

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

**(Mark One)**

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

For the quarterly period ended March 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**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**46-5087339**  
(I.R.S. Employer  
Identification Number)

**800 Boylston Street, 24<sup>th</sup> Floor, Boston, MA 02199**  
(Address of principal executive offices)(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 874-1821

Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report: Not Applicable

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 and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark 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.

Large Accelerated Filer

Accelerated Filer

Non-accelerated Filer

Smaller Reporting Company

Emerging Growth Company

(Do not check if  
a smaller reporting 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 April 27, 2018, there were 18,013,532 shares of common stock outstanding.

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

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements related to present facts or current conditions or historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, projected costs, expectations regarding the development of our drug product candidates, including the timing of our planned and ongoing clinical trials, and expectations regarding the commercial prospects of our consumer product, the expected timing for the reporting of data from our ongoing and future studies, prospects, plans and objectives of management, are forward looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements are not guarantees of future performance and our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, the status, timing, costs, results and interpretation of our clinical trials; the uncertainties inherent in conducting clinical trials; results from our ongoing and planned pre-clinical development; expectations of our ability to make regulatory filings and obtain and maintain regulatory approvals; our ability to develop and commercialize our consumer product; anticipated attributes of our consumer product; results of early clinical studies as indicative of the results of future trials; availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of our consumer or drug product candidates; the inherent uncertainties associated with intellectual property; and other factors discussed in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2017 and other filings with the Securities and Exchange Commission, or SEC.

As a result of these and other factors, we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

**PART I - FINANCIAL INFORMATION**
**Item 1. Financial Statements**
**FLEX PHARMA, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)**

	March 31, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 21,948,395	\$ 19,186,036
Marketable securities	1,999,399	14,129,723
Accounts receivable	12,631	10,385
Inventory	418,196	431,891
Prepaid expenses and other current assets	1,261,232	777,102
Total current assets	25,639,853	34,535,137
Property and equipment, net	266,647	331,040
Restricted cash	126,595	126,595
Total assets	\$ 26,033,095	\$ 34,992,772
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,241,402	\$ 2,004,440
Accrued expenses and other current liabilities	1,820,292	3,712,221
Deferred revenue	—	72,188
Deferred rent, current portion	58,821	58,821
Total current liabilities	4,120,515	5,847,670
Deferred rent, net of current portion	24,509	39,214
Total liabilities	4,145,024	5,886,884
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at March 31, 2018 and December 31, 2017; none issued or outstanding at March 31, 2018 and December 31, 2017	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized at March 31, 2018 and December 31, 2017; 17,984,811 and 17,972,166 shares issued at March 31, 2018 and December 31, 2017, and 17,980,852 and 17,797,178 shares outstanding at March 31, 2018 and December 31, 2017, respectively	1,798	1,780
Additional paid-in capital	141,148,465	140,184,630
Accumulated other comprehensive income (loss)	93	(1,247)
Accumulated deficit	(119,262,285)	(111,079,275)
Total stockholders' equity	21,888,071	29,105,888
Total liabilities and stockholders' equity	\$ 26,033,095	\$ 34,992,772

See accompanying notes to condensed consolidated financial statements.

**FLEX PHARMA, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)**

	<b>Three Months Ended March 31, 2018</b>	<b>Three Months Ended March 31, 2017</b>
Net product revenue	\$ 176,255	\$ 240,292
Other revenue	2,327	2,255
<b>Total revenue</b>	<b>178,582</b>	<b>242,547</b>
Costs and expenses:		
Cost of product revenue	83,934	79,106
Research and development	4,680,181	3,914,974
Selling, general and administrative	3,697,287	4,594,716
<b>Total costs and expenses</b>	<b>8,461,402</b>	<b>8,588,796</b>
<b>Loss from operations</b>	<b>(8,282,820)</b>	<b>(8,346,249)</b>
Interest income, net	59,593	77,854
<b>Net loss</b>	<b>\$ (8,223,227)</b>	<b>\$ (8,268,395)</b>
Net loss attributable to common stockholders	\$ (8,223,227)	\$ (8,268,395)
Net loss per share attributable to common stockholders — basic and diluted	\$ (0.46)	\$ (0.49)
Weighted-average number of common shares outstanding — basic and diluted	17,893,912	16,873,512

See accompanying notes to condensed consolidated financial statements.

**FLEX PHARMA, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)**

	<b>Three Months Ended March 31, 2018</b>	<b>Three Months Ended March 31, 2017</b>
Net loss	\$ (8,223,227)	\$ (8,268,395)
Other comprehensive gain (loss):		
Unrealized gain (loss) on available-for-sale securities	1,340	(10,739)
Comprehensive loss	<u>\$ (8,221,887)</u>	<u>\$ (8,279,134)</u>

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See accompanying notes to condensed consolidated financial statements.

