(97,310)	1.21		
Forfeited	(859,543)	5.76		
Expired	(820,201)	8.19		
Outstanding at December 31, 2018	2,320,981	$ 4.10	7.61	$ —
Exercisable at December 31, 2018	1,149,927	$ 5.53	6.07	$ —
Vested or expected to vest at December 31, 2018	2,320,981	$ 4.10	7.53	$ —

During 2018, 2017 and 2016, the Company granted stock options to purchase an aggregate of 1,517,544, 1,059,500, and 763,320 shares of its common stock, respectively. The weighted-average grant date fair value of option awards granted during 2018, 2017 and 2016 were $1.95, $2.80, and $6.35, respectively.

The number of stock options exercised during 2018, 2017 and 2016 were 97,310, 1,576, and 8,516, respectively. The weighted-average exercise price of options exercised during 2018, 2017 and 2016 was $1.21, $1.67, and $2.59, respectively. The total intrinsic value of options exercised during 2018, 2017 and 2016 was $349,974, $2,606, and $64,302, 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, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Expected volatility	81.56% to 82.41%	73.87% to 81.04%	71.01% to 74.20%
Risk-free interest rate	2.45% to 2.91%	1.83% to 2.40%	1.23% to 2.40%
Expected term	5.3 - 10 years	5.3 - 9.5 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, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Research and development	$ 705,687	$ 1,545,737	$ 2,435,565
Selling, general and administrative	1,233,924	2,673,428	4,137,398
Total	$ 1,939,611	$ 4,219,165	$ 6,572,963

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, 2018, there was approximately $2,160,000 of total unrecognized compensation cost related to unvested equity awards. Total unrecognized compensation cost will be adjusted for future changes in employee and non-employee forfeitures, if any. The Company expects to recognize that cost over a remaining weighted-average period of 2.74 years.

In June 2018, the Company extended the three-month post termination exercisability of 877,137 option awards held by six employees and one adviser to one-year post termination. As of December 31, 2018, three of the six employees had been terminated, but continue to provide consulting services. The Company also extended the three-month post termination exercisability of 500,000 option awards held by one employee to three-years post termination. The valuation of these awards did not change as a result of the modification of these awards and as such, the Company did not recognize any additional compensation expense related to the modification.

On June 14, 2018, the Company granted 654,544 stock options, in the aggregate, to seven employees as part of the Company's retention arrangements with these employees. These awards vest monthly over 48 months as the employees provide continuous service, and expense is being recognized over this period. As of December 31, 2018, three of the six employees had been terminated, but continue to provide consulting services and vest in these options. The awards are exercisable for one to three-years post termination depending on the employee to which the stock options were granted. The awards vest in full upon a change in control event and termination under certain circumstances. A change in control event is not currently considered probable for accounting purposes. On January 3, 2019, the Company entered into a Merger Agreement with Salarius. Unless and until the Company's

shareholders have approved this specific transaction, the Company's probability assessment regarding a change in control event is not expected to change.

14. Income taxes

For the years ended December 31, 2018, December 31, 2017 and December 31, 2016, 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 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 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. In 2018, the Company completed the analysis of the 2017 Tax Act with no material changes.

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, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Federal income tax expense at statutory rate	21.0 %	35.0 %	35.0 %
State income tax, net of federal benefit	6.0 %	5.0 %	5.0 %
Permanent differences	(0.1)%	(0.7)%	0.0 %
Stock-based compensation	(2.8)%	(1.9)%	(2.6)%
Research credits	2.6 %	2.2 %	1.9 %
Other, net	(1.6)%	(1.3)%	(0.1)%
Payroll tax credit election	(1.1)%	(0.7)%	0.0 %
Change in valuation allowance	(24.0)%	(1.1)%	(39.2)%
Deferred rate change	0.0 %	(36.5)%	0.0 %
Effective tax rate	0.0 %	0.0 %	0.0 %

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, 2018	December 31, 2017
Deferred tax assets:		
U.S. and state net operating loss carryforwards	$ 29,902,019	$ 24,744,841
Accruals and other temporary differences	336,229	202,301
Amortization	50,688	35,783
Stock-based compensation	1,220,546	1,591,131
Tax credit carryforward	2,277,428	1,964,189
Total deferred tax assets	33,786,910	28,538,245
Less valuation allowance	(33,786,910)	(28,533,755)
Deferred tax assets	—	4,490
Deferred tax liabilities:		
Stock-based compensation	—	(4,490)
Deferred tax liabilities	—	(4,490)
Net deferred tax assets	$ —	$ —

As of December 31, 2018, the Company has U.S. federal net operating loss carryforwards of approximately $110,900,000 and U.S. state net operating loss carryforwards of approximately $105,400,000 ($8,400,000 tax affected), which are available to reduce future taxable income. The Company also had federal research and development tax credit carryforwards of approximately $1,800,000 and state research and development tax credit carryforwards of approximately $570,000, which may be used to offset future tax liabilities.

