Table of Contents

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 September 30, 2016
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	**46-5087339**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

800 Boylston Street, 24th 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, or a smaller reporting company. See the definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of October 28, 2016, there were 17,970,590 shares of common stock outstanding.

FLEX PHARMA, INC.

TABLE OF CONTENTS

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, potential indications for our drug product candidates, expectations regarding the development of our drug product candidates and the commercial prospects of our consumer product, the expected timing for the reporting of data from 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 studies; the uncertainties inherent in conducting clinical studies; 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 products; anticipated positioning and attributes of our consumer products; 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, 2015 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)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 27,829,591	$ 66,686,695
Marketable securities	39,504,263	24,652,348
Accounts receivable	21,787	—
Inventory	230,778	—
Prepaid expenses and other current assets	1,554,270	908,574
Total current assets	69,140,689	92,247,617
Marketable securities	—	2,312,949
Property and equipment, net	619,371	382,437
Other assets	64,800	—
Restricted cash	126,595	126,835
Total assets	$ 69,951,455	$ 95,069,838
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,256,889	$ 875,646
Accrued expenses and other current liabilities	2,549,443	1,947,374
Deferred revenue	81,399	—
Deferred rent, current portion	25,351	24,381
Total current liabilities	3,913,082	2,847,401
Deferred rent, net of current portion	10,561	14,587
Other long term liabilities	—	15,442
Total liabilities	3,923,643	2,877,430
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at September 30, 2016 and December 31, 2015; none issued or outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at September 30, 2016 and December 31, 2015; 17,970,590 and 17,943,880 shares issued at September 30, 2016 and December 31, 2015, respectively, and 16,518,347 and 15,741,618 shares outstanding at September 30, 2016 and December 31, 2015, respectively	1,652	1,574
Additional paid-in capital	134,757,066	129,367,978
Accumulated other comprehensive income (loss)	14,672	(24,654)
Accumulated deficit	(68,745,578)	(37,152,490)
Total stockholders' equity	66,027,812	92,192,408
Total liabilities and stockholders' equity	$ 69,951,455	$ 95,069,838

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Net product revenue	$ 586,134	$ —	$ 698,819	$ —
Other revenue	12,940	—	12,940	—
Total revenue	599,074	—	711,759	—
Costs and expenses:				
Cost of product revenue	221,090	—	529,041	—
Research and development	5,665,357	3,445,200	16,147,357	9,440,324
Selling, general and administrative	5,447,847	4,722,281	15,937,326	11,842,896
Total costs and expenses	11,334,294	8,167,481	32,613,724	21,283,220
Loss from operations	(10,735,220)	(8,167,481)	(31,901,965)	(21,283,220)
Interest income, net	97,726	14,637	308,877	34,397
Net loss	$ (10,637,494)	$ (8,152,844)	$ (31,593,088)	$ (21,248,823)
Net loss attributable to common stockholders	$ (10,637,494)	$ (8,152,844)	$ (31,593,088)	$ (21,248,823)
Net loss per share attributable to common stockholders — basic and diluted	$ (0.65)	$ (0.53)	$ (1.96)	$ (1.57)
Weighted-average number of common shares outstanding — basic and diluted	16,361,617	15,290,435	16,104,510	13,520,438

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Net loss	$ (10,637,494)	$ (8,152,844)	$ (31,593,088)	$ (21,248,823)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	(24,818)	(3,676)	39,326	(3,676)
Comprehensive loss	$ (10,662,312)	$ (8,156,520)	$ (31,553,762)	$ (21,252,499)

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Operating activities		
Net loss	$ (31,593,088)	$ (21,248,823)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	165,373	36,798
Stock-based compensation expense	5,367,070	4,892,998
Amortization and accretion on investments	117,236	1,192
Changes in operating assets and liabilities:		
Restricted cash	240	(27)
Accounts receivable	(21,787)	—
Inventory	(109,701)	—
Prepaid expenses and other current assets	(645,696)	(715,105)
Other assets	(64,800)	(35,200)
Accounts payable	321,460	433,354
Accrued expenses and other current liabilities	647,455	1,339,165
Deferred revenue	81,399	—
Deferred rent	(3,056)	(13,161)
Other long term liabilities	(15,442)	—
Net cash used in operating activities	(25,753,337)	(15,308,809)
Investing activities		
Purchases of marketable securities	(28,086,686)	(21,002,641)
Proceeds from maturities and sales of marketable securities	15,469,810	10,998,295
Purchases of property and equipment	(508,987)	(223,265)
Net cash used in investing activities	(13,125,863)	(10,227,611)
Financing activities		
Proceeds from IPO, net of offering costs	—	80,435,430
Proceeds from exercise of common stock	22,096	6,372
Proceeds from early exercise of common stock	—	400,000
Net cash provided by financing activities	22,096	80,841,802
Net (decrease) increase in cash and cash equivalents	(38,857,104)	55,305,382
Cash and cash equivalents at beginning of period	66,686,695	33,854,153
Cash and cash equivalents at end of period	$ 27,829,591	$ 89,159,535
Supplemental cash flow information		
Inventory purchases included in accounts payable and accrued expense at September 30, 2016	$ 121,077	$ —
Property and equipment purchases included in accrued expense at December 31, 2015 and 2014	$ 106,680	$ 21,000
Property and equipment purchases included in accounts payable at September 30, 2015	$ —	$ 5,070
IPO issuance costs included in accounts payable and accrued expenses at December 31, 2014	$ —	$ 499,549
IPO issuance costs paid in cash through December 31, 2014	$ —	$ 575,245

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 nocturnal leg cramps, muscle cramps and spasms associated with severe neuromuscular conditions, and exercise-associated muscle cramps. The Company's consumer product and drug product candidates are based on the potential mechanism of action described as Chemical Neuro Stimulation, which is the process by which a small molecule chemical signal, acting topically, induces a neuronal sensory signal that produces a beneficial effect. The Company's consumer product and drug product candidates activate certain receptors in primary sensory neurons, which then act via neuronal circuits to reduce the repetitive firing, or hyperexcitability, of alpha-motor neurons in the spinal cord, thereby preventing or reducing the frequency and intensity of muscle cramps and spasms. The Company intends to initially focus its drug development efforts on products to treat nocturnal leg cramps and spasms, spasticity and cramping associated with multiple sclerosis and motor neuron disease, such as amyotrophic lateral sclerosis.

In the second quarter of 2016, the Company launched its consumer brand and cornerstone consumer product, HOTSHOT™, which is intended to prevent and treat exercise-associated muscle cramps. HOTSHOT is sold directly to consumers via e-commerce on the Company's branded website and is also sold to a select number of specialty retailers and sports teams.

In connection with the launch of HOTSHOT, the Company began operating as two reportable segments, Consumer Operations and Drug Development. See Note 11 for additional discussion and information on our 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, clinical studies and clinical trials, the need to obtain marketing approval for its drug product candidates, the need to successfully commercialize and gain market acceptance of its drug product candidates and its consumer products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and development by competitors of alternative products.

In February 2015, the Company sold 5,491,191 shares of common stock (inclusive of 91,191 shares of common stock sold by the Company pursuant to the exercise of an overallotment option granted to the underwriters in connection with the offering) through an underwritten initial public offering ("IPO") at a price of $16.00 per share. The aggregate net proceeds received by the Company from the offering were approximately $79,900,000, after deducting underwriting discounts and commissions and offering expenses payable by the Company of approximately $8,000,000 (See Note 2).