**FLEX PHARMA, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
<b>Operating activities</b>		
Net loss	\$ (8,223,227)	\$ (8,268,395)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	64,066	91,367
Stock-based compensation expense	908,940	1,188,752
Amortization and accretion on investments	12,231	2,454
Other non-cash items	(3,480)	—
Changes in operating assets and liabilities:		
Accounts receivable	4,514	(6,881)
Inventory	(3,297)	39,810
Prepaid expenses and other current assets	(499,023)	(659,732)
Accounts payable	236,962	(366,289)
Accrued expenses and other current liabilities	(1,895,468)	(276,168)
Deferred revenue	—	(7,707)
Deferred rent	(14,705)	37,197
Net cash used in operating activities	(9,412,487)	(8,225,592)
<b>Investing activities</b>		
Purchases of marketable securities	(1,997,751)	(9,607,422)
Proceeds from maturities and sales of marketable securities	14,117,184	16,510,076
Purchases of property and equipment	—	(22,150)
Proceeds from sales of property and equipment	500	732
Net cash provided by investing activities	12,119,933	6,881,236
<b>Financing activities</b>		
Proceeds from exercise of common stock	54,913	—
Net cash provided by financing activities	54,913	—
Net increase (decrease) in cash, cash equivalents and restricted cash	2,762,359	(1,344,356)
Cash, cash equivalents and restricted cash at beginning of period	19,312,631	22,542,635
Cash, cash equivalents and restricted cash at end of period	\$ 22,074,990	\$ 21,198,279
<b>Supplemental cash flow information</b>		
Property and equipment purchases included in accounts payable and accrued expenses at December 31, 2016	\$ —	\$ 7,100

See accompanying notes to condensed consolidated financial statements.

**FLEX PHARMA, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)**

**1. Organization and operations**

***The Company***

Flex Pharma, Inc. (the "Company") is a biotechnology company that is developing innovative and proprietary treatments for muscle cramps, spasms and spasticity associated with severe neurological conditions such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) and Charcot-Marie-Tooth (CMT). The Company's lead drug product candidate, FLX-787, is currently being studied in two Phase 2 clinical trials in the United States. One Phase 2 clinical trial in the United States is in patients with motor neuron disease, primarily with ALS, who suffer from muscle cramps. FLX-787 is being developed for ALS under fast track designation which was granted by the United States Food and Drug Administration in July 2017. The other Phase 2 clinical trial in the United States is in patients with CMT who suffer from muscle cramps. In 2016, the Company launched its consumer product, HOTSHOT®, to prevent and treat exercise-associated muscle cramps.

The Company operates as two reportable segments, Consumer Operations and Drug Development. See Note 12 for additional discussion and information on the reportable segments.

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

***Liquidity***

The Company has incurred an accumulated deficit of \$119,262,285 since inception and will require substantial additional capital to fund its research and development and expenses related to its consumer brand and HOTSHOT. The Company had unrestricted cash, cash equivalents and marketable securities of \$23,947,794 at March 31, 2018. The Company's operating plan assumes: (1) the efforts of the Company's Drug Development segment are focused on the support and completion of current clinical trials; (2) reduced spending compared to the prior year by the Consumer Operations segment, including reduced marketing spend; and (3) limited headcount additions and corporate expenditures. Based on the Company's implemented operating plan, the Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to allow the Company to fund its current operating plan for at least 12 months from the date the financial statements are issued. Management expects the Company to incur a loss for the foreseeable future. The Company's ability to achieve profitability in the future is dependent upon the successful development, approval and commercialization of its drug product candidates, and achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through additional private or public debt or equity offerings, and may seek additional capital through arrangements with collaborators or from other sources. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all. If the Company is unable to raise additional capital in sufficient amounts or on acceptable terms, the Company may have to significantly delay, scale back or discontinue the development or commercialization of one or more of its drug product candidates or sell or license assets in the Drug Development and Consumer Operations segments.

**2. Summary of significant accounting policies and recent accounting pronouncements**

The accompanying unaudited condensed consolidated financial statements reflect the application of certain significant accounting policies as described below and elsewhere in these notes to the condensed consolidated financial statements. As of March 31, 2018, the Company's significant accounting policies, which are detailed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (the "2017 10-K"), have not changed, other than as noted below.

***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 collection is



probable based on the customer's intent and ability to pay. Receivables are evaluated for collection probability on a regular basis and an allowance for doubtful accounts is recorded, if necessary. No allowance for doubtful accounts was deemed necessary at March 31, 2018 or December 31, 2017.

### **Restricted cash**

The Company has restricted cash in the form of a letter of credit it maintains as a security deposit on the lease of its office space in Boston, Massachusetts.

### **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 expenses in the condensed consolidated statement of operations, and were approximately \$508,000 for the three months ended March 31, 2018 and approximately \$665,000 for the three months ended March 31, 2017.