The Company's pre-2018 federal loss carryforwards will expire at various dates through 2037. Any federal net operating losses generated in 2018 or after will not expire as a result of the Tax Cuts and Jobs Act. Any state operating loss carryforwards and tax credit carryforwards will expire at various dates through 2038. 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 the merger with Salarius could result in a change in control. The Company has not conducted an assessment to determine whether there may have been a Section 382 or 383 ownership changes.

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 2018 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 $5,250,000 from December 31, 2017 to December 31, 2018, 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, 2018 and 2017, 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 and $156,000 of the credit as a decrease to its payroll tax expense in 2017 and 2018, respectively. The Company elected an additional $250,000 credit on its 2017 tax return.

15. 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, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Options to purchase common stock	2,320,981	2,580,491	2,156,250
Unvested restricted common stock	2,084	174,988	1,196,792
Total	2,323,065	2,755,479	3,353,042

16. 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; previously to treat muscle cramps, spasms and spasticity associated with severe neurological conditions.

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, 2018, December 31, 2017, and December 31, 2016 are as follows:

Year Ended December 31, 2018	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	$ 838,142	—	—	$ 838,142
Loss from operations	$ 1,975,792	11,887,108	8,211,323	$ 22,074,223
Interest income, net	$ —	—	152,006	$ 152,006

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

17. 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, 2018, December 31, 2017 and December 31, 2016 totaled approximately $17,000, $25,000 and $20,000, respectively, including approximately $3,000, $3,000 and $4,000 not yet paid as of year end, respectively. Royalty expense is recorded in cost of product revenue in the consolidated statement of operations.

In January 2019, the Founders entered into a royalty agreement with Flex Innovation Group LLC, which, in part, replaces the royalty agreement with Flex Pharma, Inc. described above. The royalty is payable over twenty years from the date of the agreement, with a 2% royalty due on product sales, as defined in the agreement, for the first ten years and a 1% royalty due for the following ten years.

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.

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

18. Quarterly financial information (unaudited)

	First Quarter Ended March 31, 2018	Second Quarter Ended June 30, 2018	Third Quarter Ended September 30, 2018	Fourth Quarter Ended December 31, 2018
Net product revenue	$ 176,255	$ 241,416	$ 247,284	$ 161,560
Other revenue	2,327	4,086	3,707	1,507
Total revenue	178,582	245,502	250,991	163,067
Costs and expenses:				
Cost of product revenue	83,934	179,945	91,937	74,934
Research and development	4,680,181	6,174,589	865,765	187,759
Selling, general and administrative	3,697,287	2,994,649	1,959,872	1,921,513
Total costs and expenses	8,461,402	9,349,183	2,917,574	2,184,206
Loss from operations	(8,282,820)	(9,103,681)	(2,666,583)	(2,021,139)
Interest income, net	59,593	51,809	28,210	12,394
Net loss	$ (8,223,227)	$ (9,051,872)	$ (2,638,373)	$ (2,008,745)
Net loss per share attributable to common stockholders — basic and diluted	$ (0.46)	$ (0.50)	$ (0.15)	$ (0.11)
Weighted-average number of common shares outstanding — basic and diluted	17,893,912	18,037,274	18,066,548	18,067,179

	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

On January 1, 2018, the Company adopted ASC 606 using the modified retrospective method applied to contracts not yet completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and are reported in accordance with the Company's historical accounting under ASC 605.

The Company would have recognized approximately $18,000, $10,000, $1,000 and $15,000 of additional total revenue during the quarters ended March 31, 2018, June 30, 2018, September 30, 2018 and December 31, 2018, respectively, if the Company had continued to recognize revenue under ASC 605.

19. Subsequent events

The Company has completed an evaluation of all subsequent events after the balance sheet date of December 31, 2018 through the date these consolidated financial statements were issued. The Company has concluded that no subsequent events have occurred that require disclosure, except as described below.

Agreement and Plan of Merger

On January 3, 2019, the Company, Merger Sub, and Salarius entered into the Merger Agreement. Pursuant to the Merger Agreement, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Salarius, with Salarius continuing as a wholly owned subsidiary of the Company and the surviving corporation.

The Merger Agreement (i) values the Company at $10.5 million, subject to adjustment, on a dollar-for-dollar basis, based on the Company's net cash balance at the closing of the merger compared to a target net cash of $3.3 million, and (ii) values Salarius at $36.6 million, subject to adjustment, on a dollar-for-dollar basis, based on the sale of Series A Preferred units pursuant to subscription agreements that Salarius entered into prior to the Merger Agreement compared to the target sale of $7.0 million of Series A Preferred units.

At the closing of the merger, each outstanding common unit, profits interest common unit and Series A Preferred unit of Salarius will convert into the right to receive shares of the Company's common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to an anticipated reverse stock split of the Company’s common stock) at the conversion ratio formulae described in the Merger Agreement. Under those formulae, immediately following the effective time of the merger, the Company's current stockholders will own approximately 19.9% of the combined company (on a partially-diluted basis, excluding the effect of certain options, the dividend or distribution of rights and warrants to the Company's current stockholders and the possible issuance of a warrant to Wedbush) and Salarius’ current members will own approximately 80.1% of the combined company (on a partially-diluted basis, excluding the effect of certain options, the dividend or distribution of rights and Warrants to our current stockholders and the possible issuance of a warrant to Wedbush). For purposes of calculating the conversion ratios, the number of outstanding shares of the Company's common stock immediately before the merger takes into account the dilutive effect of approximately 849,610 shares of the Company's common stock underlying options outstanding as of January 3, 2019 that have an exercise price less than or equal to $1.35 per share of our common stock. Approximately 1,447,426 shares of the Company's common stock that underlie options outstanding as of January 3, 2019 have an exercise price greater than $1.35 per share of the Company's common stock.