Liquidity

The Company has incurred an accumulated deficit of $68,745,578 since inception and will require substantial additional capital to fund its research and development and commercialization and growth of its consumer brand and HOTSHOT. The Company had unrestricted cash, cash equivalents and marketable securities of $67,333,854 at September 30, 2016. The Company believes its existing cash, cash equivalents and marketable securities will be sufficient to allow the Company to fund its current operating plan for at least the next 12 months.

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 September 30, 2016, 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, 2015 (the "2015 10-K"), have not changed, other than as noted below.

Revenue

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

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

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

The Company had no customers that represented greater than 10% of total revenue during the three and nine months ended September 30, 2016. All revenue was generated from sales within the United States.

Accounts receivable and allowance for doubtful accounts

Accounts receivable are stated at their carrying values, net of any allowances for doubtful accounts. Accounts receivable consist primarily of amounts due from specialty retailers and sports teams, for which collectibility is reasonably assured. Receivables are evaluated for collectibility on a regular basis and an allowance for doubtful accounts is recorded, if necessary. No allowance for doubtful accounts was deemed necessary at September 30, 2016.

Cost of product revenue

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

Inventory

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

The Company outsources the manufacture of HOTSHOT to a co-packer. Inventory at September 30, 2016 includes raw materials available for future production runs, as well as finished goods.

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

Advertising expense

Advertising expense consists of media and production costs related to print and digital advertising. All advertising is expensed as incurred. Total advertising expenses are included in selling, general and administrative and were approximately $1,154,000 and $2,580,000 for the three and nine months ended September 30, 2016, respectively.

Shipping and handling costs

Shipping and handling costs related to the movement of inventory to the Company's co-packer and from the co-packer to the Company's third party warehousing partner is capitalized as inventory and expensed as a cost of product revenue when revenue is recognized. Shipping and handling costs to move finished goods from the Company's warehousing partner to the Company's third party fulfillment partner or to customer locations are included in selling, general and administrative expenses in the condensed consolidated statement of operations, and were approximately $98,000 and $126,000 for the three and nine months ended September 30, 2016, respectively. There were no such costs in 2015 as the Company had not yet launched HOTSHOT.

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 2015 10-K.

The condensed consolidated financial statements as of September 30, 2016, for the three and nine months ended September 30, 2016 and September 30, 2015, 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 September 30, 2016, and the statements of operations, comprehensive loss and cash flows for the three and nine month periods ended September 30, 2016 and 2015. The results for the three and nine months ended September 30, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016, or any other future annual or interim periods.

Initial public offering

On February 3, 2015, the Company completed its IPO, whereby the Company sold 5,491,191 shares of its common stock (inclusive of 91,191 shares of common stock sold by the Company pursuant to the exercise of an overallotment option granted to the underwriters in connection with the IPO) at a price of $16.00 per share. The shares began trading on the Nasdaq Global Market on January 29, 2015. The aggregate net proceeds received by the Company from the IPO were approximately $79,900,000, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. Upon the closing of the IPO, all outstanding shares of convertible preferred stock converted into 6,971,108 shares of common stock. Additionally, the Company is now authorized to issue 100,000,000 shares of common stock.

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

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.

Concentration of risk

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

Recent accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The ASU provides for a single comprehensive model for use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2016 with no early adoption permitted. In July 2015, the FASB deferred the effective date of this accounting update to annual periods beginning after December 15, 2017, along with an option to permit early adoption as of the original effective date. The Company is required to adopt the amendments in the ASU using one of two acceptable methods: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. In March 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers, Principal versus Agent Considerations (Reporting Revenue Gross versus Net),* clarifying the implementation guidance on principal versus agent considerations. Specifically, an entity is required to determine whether the nature of a promise is to provide the specified good or service itself (that is, the entity is a principal) or to arrange for the good or service to be provided to the customer by the other party (that is, the entity is an agent). The determination influences the timing and amount of revenue recognition. The effective date and transition requirements for ASU 2016-08 are the same as the effective date and transition requirements for ASU 2014-09. The Company is currently evaluating the impact of the guidance related to the Company's launch of HOTSHOT, and does not expect the impact to be material.

In August 2014, the FASB issued ASU No. 2014-15 *Presentation of Financial Statements - Going Concern (Subtopic 205-40)*. The ASU requires management of public and private companies to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. If conditions or events raise substantial doubt about an entity's ability to continue as a going concern, and substantial doubt is not alleviated after consideration of management's plans, an entity should include a statement in the footnotes indicating that there is substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The new standard is effective for annual periods ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company has concluded that if this standard had been adopted as of September 30, 2016, no additional disclosures would be required.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330)*. This ASU simplifies the measurement of inventory by requiring certain inventory to be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016 and for interim periods therein. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The Company is currently in the process of evaluating the impact of the guidance related to the launch of HOTSHOT.

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 for all entities. The Company is currently evaluating the impact of ASU 2016-02 on its consolidated financial statements and disclosures.

In March 2016, the FASB issued ASU No. 2016-09 *Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The ASU simplifies several aspects of the accounting for employee share-based payment transactions. The amendments in the update include income tax consequences related to excess tax benefits and tax deficiencies, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for all entities in any interim or annual period. The Company is currently evaluating the impact of ASU 2016-09 on its consolidated financial statements and disclosures.

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

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. 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 September 30, 2016 and December 31, 2015:

	Level 1	Level 2	Level 3	Balance as of September 30, 2016
Cash equivalents	$ 20,697,042	$ —	$ —	$ 20,697,042
Marketable securities:				
Corporate debt securities	—	11,418,230	—	11,418,230
U.S. government agency securities	—	28,086,033	—	28,086,033
	$ 20,697,042	$ 39,504,263	$ —	$ 60,201,305

	Level 1	Level 2	Level 3	Balance as of December 31, 2015
Cash equivalents	$ 58,575,348	$ 1,410,322	$ —	$ 59,985,670
Marketable securities:				
Corporate debt securities	—	26,965,297	—	26,965,297
	$ 58,575,348	$ 28,375,619	$ —	$ 86,950,967

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 September 30, 2016. After completing its validation procedures, the Company did not adjust or override any fair value carrying amounts as of September 30, 2016.

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 nine months ended September 30, 2016 or the year ended December 31, 2015. The Company had no financial assets or liabilities that were classified as Level 3 at any time during the nine months ended September 30, 2016 or the year ended December 31, 2015.

4. 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 September 30, 2016 and December 31, 2015 consisted of money market funds.

Marketable securities as of September 30, 2016 consisted of corporate debt securities and U.S. government agency securities. Marketable securities as of December 31, 2015 consisted of 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 immaterial realized gains on marketable securities during the three and nine months ended September 30, 2016 and 2015.