### **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 are capitalized as inventory and expensed as cost of product revenue when revenue is recognized. Shipping and handling costs to move finished goods from the Company's third-party warehousing and fulfillment partners to customer locations are included in selling, general and administrative expenses in the condensed consolidated statement of operations, and were approximately \$25,000 for the three months ended March 31, 2018, and approximately \$34,000 for the three months ended March 31, 2017.

### **Unaudited interim financial information**

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the 2017 10-K.

The condensed consolidated financial statements as of March 31, 2018, for the three months ended March 31, 2018 and 2017, and the related information contained within the notes to the condensed consolidated financial statements, are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as annual audited consolidated financial statements, and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's condensed consolidated financial position as of March 31, 2018, and the statements of operations, comprehensive loss and cash flows for the three month periods ended March 31, 2018 and 2017. The results for the three months ended March 31, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, or any other future annual or interim periods.

### **Basis of presentation and use of estimates**

The accompanying condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to clinical study accruals, estimates related to inventory realizability, 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 condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries: TK Pharma, Inc., a Massachusetts Securities Corporation, and Flex Innovation Group LLC, a Delaware limited liability company, which contains the Company's consumer-related operations. All significant intercompany balances and transactions have been eliminated in consolidation.

**Recent accounting pronouncements**

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers ("ASC 606")*. ASC 606 supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition ("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*. The ASU requires lessees to recognize the assets and liabilities on their balance sheet for the rights and obligations created by most leases and continue to recognize expenses on their income statements over the lease term. It will also require disclosures designed to give financial statement users information on the amount, timing and uncertainty of cash flows arising from leases. The guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted. While the Company is currently evaluating the effect this standard will have on its consolidated financial statements, the Company expects that upon adoption, it will recognize right-of-use assets and lease liabilities and those amounts could be material.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. The update amends the guidance in ASU Topic 230 and clarifies how entities should classify certain cash receipts and cash payments on the statement of cash flows with the objective of reducing the existing diversity in practice related to eight specific cash flow issues. The Company adopted ASU 2016-15 in the first quarter of 2018, retrospectively. The adoption of ASU 2016-15 did not have a significant impact on the consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows*, which amends ASU Topic 230. This update requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities 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 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:

	March 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 21,948,395	\$ 19,186,036
Restricted cash	126,595	126,595
Cash, cash equivalents and restricted cash shown on the condensed consolidated statement of cash flows	<u>\$ 22,074,990</u>	<u>\$ 19,312,631</u>

In May 2017, the FASB issued ASU No. 2017-09, *Stock Compensation (Topic 718): Scope of Modification Accounting*, to provide clarity and reduce diversity in practice, cost and complexity when applying the guidance 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 this guidance in the first quarter of 2018, which did not impact the Company's condensed consolidated financial statements or 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.

### **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 relates 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 of approximately \$70,000 and deferred cost of product revenue and selling fees of approximately \$30,000, that were recorded on the consolidated balance sheet at December 31, 2017. The Company would have recognized approximately \$18,000 of additional total revenue during the first quarter of 2018 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 the 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. The Company issues refunds to e-commerce customers, upon request, within 30 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. 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 \$8,000 and \$46,000 for the three months ended March 31, 2018 and 2017, respectively.

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

### 4. Determine the satisfaction of performance obligations

Revenue is recognized when control of the bottled finish goods are 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 three months ended March 31, 2018 or the three months ended March 31, 2017. The vast majority of revenue was generated from sales within the United States.

### 4. Fair value measurements

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

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

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

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

The following tables summarize the cash equivalents and marketable securities measured at fair value on a recurring basis as of March 31, 2018 and December 31, 2017:

	Level 1	Level 2	Level 3	Balance as of March 31, 2018
Cash equivalents	\$ 11,243,193	\$ —	\$ —	\$ 11,243,193
Marketable securities:				
U.S. government agency securities	—	1,999,399	—	1,999,399
	<u>\$ 11,243,193</u>	<u>\$ 1,999,399</u>	<u>\$ —</u>	<u>\$ 13,242,592</u>

	Level 1	Level 2	Level 3	Balance as of 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 majority of the Company's cash equivalents consist of money market funds that are valued based on publicly available quoted market prices for identical securities as of March 31, 2018. After completing its validation procedures, the Company did not adjust or override any fair value carrying amounts as of March 31, 2018.

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

## 5. Cash equivalents and marketable securities

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. Cash equivalents as of March 31, 2018 and December 31, 2017 consisted of money market funds.

Marketable securities as of March 31, 2018 consisted of U.S. government agency securities. 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 condensed 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 three months ended March 31, 2018, or during the three months ended March 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.