In addition, at or prior to the closing of the merger, the Company will pay a dividend of or distribute one right per share of common stock to stockholders of record as of a date and time determined by the board of directors. Each right will entitle such stockholders to receive a warrant to purchase shares of the Company's common stock six months and one day following the closing date of the merger.

The warrants will contain customary terms and conditions, provided that the Warrants:

- will have an exercise price per share of the Company's common stock equal to the fair market value of a share of the Company's common stock on the closing date of the merger (such exercise price subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Company's common stock);
- will be immediately exercisable upon receipt, which receipt will be six months and one day following the closing date of the merger;
- will be exercisable for five years after receipt;
- will be subject to a cashless exercise, at the Company's option, under certain circumstances; and
- will be exercisable, in the aggregate, with respect to that number of shares of the Company's common stock equal to the Warrant Aggregate Value (as defined in the Merger Agreement) divided by the value (determined using the Black-Scholes-Merton option pricing formula) of a warrant to purchase a share of the Company's common stock on the closing date of the merger.

The Warrant Aggregate Value generally represents the difference between (i) the Company's value and (ii) the value of the Company’s common stock that the Company’s current stockholders will have in the combined company. Accordingly, the Warrant Aggregate Value will be based in part on the Company’s net cash balance at the time of

closing of the merger and adjusted for the amount of additional financing consummated by Salarius at or before the closing of the merger, as further described in the Merger Agreement.

The Merger Agreement contains certain termination rights for both the Company and Salarius, and further provides that, upon termination of the Merger Agreement under specified circumstances, either party may be required to pay the other party a termination fee of $0.35 million, or in some circumstances the Company may be required to reimburse Salarius' expenses up to a maximum of $0.2 million. In addition, in certain specified circumstances, Salarius may be required to pay us a termination fee of $1.0 million.

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 William McVicar, Ph.D.	President, Chief Executive Officer, Member of the Board of Directors (Principal Executive Officer)	March 6, 2019
/s/ John McCabe John McCabe	Chief Financial Officer (Principal Financial and Accounting Officer)	March 6, 2019
/s/ Peter Barton Hutt Peter Barton Hutt	Member of the Board of Directors	March 6, 2019
/s/ Marc Kozin Marc Kozin	Member of the Board of Directors	March 6, 2019
/s/ Stuart Randle Stuart Randle	Member of the Board of Directors	March 6, 2019
/s/ Michelle Stacy Michelle Stacy	Member of the Board of Directors	March 6, 2019
/s/ Roger Tung Roger Tung	Member of the Board of Directors	March 6, 2019

Exhibit 21.1

Flex Pharma, Inc.

The following is a list of subsidiaries of the Company as of December 31, 2018:

Name	Jurisdiction of Incorporation
TK Pharma, Inc.	Delaware
Flex Innovation Group LLC	Delaware
Falcon Acquisition Sub LLC	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-201816) pertaining to the 2014 Equity Incentive Plan, 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of Flex Pharma, Inc.;

(2) Registration Statement (Form S-8 Nos. 333-210283, 333-216534 and 333-223499) pertaining to the 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of Flex Pharma, Inc.;

(3) Registration Statement (Form S-3 No. 333-210289) of Flex Pharma, Inc.; and

(4) Registration Statement (Form S-4 No. 333-229666) of Flex Pharma, Inc.

of our report dated March 6, 2019, with respect to the consolidated financial statements of Flex Pharma, Inc. included in this Annual Report (Form 10-K) of Flex Pharma, Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 6, 2019

Exhibit 31.1

Certification Pursuant to Securities Exchange Act Rules 13a-14 and 15d-14 as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, William McVicar, Chief Executive Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K of Flex Pharma, Inc.;

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

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

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

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

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

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

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

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

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

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

/s/ William McVicar

William McVicar, Ph.D.

President and Chief Executive Officer
(Principal Executive Officer)

March 6, 2019

Exhibit 31.2

Certification Pursuant to Securities Exchange Act Rules 13a-14 and 15d-14 as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, John McCabe, Chief Financial Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K of Flex Pharma, Inc.;

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

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

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

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

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

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

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

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

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

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

/s/ John McCabe

John McCabe

Chief Financial Officer
(Principal Financial and Accounting Officer)

March 6, 2019

Exhibit 32.1

Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 10-K of Flex Pharma, Inc. (the "Company") for the period ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of their knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

/s/ William McVicar

William McVicar, Ph.D.

President and Chief Executive Officer
(Principal Executive Officer)

March 6, 2019

/s/ John McCabe

John McCabe

Chief Financial Officer
(Principal Financial and Accounting Officer)

March 6, 2019

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Flex Pharma, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.