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 September 30, 2016 and December 31, 2015 consisted of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
As of September 30, 2016				
Current (due within 1 year):				
Corporate debt securities	$ 11,418,571	$ 334	$ (675)	$ 11,418,230
U.S. government agency securities	28,071,020	17,937	(2,924)	28,086,033
Total	$ 39,489,591	$ 18,271	$ (3,599)	$ 39,504,263

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
As of December 31, 2015				
Current (due within 1 year):				
Corporate debt securities	$ 24,666,607	$ 1,878	$ (16,137)	$ 24,652,348
Noncurrent (due after 1 year through 5 years):				
Corporate debt securities	2,323,344	—	(10,395)	2,312,949
Total	$ 26,989,951	$ 1,878	$ (26,532)	$ 26,965,297

At September 30, 2016, all investments held by the Company were classified as current. The Company had $24,652,348 of marketable securities classified as current and $2,312,949 of marketable securities classified as noncurrent as of December 31, 2015. 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.

The Company held four and eleven debt securities that were in an unrealized loss position at September 30, 2016 and December 31, 2015, 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 $10,604,705 and $24,967,915 at September 30, 2016 and December 31, 2015, respectively. There were no individual securities that were in a significant unrealized loss position as of September 30, 2016 or December 31, 2015. The Company evaluated its securities for other-than-temporary impairment and no marketable securities were considered to be other-than-temporarily impaired as of September 30, 2016.

5. Inventory

The Company began capitalizing inventory as of March 31, 2016, when it was determined that the inventory had a probable future economic benefit. Inventory has been recorded at cost as of September 30, 2016. Costs capitalized at September 30, 2016 relate to finished goods from the initial production run of HOTSHOT, as well as raw materials to be used in the second production run, planned for the fourth quarter of 2016. The Company held no inventory at December 31, 2015.

The following table presents inventory:

	September 30, 2016	December 31, 2015
Raw materials	$ 158,239	$ —
Finished goods	72,539	—
Total inventory	$ 230,778	$ —

In the first quarter of 2016, the Company wrote off materials purchased for the initial production run of HOTSHOT finished goods that, upon completion, were not expected to be sold based upon projected sales, estimated product shelf life, the number of units produced and production level requirements. The initial production run of HOTSHOT finished goods was completed in the second quarter of 2016, at which time the Company wrote off production costs incurred for those finished goods that were not expected to be sold. During the third quarter of 2016, the Company wrote off additional finished goods that are not expected to be sold based on shelf life requirements and the Company's next production run, which is planned to take place during the fourth quarter of 2016. Write-offs totaled $32,734 and $258,684 for the three and nine months ended September 30, 2016, respectively, and are included in cost of product revenue in the accompanying condensed consolidated statement of operations.

The cost of product revenue related to deferred revenue is capitalized and recorded as cost of product revenue at the time the revenue is recognized.

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2016	December 31, 2015
Payroll and employee-related costs	$ 1,411,663	$ 1,299,248
Research and development costs	767,327	307,666
Professional fees	211,805	129,625
Consumer product-related costs	130,679	198,887
Other	27,969	11,948
Total	$ 2,549,443	$ 1,947,374

7. Common stock

As of September 30, 2016, 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 recipients, an additional 867,314 shares of restricted common stock were sold to the same recipients, after which the anti-dilution provisions were terminated. The restricted common stock vested 25% upon issuance, and the remaining 75% vests ratably over four years, during which time the Company has the right to repurchase the unvested shares held by a recipient if the relationship between such recipient and the Company ceases. If the relationship terminates, the Company has 90 days to repurchase unvested shares at $0.0004 per share. Such shares are not accounted for as outstanding until they vest. There were 3,980,695 shares of restricted common stock outstanding as of September 30, 2016. 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, 2015	2,202,262	$ 0.10
Issued	—	—
Vested	(762,228)	0.10
Unvested at September 30, 2016	1,440,034	$ 0.10

Restricted common stock to consultants

During the nine months ended September 30, 2016, the Company issued 18,194 shares of restricted common stock to non-employee consultants and advisors. The Company has the right to repurchase any unvested shares held by a recipient if the relationship between such recipient and the Company ceases. If the relationship terminates, the Company has 90 days to repurchase unvested shares at $0.0001 per share. Such shares are not accounted for as outstanding until they vest. There were 5,985 shares of restricted common stock issued to consultants outstanding as of September 30, 2016. 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, 2015	—	$ —
Issued	18,194	9.51
Vested	(5,985)	9.25
Unvested at September 30, 2016	12,209	$ 9.63

8. 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 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 September 30, 2016, there were 402,326 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 nine months ended September 30, 2016:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	1,824,973	$ 8.34		
Granted	759,820	10.04		
Exercised	(8,516)	2.59		
Cancelled or forfeited	(256,030)	11.99		
Outstanding at September 30, 2016	2,320,247	$ 8.51	8.37	$ 9,167,034
Exercisable at September 30, 2016	773,252	$ 7.31	8.05	$ 4,216,112
Vested or expected to vest at September 30, 2016	2,161,668	$ 8.69	7.99	$ 8,229,864

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 statement of operations as follows:

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Research and development	$ 783,603	$ 617,476	$ 2,063,764	$ 2,429,769
Selling, general and administrative	1,076,985	889,203	3,303,306	2,463,229
Total	$ 1,860,588	$ 1,506,679	$ 5,367,070	$ 4,892,998

As of September 30, 2016, there was approximately $14,469,895 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 2.10 years.

In November 2015, the Company granted 150,000 performance-based stock options to an employee, which would have vested upon the achievement of certain future revenue milestones. During the third quarter of 2016, these options were cancelled in conjunction with an employment termination agreement. The vesting conditions had not previously been considered probable, and no stock-based compensation expense was recorded related to this award.

In May 2016, in connection with an amendment to an employment agreement, the Company recorded stock-based compensation expense for a modification to an option award that totaled approximately $227,000. In August 2016, in connection with an employment termination agreement, the Company recorded stock-based compensation expense for a modification to an option award that totaled approximately $58,000.

Employee stock purchase plan

In January 2015, the Company's board of directors adopted, and the Company's stockholders approved, the 2015 Employee Stock Purchase Plan (the "ESPP"), which became effective upon the date of execution of the underwriting agreement pursuant to which the Company's common stock was priced in connection with the IPO. As of September 30, 2016, the Company had not yet instituted any offering periods under the ESPP and no shares of the Company's common stock have been purchased under the ESPP.

9. 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 or nine months ended September 30, 2016 or 2015.

10. Net loss per share

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

Because the Company has reported 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:

	September 30, 2016	September 30, 2015
Options to purchase common stock	2,320,247	1,342,141
Unvested restricted common stock	1,452,243	2,456,338
Unvested restricted common stock issued upon early exercise of stock options	—	37,064
Total	3,772,490	3,835,543

11. Segment Information

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

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

The Company discloses information about its reportable segments based on the way that the Company's Chief Operating Decision Maker, who the Company has identified as the Chief Executive Officer, and management, organizes segments within the Company for making operating decisions and assessing financial performance. The Company evaluates the performance of its reportable segments based on revenue and operating income or loss. The accounting policies of the segments are the same as those described herein as well as those described in Note 1 to the audited consolidated financial statements in the 2015 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 September 30, 2016 and 2015 are as follows:

Three months Ended September 30, 2016	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	$ 599,074	—	—	$ 599,074
Interest income, net	$ —	—	97,726	$ 97,726
Loss from operations	$ 2,690,601	5,550,853	2,493,766	$ 10,735,220

Three months Ended September 30, 2015	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	$ —	—	—	$ —
Interest income, net	$ —	—	14,637	$ 14,637
Loss from operations	$ 2,578,891	3,258,877	2,329,713	$ 8,167,481

Information for the Company's reportable segments for the nine months ended September 30, 2016 and 2015 are as follows:

Nine months Ended September 30, 2016	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	$ 711,759	—	—	$ 711,759
Interest income, net	$ —	—	308,877	$ 308,877
Loss from operations	$ 8,461,803	15,517,670	7,922,492	$ 31,901,965

Nine months Ended September 30, 2015	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	$ —	—	—	$ —
Interest income, net	$ —	—	34,397	$ 34,397
Loss from operations	$ 5,412,144	9,177,410	6,693,666	$ 21,283,220

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, 2015. 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, 2015, 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 (MD&A) is provided in addition to the accompanying 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 and nine months ended September 30, 2016 to the three and nine months ended September 30, 2015.