Marketable securities at March 31, 2018 and December 31, 2017 consisted of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>As of March 31, 2018</b>				
Current (due within 1 year):				
U.S. government agency securities	\$ 1,999,306	\$ 93	\$ —	\$ 1,999,399
Total	<u>\$ 1,999,306</u>	<u>\$ 93</u>	<u>\$ —</u>	<u>\$ 1,999,399</u>
<b>As of December 31, 2017</b>				
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	<u>\$ 14,130,970</u>	<u>\$ 38</u>	<u>\$ (1,285)</u>	<u>\$ 14,129,723</u>

The Company held zero and six debt securities that were in an unrealized loss position at March 31, 2018 and December 31, 2017, respectively, all of which have been in a continuous loss position for less than 12 months. The aggregate fair value of debt securities in an unrealized loss position was \$0 and \$8,191,315 at March 31, 2018 and December 31, 2017, respectively. There were no individual securities that were in a significant unrealized loss position as of March 31, 2018 or December 31, 2017. The Company evaluated its securities for other-than-temporary impairment and no marketable securities were considered to be other-than-temporarily impaired as of March 31, 2018.

At March 31, 2018 and 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.

## 6. Inventory

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

The following table presents inventory:

	March 31, 2018	December 31, 2017
Raw materials	\$ 57,629	\$ 17,411
Finished goods	360,567	414,480
Total inventory	<u>\$ 418,196</u>	<u>\$ 431,891</u>

There were no inventory write-offs during the three months ended March 31, 2018 or March 31, 2017.

## 7. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2018	December 31, 2017
Research and development costs	\$ 985,763	\$ 2,502,400
Payroll and employee-related costs	351,823	874,246
Professional fees	351,192	227,980
Consumer product-related costs	131,514	107,595
<b>Total</b>	<b>\$ 1,820,292</b>	<b>\$ 3,712,221</b>

## 8. Common stock

As of March 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 founders had vested as of March 31, 2018, and is no longer subject to re-valuation or 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	—	—
<b>Unvested at March 31, 2018</b>	<b>—</b>	<b>\$ —</b>

### *Restricted common stock to consultants*

During 2016, the Company issued 18,194 shares of restricted common stock to non-employee consultants and advisors. Such shares are not accounted for as outstanding until they vest. There were 14,235 shares of restricted common stock issued to consultants outstanding as of March 31, 2018. Unvested restricted common stock awards to non-employees are re-measured at each vest date and each financial reporting date.

The following is a summary of restricted common stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2017	5,334	\$ 10.51
Issued	—	—
Vested	(1,375)	8.95
Forfeited	—	—
Unvested at March 31, 2018	<u>3,959</u>	<u>\$ 11.05</u>

## 9. 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 to purchase up to 116,754 shares of common stock. In April 2014, the Company amended the 2014 Plan to reserve for the issuance of up to 1,451,087 shares of common stock pursuant to equity awards. In September 2014, the Company further amended the 2014 Plan to reserve for the issuance of up to 2,070,200 shares of common stock pursuant to equity awards. Terms of stock award agreements, including vesting requirements, were determined by the board of directors, subject to the provisions of the 2014 Plan. For options granted under the 2014 Plan, the exercise price equaled the fair market value of the common stock as determined by the board of directors on the date of grant. No further awards will be granted under the 2014 Plan.

In January 2015, the Company's board of directors adopted, and the Company's stockholders approved, the 2015 Equity Incentive Plan (the "2015 Plan"), which became effective immediately prior to the closing of the Company's initial public offering ("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 March 31, 2018, there were 1,017,543 shares remaining available for the grant of stock awards under the 2015 Plan.

The Company has awarded stock options to its employees, directors, advisors and consultants, pursuant to the plans described above. Stock options subsequent to the completion of the Company's IPO are granted with an exercise price equal to the closing market price of the Company's common stock on the date of grant. Stock options generally vest over one to four years and have a contractual term of ten years. Stock options are valued using the Black-Scholes option pricing model and compensation cost is recognized based on the resulting value over the service period. Unvested awards to non-employees are re-measured at each vest date and at each financial reporting date. The following table summarizes stock option activity for employees and non-employees for the three months ended March 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	813,000	3.98		
Exercised	(12,645)	4.34		
Forfeited	(216,350)	7.82		
Expired	(35,977)	15.03		
Outstanding at March 31, 2018	3,128,519	\$ 5.78	7.33	\$ 3,017,213
Exercisable at March 31, 2018	1,518,128	\$ 6.90	5.35	\$ 1,507,813
Vested or expected to vest at March 31, 2018	3,128,519	\$ 5.78	7.33	\$ 3,017,213

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 condensed consolidated statements of operations as follows:

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
Research and development	\$ 386,537	\$ 394,417
Selling, general and administrative	522,403	794,335
Total	\$ 908,940	\$ 1,188,752

As of March 31, 2018, there was approximately \$5,011,000 of total unrecognized compensation cost related to unvested equity awards. Total unrecognized compensation cost will be adjusted for the re-measurement of non-employee awards as well as future changes in employee and non-employee forfeitures, if any. The Company expects to recognize that cost over a remaining weighted-average period of 2.95 years.

#### **Employee stock purchase plan**

In 2015, the Company's board of directors adopted, and the Company's stockholders approved, the 2015 Employee Stock Purchase Plan (the "ESPP"). As of March 31, 2018, no shares of common stock have been purchased under the ESPP.

#### **10. Income taxes**

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Based upon the Company's history of operating losses and the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets. There was no significant income tax provision or benefit for the three months ended March 31, 2018 or 2017.

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740), Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*. The ASU adds various Securities and Exchange Commission ("SEC") paragraphs pursuant to the issuance of the December 2017 SEC Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118)*, which was effective immediately. The SEC

issued SAB 118 to address concerns about a reporting entity's ability to timely comply with the accounting requirements to recognize all of the effects of the Tax Cuts and Jobs Act in the period of enactment. SAB 118 allows disclosure that timely determination of some or all of the income tax effects from the Tax Cuts and Jobs Act are incomplete by the due date of the financial statements and, if possible, to provide a reasonable estimate. The Company's accounting for certain income tax effects is incomplete, but it has determined reasonable estimates for those effects and has included provisional amounts in its condensed consolidated financial statements as of March 31, 2018 and December 31, 2017.

## 11. 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.

As the Company has reported a net loss 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:

	March 31, 2018	March 31, 2017
Options to purchase common stock	3,128,519	2,672,069
Unvested restricted common stock	3,959	941,341
Total	3,132,478	3,613,410

## 12. Segment Information

The Company operates as two reportable segments:

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

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, organize 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 to the audited consolidated financial statements in the 2017 Form 10-K. 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 three months ended March 31, 2018 and 2017 are as follows:

Three Months Ended March 31, 2018	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	\$ 178,582	—	—	\$ 178,582
Interest income, net	\$ —	—	59,593	\$ 59,593
Loss from operations	\$ 1,257,306	4,664,077	2,361,437	\$ 8,282,820

Three Months Ended March 31, 2017	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	\$ 242,547	—	—	\$ 242,547
Interest income, net	\$ —	—	77,854	\$ 77,854
Loss from operations	\$ 1,987,810	3,828,281	2,530,158	\$ 8,346,249

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion and analysis should be read in conjunction with the unaudited financial information and the notes thereto included herein, as well as our audited consolidated financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2017. This discussion contains forward-looking statements that involve risks and uncertainties. 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" discussed in our Annual Report on Form 10-K for the year ended December 31, 2017, in other subsequent filings with the SEC, and elsewhere in this Quarterly Report on Form 10-Q. These statements, like all statements in this report, speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.*

### Introduction

Our Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, is provided in addition to the accompanying unaudited condensed 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 three months ended March 31, 2018 to the three months ended March 31, 2017.

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

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

### Overview

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

Muscle cramps and spasms are involuntary, often painful, contractions that can last several minutes and, in many instances, result in prolonged soreness. Muscle cramps and spasms are thought to result from hyperexcitable

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

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

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

We operate as the following 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 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 12 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 at least the next several years. Our net loss was \$8.2 million and \$8.3 million for the three months ended March 31, 2018 and March 31, 2017, respectively. Our accumulated deficit was \$119.3 million as of March 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. We expect to continue incurring significant research and development expenses related to the development of our drug product candidates and significant selling, general and administrative expenses as we support our research and development efforts, operate as a public company and continue to commercialize HOTSHOT. As a result, we will need additional capital to fund our future operations.

## Recent Developments

### *Clinical Trial Updates*

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 an exploratory Phase 2 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 the following:

- 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 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.

In 2017, we initiated our Phase 2 clinical trial in patients with MND, referred to as the COMMEND trial, and expect topline data from this clinical trial by early 2019. In 2017, we also initiated the COMMIT trial, our Phase 2 clinical trial in patients with CMT, and expect topline data from this clinical trial in early 2019, although enrollment rates will need to increase in the COMMIT trial to meet this timeframe.

## 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 relates 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*, or ASC 605, all revenue and related costs were deferred and recognized once the refund period lapsed. Please refer to Note 3 in the accompanying financial statements for a discussion of the impact of adoption of ASC 606 on our condensed 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. 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. We offer refunds to e-commerce customers, upon request, within 30 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 bottles or 24 bottles, and starting in 2018, are offered a first-time purchase discount for a 3 pack. Previously, we offered a first-time purchase discount for a 6 pack. We also sell HOTSHOT via third-party e-commerce websites, including a retailer that offers international shipping. Generally, we realize higher revenue per bottle from our e-commerce sales as opposed to third-party website, sports team and specialty retailer sales. HOTSHOT is generally sold to specialty retailers and sports teams in multi-pack cases.