Liquidity and Capital Resources - An analysis of changes in our 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 nocturnal leg cramps, muscle cramps and spasms associated with severe neuromuscular conditions, and exercise-associated muscle cramps. Our consumer product and our drug product candidates are based on the potential mechanism of action we describe as Chemical Neuro Stimulation, which is the process by which a small molecule chemical signal, acting topically, induces a neuronal sensory signal that produces a beneficial effect. Our consumer product and drug product candidates activate certain receptors in primary sensory neurons, which then act via neuronal circuits to reduce the repetitive firing, or hyperexcitability, of alpha-motor neurons in the spinal cord, thereby preventing or reducing the frequency and intensity of muscle cramps and spasms. We intend to initially focus our drug development efforts on products to treat nocturnal leg cramps and spasms, spasticity and cramping associated with multiple sclerosis and motor neuron disease, such as amyotrophic lateral sclerosis.

In the second quarter of 2016, we launched our consumer brand and cornerstone consumer product, HOTSHOT™, which is scientifically proven to prevent and treat exercise-associated muscle cramps, or EAMCs. HOTSHOT is sold directly to consumers on our branded website and is also sold to a select number of specialty retailers and sports teams.

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 $10.6 million and $31.6 million for the three and nine months ended September 30, 2016 and $8.2 million and $21.2 million for the three and nine months ended September 30, 2015. Our accumulated deficit was $68.7 million as of September 30, 2016. 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 continue to commercialize HOTSHOT. As a result, we will need additional capital to fund our future operations.

Recent Developments

Regulatory and Clinical Update of FLX-787 for Nocturnal Legal Cramps

On October 13, 2016, we issued a press release providing a regulatory and clinical update regarding our nocturnal leg cramps program for our lead drug product candidate, FLX-787. We announced that in September 2016 we received written responses from the U.S. Food and Drug Administration, or FDA, to our pre-Investigational New Drug Application, or IND, meeting request. In its response, FDA indicated that cramp frequency “could be an acceptable primary efficacy endpoint.” FDA also recommended that we utilize a parallel design in a planned IND-opening study due to the potential for confounding clinical results caused by carry-over effects, unblinding and other concerns associated with crossover studies.

In our FLX-787 update, we also announced the results of two exploratory studies in subjects with nocturnal leg cramps, or NLC, as well as the results from a dose-ranging efficacy study using our electrically induced cramp model.

Our first NLC study was a randomized, blinded, controlled, crossover study of 72 subjects (40-79 years of age) who reported suffering from NLC at least four nights per week. Subjects were enrolled at three clinical sites. After an initial two-week placebo run-in period, subjects were randomized to receive orally disintegrating tablets, or ODT, containing either 17 mg of FLX-787 or placebo for three weeks. Subjects were then crossed over to the other treatment for an additional three weeks. Preliminary analysis of the entire crossover data set did not demonstrate a statistically significant difference versus placebo on the pre-specified endpoints of muscle cramp frequency or

cramp-free nights. However, when data from one site is excluded and analysis is restricted to patients from the two other sites (n=37), FLX-787 shows a strong trend on muscle cramp frequency versus placebo (p=0.06) during the initial two-week parallel design portion of the study as compared to the baseline run-in period, despite the limited data set not being adequately powered to show statistical significance. We continue to analyze the data between the sites to determine whether concerns regarding the data at the excluded site are meaningful. FLX-787 was well-tolerated in the study, with no serious adverse events reported.

Our second NLC study was conducted to help inform the optimal dose and design of the Phase 2 clinical trial we expect to begin next year. This study was a sequential, multiple crossover study to generate safety and efficacy data in subjects exposed to different formulations and dosages of FLX-787. The 29 subjects in this study had participated in the prior NLC crossover study with our extract formulation. In this study of FLX-787, the subjects received liquid or ODT formulations of FLX-787 and matched placebos, in four rapidly successive crossover periods. Muscle cramp frequency was reduced ($p<0.05$) at two weeks in the parallel portion of the first phase, which tested 19 mg of FLX-787 in liquid formulation versus placebo. In the crossover data sets, efficacy ($p<0.05$) was generally seen for the pre-specified endpoints of muscle cramp frequency and cramp free nights in the early study arms. In the latter arms, FLX-787 did not show statistical significance versus placebo, which we believe resulted from a potential carryover effect. We believe this human efficacy data further supports the use of a parallel design in future studies, consistent with FDA recommendations.

We also reported the results of a study of FLX-787 using our electrically-induced cramp model. In this study of five subjects, an ODT formulation of FLX-787 reduced the intensity and duration of electrically-induced muscle cramps in a dose-dependent manner ($p<0.05$). Seven doses (0.5, 2.5, 6, 10, 18, 32, and 60 mg) of FLX-787 showed an effect consistent with a classic sigmoidal dose response curve, with virtually no effect at the lowest doses and a maximal effect at the highest doses.

We believe that the data sets from these studies establish the positive effects of FLX-787 on human muscle cramping and we are now planning a parallel design Phase 2 study in NLC to be initiated in the first half of 2017 after our IND has been submitted.

Other Developments

On August 26, 2016, we announced that W. Larry Kenney, Ph.D. had joined our Scientific Advisory Board. Dr. Kenney is the Marie Underhill Noll Chair in Human Performance and Professor of Physiology and Kinesiology at Penn State University.

On September 13, 2016, we announced the initiation of an exploratory Phase 2 study of FLX-787 in amyotrophic lateral sclerosis, or ALS, patients in Australia. The study is a randomized, controlled, blinded, crossover study designed to evaluate the safety and efficacy of an ODT formulation of FLX-787 in patients who suffer from cramps and/or spasticity as a consequence of ALS. The study will include up to 50 patients, who will be assessed on the initial parallel portion of the studies as well as the overall crossover results.

Components of Operating Results

Revenue

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

When purchasing via our branded website, customers may purchase HOTSHOT in packs of 6 or 12 bottles and are offered a first-time purchase discount for a 6 pack. We expect that a significant portion of our total revenue will be generated through our branded website. In the fourth quarter of 2016, we began selling HOTSHOT through a third party e-commerce website, and we may consider selling HOTSHOT via additional websites or e-commerce partners in the future. Generally, we realize higher revenue per bottle from our e-commerce sales versus specialty retailer sales.