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

In the future, we may generate revenue from a combination of consumer product sales, drug product sales, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or a combination of these sources. To the extent any of our drug products are successfully commercialized, we expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of payments that we receive from the sale of our drug products, the timing and amount of license fees, milestone and other payments. If we fail to complete the development of our drug product candidates in a timely manner, obtain regulatory approval for them, or fail to successfully commercialize these drug products, our results of operations and financial position would be materially adversely affected.

### Cost of Product Revenue

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

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

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

### ***Research and Development Expenses***

Our research and development expenses to date include the costs incurred related to the development and testing of our extract formulation and expenses related to the testing and development of our drug product candidates, including FLX-787. Research and development costs include salaries and other compensation-related costs, such as stock-based compensation for research and development employees, costs of clinical studies of our extract formulation and drug product candidates, drug substance production costs, formulation and production costs of clinical supply, including FLX-787, to support clinical studies, costs for consultants who we utilize to supplement our personnel, fees paid to third parties, facilities and overhead expenses, cost of laboratory supplies and other outside expenses.

Research and development activities are central to our business model. Drug product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect to continue incurring significant research and development expenses related to the development of our drug product candidates. It is difficult to determine, with certainty, the duration and completion costs of our current or future pre-clinical programs and clinical trials of our drug product candidates.

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

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

### ***Selling, General and Administrative Expenses***

Selling, general and administrative expenses 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 our product is in salable condition.

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

### ***Interest Income, Net***

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

### ***Three Months Ended March 31, 2018 Compared to the Three Months Ended March 31, 2017***

The following table sets forth the condensed consolidated results of operations, including information related to our Consumer Operations and Drug Development segments, for the three months ended March 31, 2018 compared to the three months ended March 31, 2017.

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017	Change	
			\$	%
Net product revenue	\$ 176,255	\$ 240,292	\$ (64,037)	(27)%
Other revenue	2,327	2,255	72	3 %
Total revenue	178,582	242,547	(63,965)	(26)%
<b>Costs and expenses:</b>				
Cost of product revenue	83,934	79,106	4,828	6 %
Research and development	4,680,181	3,914,974	765,207	20 %
Selling, general and administrative	3,697,287	4,594,716	(897,429)	(20)%
Total costs and expenses	8,461,402	8,588,796	(127,394)	(1)%
Loss from operations	(8,282,820)	(8,346,249)	63,429	(1)%
Interest income, net	59,593	77,854	(18,261)	(23)%
Net loss	\$ (8,223,227)	\$ (8,268,395)	\$ 45,168	(1)%

### **Total Revenue**

Our Consumer Operations segment generated all of our revenue during the three months ended March 31, 2018, totaling \$0.2 million, as compared to \$0.2 million for the three months ended March 31, 2017 through sales of HOTSHOT and expedited shipping and handling purchases. Revenue was driven by our HOTSHOT marketing, sales and promotional efforts, including our print and digital media campaigns, public relations efforts, field marketing efforts and other sales and promotional activities.

Sales via e-commerce represented approximately 87% of our total revenue for both the three months ended March 31, 2018 and March 31, 2017.

During the three months ended March 31, 2018, we sold approximately 39,000 bottles of HOTSHOT at an average total revenue per bottle of \$4.58, compared to 52,000 bottles at an average total revenue per bottle of \$4.66 during the three months ended March 31, 2017. The decrease in average total revenue per bottle is primarily due to the price promotion we began offering in 2018 on the new 3 pack configuration to attract new customers. The decrease in the number of bottles sold primarily 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, as well a decrease in demand.

### **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 \$0.1 million for the three months ended March 31, 2018 compared to \$0.1 million for the three months ended March 31, 2017. Cost of product revenue during the three months ended March 31, 2018 includes the cost of HOTSHOT sold, royalty expense and depreciation expense of approximately \$35,000 related to manufacturing equipment used to support production. There were no write-offs of inventory during the three months ended March 31, 2018. Cost of product revenue during the three months ended March 31, 2017 included the cost of HOTSHOT sold, royalty expense and depreciation expense of approximately \$35,000. There were no write-offs of inventory during the three months ended March 31, 2017.

### **Research and Development Expenses**

Our Drug Development segment incurred the majority of our research and development expenses, which were \$4.7 million for the three months ended March 31, 2018 compared to \$3.9 million for the three months ended March 31, 2017. The 20% increase of \$0.8 million was primarily related to:

- \$1.2 million increase in clinical activities and related work, primarily related to clinical trial costs for our FLX-787 Phase 2 clinical trials in the United States, which commenced during the first quarter of 2017 with start-up activities and began increasing in activity in mid-2017;
- \$0.3 million decrease in consulting expenses as we increased the use of consultants in the prior year to assist with our IND filing and other research activities in 2017; and
- \$0.1 million decrease related to salaries and benefits, specifically employer taxes, as we elected to utilize a qualified small business federal research and development tax credit to offset our payroll tax liability.

### ***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 \$3.7 million for the three months ended March 31, 2018 compared to \$4.6 million for the three months ended March 31, 2017. The 20% decrease of \$0.9 million was primarily related to:

- \$0.7 million decrease related to salaries and benefits, as Consumer Operations and corporate headcount decreased from the prior year;
- \$0.3 million decrease in stock-based compensation expense, related primarily to the valuation of employee options at lower valuations than the prior year due to decreased stock price as well as decrease in headcount compared to the prior year;
- \$0.1 million of decreased marketing costs within our Consumer Operations segment for HOTSHOT, offset by an increase in external consulting costs to supplement our Consumer segment personnel;
- \$0.1 million decrease in employee travel and recruiting costs, related to decreased Consumer Operations and corporate headcount from prior year;
- \$0.1 million decrease in rent, office and other expenses due to the termination of our lease agreement for our office in New York, NY in the third quarter of 2017; and
- \$0.4 million increase in consulting, legal and professional expenses to supplement our corporate personnel.

### ***Loss from Operations***

Our consolidated loss from operations for the three months ended March 31, 2018 totaled \$8.3 million. Of this total, \$1.3 million of the operating loss was incurred by our Consumer Operations segment, \$4.7 million was incurred by our Drug Development segment and the remaining \$2.4 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 three months ended March 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, as well as consulting costs.

### ***Interest Income, net***

Interest income, net, decreased by \$18,261 in the three months ended March 31, 2018 compared to the three months ended March 31, 2017 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 at least the next several years. To date, we have generated limited revenue from sales of HOTSHOT, and have generated no revenue from any of our drug product candidates. We may not be successful in generating significant revenue from HOTSHOT. We expect to continue incurring significant research and development expenses related to the development of our drug product candidates as well as selling, general and administrative expenses related to supporting our research and development efforts, operating as a public company and supporting our HOTSHOT commercial efforts. As a result, we will need additional capital to fund our operations, which we may raise through a



combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

### **Sources of Liquidity**

At March 31, 2018, we had \$21.5 million of working capital and our cash, cash equivalents and marketable securities totaled \$23.9 million, which were held in bank deposit accounts, money market funds and U.S. government agency securities. Our cash, cash equivalents and marketable securities balance decreased during the three months ended March 31, 2018, due primarily to our net loss incurred.

### **Cash Flows**

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
Net cash (used in) provided by:		
Operating activities	\$ (9,412,487)	\$ (8,225,592)
Investing activities	12,119,933	6,881,236
Financing activities	54,913	—
Net increase (decrease) in cash and cash equivalents	<u>\$ 2,762,359</u>	<u>\$ (1,344,356)</u>

### **Operating Activities**

Net cash used in operating activities for the three months ended March 31, 2018 was \$9.4 million, an increase of \$1.2 million compared to the same period in the prior year. The use of cash for the three months ended March 31, 2018 was primarily related to our net loss for the period of \$8.2 million, offset by non-cash charges consisting of stock-based compensation expense of \$0.9 million, as well as depreciation, amortization and accretion on investments and other non-cash items, which totaled \$0.1 million. Cash used in operations also included a cash outflow of \$2.2 million from changes in operating assets and liabilities.

The \$2.2 million cash outflow from changes in operating assets and liabilities was driven primarily by outflows from an increase in prepaid expenses and other current assets of \$0.5 million and a decrease in accrued expenses and other current liabilities of \$1.9 million. The increase in prepaid expenses and other current assets relates to the timing of payments for our insurance policies. The decrease in accrued expenses and other current liabilities relates primarily to delayed billings of 2017 invoices, primarily related to clinical trial activities for our FLX-787 Phase 2 clinical trials in the United States and a decrease in accrued bonus as the 2017 employee bonuses were paid in the first quarter of 2018. These outflows were offset by inflows, primarily from an increase in accounts payable of \$0.2 million. The increase in accounts payable related to the timing of payments at March 31, 2018 compared to December 31, 2017.

### **Investing Activities**

Net cash provided by investing activities for the three months ended March 31, 2018 compared to the three months ended March 31, 2017 increased \$5.2 million, related to a \$5.2 million increase in net purchases and sales of marketable securities. This included a \$7.6 million decrease in purchases of marketable securities and a \$2.4 million decrease in proceeds from maturities and sales of marketable securities.

### **Financing Activities**

Net cash provided by financing activities for the three months ended March 31, 2018 did not change significantly compared to the three months ended March 31, 2017. Cash provided by financing activities during the three months ended March 31, 2018 was \$54,913, and related to proceeds from exercises of common stock. There was no cash used in or provided by financing activities during the three months ended March 31, 2017.

As of March 31, 2018, we had no long-term debt.