HOTSHOT is generally sold to specialty retailers and sports teams in multi-pack cases and our sales terms to specialty retailers and sports teams do not allow for a right of return or refund.

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, those that purchase from the website, the potential impact of 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 e-commerce and retail revenues would have a materially adverse impact on our 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.

We began the initial production run of HOTSHOT in the first quarter of 2016, in advance of our planned launch in the second quarter of 2016. In the first quarter of 2016, we wrote off materials purchased for the initial production run of HOTSHOT finished goods that upon completion were not expected to be sold based upon projected sales, estimated product shelf life, the number of units produced and production level requirements. The initial production run of HOTSHOT finished goods was completed in the second quarter of 2016, at which time we wrote off the production fees associated with those finished goods that were not expected to be sold. During the third quarter of 2016, we wrote off additional finished goods that are not expected to be sold based on shelf life requirements and our next production run, which is planned to take place during the fourth quarter of 2016.

Cost of product revenue will include any future 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 any future inventory write-off 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, additional inventory write-offs may be required.

Cost of product revenue also includes depreciation expense related to manufacturing equipment purchased to support production.

Research and Development Expenses

Our research and development expenses to date include the costs incurred related to the development and testing of our extract formulation for muscle cramps in the United States and expenses related to the testing and development of a single molecule, chemically synthesized, TRP ion channel activator, 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 including costs of 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, clinical studies 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, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of our drug product candidates, as well as an assessment of each product candidate's commercial potential.

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

Selling, General and Administrative Expenses

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

Selling, general and administrative expenses also include costs related to our Consumer Operations segment for our consumer brand and HOTSHOT. Prior to the launch of HOTSHOT, these costs included personnel costs, brand development costs, market research costs, product design costs, pre-launch activity costs and other external costs. Since the launch of HOTSHOT, we continue to incur costs related to personnel and market research, and are also incurring costs related to our launch print and digital media campaign, public relations activities and costs related to the distribution of our product. These distribution costs include shipping and handling costs incurred once our product is in salable condition.

We expect to incur significant selling, general and administrative expenses as we continue to commercialize HOTSHOT. In the future, we may also pursue relationships with endurance athletes, figures or teams prominent in the athletic community.

Our selling, general and administrative expenses may increase as we support the efforts of our Drug Development segment as well as the needs of our corporate functions.

Interest Income, Net

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

Results of Operations

Three Months Ended September 30, 2016 Compared to the Three Months Ended September 30, 2015

The following table sets forth the condensed consolidated results of our operations, including information related to our Consumer Operations and Drug Development segments for the three months ended September 30, 2016 compared to the three months ended September 30, 2015.

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Change	
Net product revenue	$ 586,134	$ —	$ 586,134	N/A
Other revenue	12,940	—	12,940	N/A
Total revenue	599,074	—	599,074	N/A
Costs and expenses:				
Cost of product revenue	221,090	—	221,090	N/A
Research and development	5,665,357	3,445,200	2,220,157	64%
Selling, general and administrative	5,447,847	4,722,281	725,566	15%
Total costs and expenses	11,334,294	8,167,481	3,166,813	39%
Loss from operations	(10,735,220)	(8,167,481)	(2,567,739)	31%
Interest income, net	97,726	14,637	83,089	568%
Net loss	$ (10,637,494)	$ (8,152,844)	$ (2,484,650)	30%

Total Revenue

Our Consumer Operations segment generated all of our revenue during the three months ended September 30, 2016, through sales of HOTSHOT and expedited shipping and handling purchases. Total revenue was $0.6 million for the three months ended September 30, 2016, driven primarily by HOTSHOT launch efforts, including our print and digital media campaign, public relation efforts and other sales and promotional activities. Sales via e-commerce on our branded website represented approximately 93% of our total revenue and we expect that e-commerce will continue to represent a significant portion of our future total revenue. Customers purchase HOTSHOT in 6 or 12 pack configurations via our website and first time purchasers of a 6 pack are offered a one-time discount. Discounts are recorded as a reduction of net product revenue. During the third quarter of 2016, we began to offer customers the option to purchase expedited shipping. Revenue related to expedited shipping and handling is included in other revenue.

For sales through September 30, 2016, we issued refunds to e-commerce customers, upon request, within 21 days of shipment. As we currently do not have adequate history to accurately estimate refunds, all e-commerce sales, and their related costs, are deferred and total revenue is recognized once the refund period lapses. When we began selling HOTSHOT on a third party e-commerce website in October 2016, the refund period and related deferral period increased, as we began offering refunds to e-commerce customers, upon request, within 30 days of delivery, for purchases subsequent to September 30, 2016.

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 $0.2 million for the three months ended September 30, 2016 and included the cost of HOTSHOT sold, depreciation expense related to manufacturing equipment purchased to support production and an inventory write-off totaling approximately $32,700. This write-off related to HOTSHOT finished goods from the initial production run that are not expected to be sold based on shelf life requirements and the our next production run which is planned to take place during the fourth quarter of 2016. There was no cost of product revenue for the three months ended September 30, 2015.

Research and Development Expenses

Our Drug Development segment incurred the majority of our research and development expenses, which were $5.7 million for the three months ended September 30, 2016 compared to $3.4 million for the three months ended September 30, 2015. The 64% increase of $2.2 million was primarily related to:

- $1.8 million of increased costs primarily related to clinical studies of our drug product candidate, a single molecule, chemically synthesized, TRP ion channel activator and IND-supporting pre-clinical activities for our drug product candidate;

- $0.3 million of increased costs for clinical studies of our drug product candidate outside the United States;
- $0.2 million increase in stock-based compensation expense, primarily due to the revaluation of stock awards related to the conversion of an employee to a consultant; and
- $0.1 million decrease in salaries expense due to personnel changes.

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 costs were $5.4 million for the three months ended September 30, 2016 compared to $4.7 million for the three months ended September 30, 2015. The 15% increase of $0.7 million was primarily related to:

- $0.5 million of increased costs within our Consumer Operations segment for print and digital media campaigns, sponsorships, marketing and promotional costs for our consumer brand and HOTSHOT;
- $0.3 million of increased corporate personnel costs, including salaries and other compensation-related costs such as stock-based compensation, related to additional administrative personnel hired to support our growth and increased activities;
- $0.2 million of increased personnel costs incurred by our Consumer Operations segment, including salaries and other compensation-related costs such as stock-based compensation, primarily related to employee termination costs;
- $0.1 million of costs within our Consumer Operations segment for HOTSHOT distribution expenses related to HOTSHOT sales;
- $0.1 million increase in other costs, primarily facility and office-expense related; and
- $0.5 million decrease in external consulting costs within our Consumer Operations segment due to decreased use.

Loss from Operations

Our consolidated loss from operations for the three months ended September 30, 2016 totaled $10.7 million. Of this total, $2.7 million of the operating loss was incurred by our Consumer Operations segment, $5.6 million was incurred by our Drug Development segment and the remaining $2.5 million related to corporate and unallocated costs. The operating loss incurred by the Consumer Operations segment was primarily driven by production costs, marketing, promotional and branding costs related to the launch of HOTSHOT, and personnel-related expenses, including stock-based compensation. These costs were slightly offset by the total revenue generated from HOTSHOT sales in the third quarter of 2016. The operating loss incurred by the Drug Development segment relates to costs incurred for pre-clinical and clinical activities, as well as personnel-related expenses, including stock-based compensation.

Interest Income, net

Interest income, net, increased by $0.1 million in the comparative quarters as we increased our investments in U.S. government securities and corporate debt from money market accounts and interest rates increased, offset by lower available cash to invest.

Nine Months Ended September 30, 2016 Compared to the Nine Months Ended September 30, 2015

The following table sets forth the condensed consolidated results of operations, including information related to our Consumer Operations and Drug Development segments for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015.

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Change	
Net product revenue	$ 698,819	$ —	$ 698,819	N/A
Other revenue	12,940	—	12,940	N/A
Total revenue	711,759	—	711,759	N/A
Costs and expenses:				
Cost of product revenue	529,041	—	529,041	N/A
Research and development	16,147,357	9,440,324	6,707,033	71%
Selling, general and administrative	15,937,326	11,842,896	4,094,430	35%
Total costs and expenses	32,613,724	21,283,220	11,330,504	53%
Loss from operations	(31,901,965)	(21,283,220)	(10,618,745)	50%
Interest income, net	308,877	34,397	274,480	798%
Net loss	$ (31,593,088)	$ (21,248,823)	$ (10,344,265)	49%

Total Revenue

Our Consumer Operations segment generated all of our revenue in the nine months ended September 30, 2016, totaling $0.7 million, through sales of HOTSHOT and expedited shipping and handling purchases. Revenue was driven by our HOTSHOT launch efforts, including our print and digital media campaign, public relation efforts, pre-launch efforts and other sales and promotional activities. Sales via e-commerce on our branded website represented approximately 92% of our total revenue for the nine months ended September 30, 2016.

Cost of Product Revenue

All costs of product revenue are recorded by our Consumer Operations segment and relate to the production and sale of HOTSHOT. Cost of product revenue was $0.5 million for the nine months ended September 30, 2016, and included the cost of HOTSHOT sold, depreciation expense related to manufacturing equipment purchased to support production, and inventory write-offs which totaled approximately $0.3 million related to HOTSHOT finished goods that were not expected to be sold based upon projected sales, estimated product shelf life, the number of units produced, production level requirements and timing of future production runs. There was no cost of product revenue for the nine months ended September 30, 2015.

Research and Development Expenses

Our Drug Development segment incurred the majority of our research and development expenses, which were $16.1 million for the nine months ended September 30, 2016 compared to $9.4 million for the nine months ended September 30, 2015. The 71% increase of $6.7 million was primarily related to:

- $5.3 million of increased costs related to clinical studies of our drug product candidate, a single molecule, chemically synthesized, TRP ion channel activator, IND-supporting pre-clinical activities for our drug product candidate, clinical studies of alternate formulations of our extract formulation and manufacture of clinical supply;
- $1.0 million of increased costs for clinical studies of our drug product candidate outside of the United States;
- $0.3 million increase related to our Consumer Operations segment for continued research of our consumer product;
- $0.2 million increase in consulting expenses to supplement Drug Development segment personnel due to increased activities; and
- $0.1 million decrease in other costs, primarily allocated insurance and office-related expenses.

Selling, General and Administrative Expenses

Selling, general and administrative includes expenses that are incurred by our Consumer Operations segment as well as corporate and unallocated amounts that do not relate to a reportable segment. Selling, general and administrative expenses were $15.9 million for the nine months ended September 30, 2016 compared to $11.8 million for the nine months ended September 30, 2015. The 35% increase of $4.1 million was primarily related to:

- $1.3 million of increased external costs within our Consumer Operations segment related to developing our consumer brand and HOTSHOT, including brand development and strategy costs, and marketing and promotional costs for pre-launch and launch activities, as selling commenced in the second quarter of 2016;
- $1.1 million of increased corporate personnel costs, including salaries and other compensation-related costs such as stock-based compensation, related to additional administrative personnel hired to support our growth and increased activities;
- $1.0 million of increased personnel costs incurred by our Consumer Operations segment, including salaries and other compensation-related costs such as stock-based compensation, due to hiring additional personnel to support the launch of HOTSHOT, as well as employee termination costs;
- $0.4 million of increased external consulting costs for our Consumer Operations segment, as well as professional general and administrative costs; and
- $0.3 million increase in other costs, primarily facility and office-expense related.

Loss from Operations

Our consolidated loss from operations for the nine months ended September 30, 2016 totaled $31.9 million. Of this total, $8.5 million of the operating loss was incurred by our Consumer Operations segment, $15.5 million was incurred by our Drug Development segment and the remaining $7.9 million related to corporate and unallocated costs. The operating loss incurred by the Consumer Operations segment was driven by production costs, marketing, promotional and branding costs related to preparing for, and executing, the launch of HOTSHOT, and personnel-related expenses, including stock-based compensation. These costs were slightly offset by the total revenue generated from HOTSHOT sales during the nine months ended September 30, 2016. The operating loss incurred by the Drug Development segment relates to costs incurred for pre-clinical and clinical activities, personnel-related expenses, including stock-based compensation, as well as consulting costs.

Interest Income, net

Interest income, net, increased by $0.3 million in the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 as as we increased our investments in U.S. government securities and corporate debt from money market accounts and interest rates increased, offset by lower available cash to invest.

Liquidity and Capital Resources

Overview

Since inception, we have incurred an operating loss and we anticipate that we will continue to incur operating losses for at least the next several years. To date, we have generated limited revenue from sales of HOTSHOT. 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 continue to commercialize HOTSHOT. 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.

Since our inception, we have financed our operations through private placements of equity securities and our IPO, which we completed in February 2015. As of September 30, 2016, we had $67.3 million in cash, cash equivalents and marketable securities, which were held in bank deposit accounts, money market funds, corporate debt and U.S. government agency securities.

Sources of Liquidity

At September 30, 2016, we had $65.2 million of working capital and our cash, cash equivalents and marketable securities totaled $67.3 million. Our cash, cash equivalents and marketable securities balance decreased during the nine months ended September 30, 2016, due primarily to our net loss incurred.

Cash Flows

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Net cash (used in) provided by:		
Operating activities	$ (25,753,337)	$ (15,308,809)
Investing activities	(13,125,863)	(10,227,611)
Financing activities	22,096	80,841,802
Net (decrease) increase in cash and cash equivalents	$ (38,857,104)	$ 55,305,382

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2016 was $25.8 million, an increase of $10.4 million compared to the same period in the prior year. The use of cash for the nine months ended September 30, 2016 was primarily related to our net loss for the period of $31.6 million, offset by non-cash charges consisting of stock compensation expense of $5.4 million, depreciation expense of $0.2 million and amortization and accretion on investments of $0.1 million. Cash used in operations was also offset by a $0.2 million cash inflow from changes in operating assets and liabilities. This inflow was driven by an increase in accounts payable, accrued expenses and other current liabilities of $1.0 million, offset by an increase in prepaid expenses and other current and noncurrent assets of $0.7 million and an increase in inventory of $0.1 million. The increase in accounts payable, accrued expenses and other current liabilities was primarily due to an increase in clinical trial activity and an increase in compensation-related accruals. The increase in prepaid expenses and other current assets relates to the timing of payments for clinical trials and related activities, and the increase in inventory relates to the launch of HOTSHOT in the second quarter of 2016. Net cash used in operating activities for the nine months ended September 30, 2015 totaled $15.3 million and was primarily related to our net loss for the period of $21.2 million, offset by non-cash charges of $4.9 million, primarily related to stock compensation expense, and a cash inflow of $1.0 million from changes in operating assets and liabilities, primarily related to an increase in accrued expenses and other current liabilities.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015, increased $2.9 million, primarily related to $2.6 million increase in net purchases and sales of marketable securities. Property and equipment acquisitions increased $0.3 million, which was primarily related to manufacturing equipment used to produce HOTSHOT and the development of our branded website for e-commerce sales.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015, decreased by $80.8 million. During the nine months ended September 30, 2015, we completed our IPO, which resulted in net proceeds of $79.9 million.