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

### **Funding Requirements**

We expect that we will require additional funding to develop and commercialize our drug product candidates. In addition, if we receive regulatory approval for any of our drug product candidates, and if we choose not to grant rights to commercialize our drug products to partners, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution activities. We also expect to incur additional costs to support our operations as well as the costs associated with operating as a public company.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or sell or license some of our assets. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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

### **Drug Product Candidates**

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

- receiving regulatory approval to conduct clinical trials;
- successfully enrolling, and completing, clinical trials;
- receiving marketing approvals from applicable regulatory authorities;
- establishing arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others.

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

As our drug product candidate, FLX-787, is in the early stage of development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of FLX-787.

### **Consumer Brand and Products**

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

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

### **Outlook**

Based on our research and development plans, our consumer brand and HOTSHOT expenditure plans and our expectations of timing related to the progress of our clinical programs, we expect that our existing cash resources and marketable securities will enable us to fund our costs and expenses, working capital and capital expenditure requirements to mid-2019. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect. Additionally, the process of testing drug product candidates in clinical trials is costly, and the timing of progress of these efforts is uncertain.

### **Contractual Obligations**

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K for the year ended December 31, 2017.

### **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 condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these condensed consolidated 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 condensed consolidated balance sheet and the reported amounts of 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.

There have been no material changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2017, except that we have updated our revenue recognition policies in conjunction with our adoption of ASC 606 as further described in Note 2 and Note 3 to the accompanying unaudited condensed consolidated financial statements. Readers should refer to our 2017 Form 10-K under "Management's Discussion and Analysis of Financial Condition and Results of Operation—Critical Accounting Policies and Use of Estimates" and Note 2 to the accompanying financial statements for descriptions of these policies and estimates.

### **Item 3. 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 March 31, 2018, we had cash, cash equivalents and marketable securities of \$23.9 million. We invest our cash in a variety of financial instruments, principally money market funds, U.S. government securities, investment-grade corporate notes and commercial paper. 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. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

### **Item 4. 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 March 31, 2018, we have evaluated, under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon our evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

### **Changes in Internal Control over Financial Reporting**

During the three months ended March 31, 2018, there was no significant change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II - OTHER INFORMATION**

### **Item 1. Legal Proceedings**

We are not currently a party to any material legal proceedings.

### **Item 1A. Risk Factors**

You should carefully review and consider the information regarding certain factors that could materially affect our business, financial condition or future results set forth under Item 1A. (Risk Factors) in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

There have been no material changes to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, except as follows:

#### ***Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.***

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our, our third-party vendors' and/or business partners' information technology systems or other similar data security incidents could adversely affect our business operations and/or result in the loss,

misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and/or state breach notification laws and foreign law equivalents, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and/or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents.

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

### **Recent sales of unregistered securities; repurchases of equity securities**

None.

### **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 net proceeds received by us from our initial public offering were \$79.9 million, after deducting 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 or to any other persons.

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

## **Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

<u>Exhibit number</u>	<u>Description of Document</u>
3.1 (1)	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant.</a>
3.2 (2)	<a href="#">Amended and Restated Bylaws of the Registrant.</a>
4.1 (3)	<a href="#">Form of Common Stock Certificate of the Registrant.</a>
4.2 (4)	<a href="#">Amended and Restated Investors' Rights Agreement, dated July 23, 2014, by and among the Company and certain of its stockholders.</a>
31.1	<a href="#">Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</a>
31.2	<a href="#">Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</a>
32.1	<a href="#">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.</a>
101	The following materials from Flex Pharma, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, formatted in XBRL (eXtensible Business Reporting Language):(i) Unaudited Condensed Consolidated Balance Sheets, (ii) Unaudited Condensed Consolidated Statements of Operations (iii) Unaudited Condensed Consolidated Statements of Comprehensive Loss, (iv) Unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Unaudited Condensed Consolidated Financial Statements.

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(1) Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-36812), filed with the SEC on February 9, 2015.

(2) Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-36812), filed with the SEC on February 9, 2015.

(3) Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201276), as amended, filed with the SEC on January 13, 2015.

(4) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-201276), filed with the SEC on December 29, 2014.

**SIGNATURES**

Pursuant to the requirements 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 (Principal Executive Officer)*

By: /s/ John McCabe  
John McCabe  
*Chief Financial Officer (Principal Financial and Accounting Officer)*

Date: May 2, 2018



**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, President and Chief Executive Officer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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)

May 2, 2018

**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 Quarterly Report on Form 10-Q 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)

May 2, 2018

**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 Quarterly Report on Form 10-Q of Flex Pharma, Inc. (the "Company") for the fiscal period ended March 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.

May 2, 2018

President and Chief Executive Officer  
(Principal Executive Officer)

/s/ John McCabe

John McCabe

May 2, 2018

Chief Financial Officer  
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.