As of September 30, 2016, 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 support the commercialization of HOTSHOT and to develop and commercialize our drug product candidates. In addition, if we receive regulatory approval for any of our drug product candidates, and if we choose not to grant 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 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, manufacturing, 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 as well as our consumer brand and products.

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:

- successfully enrolling, and completing, clinical studies and 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 all of our drug product candidates are 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 our drug product candidates.

Consumer Brand and Products

The development and growth of our consumer brand, HOTSHOT and future products is uncertain, including the timing and resources needed to support successful commercialization. Our future success depends, in large part, on our ability to implement a growth strategy that establishes distribution and placement of our products, attracts consumers to HOTSHOT and future product offerings and maintains brand loyalty for our consumer products.

Our future funding requirements will be impacted by our ability to successfully grow our consumer brand, HOTSHOT and any future products. In addition, delays or unexpected costs related to HOTSHOT and growth plans could significantly change the costs and the timing of such costs associated with our consumer operations.

Outlook

Based on our research and development plans, our consumer brand and HOTSHOT growth 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 through late-2018. We have based this estimate on assumptions that may prove to be wrong,

however, and we could use our capital resources sooner than we expect. Additionally, the process of testing drug product candidates in clinical trials is costly, as are the resources required to commercialize a consumer brand and products, 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, 2015.

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, 2015, other than as noted below.

Inventory

Inventory consists of costs related to the production of HOTSHOT, which is produced for us by a co-packer.

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

During the three and nine months ended September 30, 2016, we recorded inventory write-offs of excess inventory totaling approximately $32,700 and $258,700, respectively, based upon our analysis of projected sales, estimated product shelf life, the number of units produced and production level requirements.

We may need to record additional inventory write-offs in the future which will vary based upon factors such as inventory levels, production levels, projected sales of our consumer product and shelf-lives of our inventory components. HOTSHOT currently has a 12 month shelf life. If we are not successful in generating sufficient levels of sales of HOTSHOT or if our other estimates prove to be inaccurate, additional inventory write-offs may be required.

Total revenue

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

sales, total revenue is recognized at the time products are delivered to customers. We do not offer a right of return or refund to specialty retailers or sports teams.

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

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

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 September 30, 2016, we had cash, cash equivalents and marketable securities of $67.3 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 Securities Exchange Act of 1934, as amended (the "Exchange Act"), with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

As of September 30, 2016, we have evaluated, under the supervision and with the participation of our management, including the chief executive officer and the principal financial and accounting 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 principal financial and accounting officer concluded that our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

During the nine months ended September 30, 2016, 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, 2015.

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, 2015, except as follows:

Risks Related to Our Reliance on Third-Parties

We depend on third party manufacturers and suppliers, including sole source manufacturers and suppliers, for our consumer product. We may not be able to maintain these relationships and could experience supply disruptions outside of our control.

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

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

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

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

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

Our inventory is concentrated in one warehouse location, which exposes us to the risk of natural disasters or other force majeure events. Losses at this location could materially adversely affect our product distributions, sales and consumer satisfaction.

The inventory of HOTSHOT is concentrated at one warehouse location, which then supplies inventory to our fulfillment partner who fulfills our customer orders. Any significant disruption to the operation of this warehouse location for any reason, such as a power failure, equipment breakdown, workforce disruption, or natural or similar disasters, could materially adversely affect our product distributions, sales and consumer satisfaction.

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

Our ability to receive and fulfill orders promptly and accurately is critical to our success and largely depends on the efficient and uninterrupted operation of our computer and communications hardware and software systems. We may experience periodic system interruptions that impair the performance of our transaction systems or make our website inaccessible to our customers. These system interruptions may prevent us from efficiently accepting and

fulfilling orders, sending out promotional emails and other customer communications in a timely manner, introducing new features on our website, or promptly responding to customers. Frequent or persistent interruptions in our services could cause current or potential customers to believe that our systems are unreliable, which could cause them to avoid our website, drive them to our competitors, and harm our reputation. To minimize future system interruptions, we must continue to improve our systems and network infrastructure to accommodate increases in website traffic and sales volume. We may be unable to promptly and effectively upgrade and expand our systems and integrate additional functionality into our existing systems. In addition, upgrades to our systems may cause existing systems to fail or operate incorrectly. Any unscheduled interruption in our services could result in fewer orders, additional operating expenses, or reduced customer satisfaction, any of which would harm our business, financial condition and operating results. In addition, the timing and cost of upgrades to our systems and infrastructure may substantially impact the costs of operating our consumer business.

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

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

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

If we are not effective in attracting and retaining customers at an acceptable cost, we will be unable to generate significant revenue for our consumer product and achieve profitability.

We will need to increase awareness of our brand and HOTSHOT in order to successfully commercialize HOTSHOT. Promoting and positioning our brand depends largely on the success of our marketing efforts and our ability to provide consistent, high quality customer experiences. We believe that, because we are a small company with low public brand awareness in a competitive market, achieving significant market awareness may require significant marketing expense. To promote our brand and HOTSHOT, we have incurred and expect to continue to incur substantial expense in our marketing efforts both to attract and to retain customers. Our promotional activities may not be effective in building our brand awareness and customer base to the extent necessary to generate sufficient revenue to become profitable. Further, we expect to build brand awareness by selling our products to retail locations in our targeted markets. If we are not able to obtain a significant retail presence, our ability to increase our brand awareness may be limited. If we are unsuccessful in increasing brand awareness, we may not generate significant revenue from HOTSHOT.

Our success depends on our ability to attract visitors to our website and convert them into customers in a cost-effective manner. Search engine and other online marketing initiatives comprise a substantial part of our marketing efforts, and our success depends in part on our ability to manage costs associated with these initiatives, or to find other channels to acquire and retain customers cost-effectively.

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

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

Recent sales of unregistered 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 dated January 28, 2015 and filed with the SEC pursuant to Rule 424(b)(4) on January 29, 2015.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On August 26, 2016, we announced Marina Hahn transitioned from her role as President, Consumer to an outside advisor. Katharine Lindemann, our Chief Operating Officer, continues to lead our consumer business for which she assumed operational responsibility in May 2016. In connection with this transition, Ms. Hahn's employment was terminated and Flex Innovation Group LLC, our wholly owned subsidiary, entered into an Advisor Agreement with Ms. Hahn pursuant to which Ms. Hahn agreed to provide us with advisory services related to the commercialization of our consumer product. On November 1, 2016, we notified Ms. Hahn that we were terminating the Advisor Agreement, effective as of November 16, 2016.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which are incorporated herein by reference.

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/ Christoph Westphal

Christoph Westphal, M.D., Ph.D.
President and Chief Executive Officer

By: /s/ John McCabe

John McCabe
Vice President, Finance (Principal Financial and Accounting Officer)

Date: November 2, 2016

EXHIBIT INDEX

Exhibit number		Description of Document
3.1	(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2	(1)	Amended and Restated Bylaws of the Registrant.
4.1	(2)	Form of Common Stock Certificate of the Registrant.
4.2	(2)	Amended and Restated Investors' Rights Agreement, dated July 23, 2014, by and among the Registrant and certain of its stockholders.
10.1	+	Advisor Agreement, dated August 24, 2016, by and among Flex Innovation Group LLC, the Registrant and Marina Hahn.
31.1		Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2		Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1		Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101		The following materials from Flex Pharma, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, 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.

(1) Incorporated by reference 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 the Registrant's Registration Statement on Form S-1 (File No. 333-201276), as amended.

+ Indicates management contract or compensatory plan.

FLEX INNOVATION GROUP LLC

ADVISOR AGREEMENT

Date: August 24, 2016

This **Advisor Agreement** (this "***Agreement***"), effective as of the date written above (the "***Effective Date***"), is between Flex Innovation Group LLC, a Delaware limited liability company (the "***Company***"), and Marina Hahn ("***Advisor***").

Whereas, in connection with Advisor's employment the Company, Advisor and the Company entered into that certain offer letter dated September 4, 2014, as amended on May 27, 2015, July 20, 2015 and May 9, 2016 (as amended, the "***Offer Letter***"); and

Whereas, on the Effective Date, Advisor's employment with the Company terminated and the Advisor will now perform advisory services for the Company in accordance with the terms hereof.

Now, Therefore, the parties hereby agree as follows:

1. **Advisory Services**. The Company retains Advisor, and Advisor agrees to provide, advisory services to the Company relating to the development and commercialization of the Company's consumer products (the "***Advisory Services***") as the Company may from time to time reasonably request; provided, however, that in no event shall Advisor be required to provide in excess of 10 hours of Advisory Services in any month during the term of this Agreement. Advisor agrees to render the Advisory Services to the Company, or to its designee, (a) at such reasonably convenient times and places as the Company may reasonably request, with due regard for Advisor's personal and professional obligations, and (b) on a commercially reasonable basis. Advisor will comply with all rules, procedures and standards promulgated from time to time by the Company with regard to Advisor's access to and use of the Company's property, information, equipment and facilities. Advisor agrees to furnish the Company with written reports with respect to the Advisory Services if and when requested by the Company, with the time spent in preparing such reports to be counted as part of the 10-hour limit. Advisor shall be permitted to continue to use her Company email account until the termination of this Agreement in accordance with section 7 below.
2. **Compensation**.

a) In consideration for the Advisory Services rendered by Advisor to the Company, Advisor shall receive a monthly retainer of three thousand dollars ($3,000), pro rated for any partial month of service and payable within ten business days following the end of each such month.

b) The parties acknowledge and agree that pursuant to the Offer Letter and that certain Stock Option Grant Notice dated November 10, 2014, including the Option Agreement attached thereto (the "***2014 Option Agreement***"), and Flex Pharma's 2014 Equity Incentive Plan, 25,925 shares of Common Stock of Flex Pharma, Inc. ("***Flex Pharma***") shall vest and become exercisable (the "***Additional Vested Shares***") upon the Company's receipt of an effective, general release of claims in favor of the Company in a form acceptable to the Company within 30 days following Advisor's employment termination date. The parties acknowledge and agree that the Additional

Vested Shares represent shares that would have vested in accordance with the 2014 Option Agreement during the period beginning on the Effective Date and ending on December 31, 2016 if Advisor continued to perform services for the Company. As such, the parties further acknowledge and agree that notwithstanding anything set forth in the 2014 Option Agreement or the Offer Letter to the contrary, no additional shares of Flex Pharma's Common Stock subject to the 2014 Option Agreement shall vest during the period beginning on the Effective Date and ending December 31, 2016. Following December 31, 2016, the shares subject to the 2014 Option Agreement shall continue to vest in accordance with the vesting schedule set forth in the 2014 Option Agreement if Advisor continues to provide Advisory Services following such date. All vested options issued to you pursuant to the 2014 Option Agreement shall remain exercisable in accordance with such agreement until the later of (i) the second anniversary of the Effective Date and (ii) the first anniversary of the termination of the Advisory Services pursuant to section 7 below. All other terms and provisions of the 2014 Option Agreement not expressly modified by this Agreement shall remain in full force and effect.

c) Advisor acknowledges and agrees that, as of the last day of Advisor's employment with the Company, (i) Advisor forfeited Advisor's option to purchase shares of Flex Pharma's Common Stock pursuant to that certain Stock Option Grant Notice dated December 9, 2015, including the Option Agreement attached thereto (the "***2015 Option Agreement***") and Flex Pharma's 2015 Equity Incentive Plan (the "***2015 Plan***"), and (ii) Advisor's rights under the 2015 Option Agreement and the 2015 Plan terminated.

3. **Inventions**.

a) **Definition**. "***Inventions***" means all inventions, discoveries, improvements, ideas, designs, processes, products, computer programs, works of authorship, databases, samples, chemical compounds, assays, mask works, trade secrets, know-how, research and creations (whether or not patentable or subject to copyright or trade secret protection) that Advisor makes, conceives or reduces to practice, either alone or jointly with others, and that (a) result from the performance of the Advisory Services, and/or (b) result from use of facilities, equipment, supplies, or Confidential Information (defined below) of the Company.

b) **Ownership**. Advisor will promptly disclose all Inventions in confidence to the Company. Advisor agrees to irrevocably transfer and assign and hereby does irrevocably transfer and assign to the Company or its successors the entire right, title and interest now existing or that may exist in the future in and to all right, title and interest in and to all Inventions and any and all related patents, patent applications, copyrights, copyright applications, trademarks, trade names, trade secrets and other proprietary rights in the United States and throughout the world ("***Work Product***"). All Work Product will be the exclusive property of the Company. For purposes of the copyright laws of the United States, all Work Product will constitute "works made for hire", except to the extent such Inventions cannot by law be "works made for hire". Advisor agrees to execute, at the Company's request and expense, all documents and other instruments necessary or desirable to confirm such assignment. In the event that Advisor does not, for any reason, execute such documents within a reasonable time of the Company's request, Advisor hereby irrevocably appoints the Company as Advisor's attorney-in-fact for the purpose of executing such documents on Advisor's behalf, which appointment is coupled with an interest. Advisor further agrees to assist the Company in every proper way to enforce the Company's rights relating to the Work Product in any and all countries, including, but not limited to, executing, verifying and delivering such documents and performing such other acts (including appearing as a witness) as the Company may

reasonably request for use in obtaining, perfecting, evidencing, sustaining and enforcing the Company's rights relating to the Work Product. Advisor shall make and maintain adequate and current written records of all Inventions, which records shall be available to and remain the property of the Company at all times.

4. **Confidential Information**

a) **Definition.** "***Confidential Information***" means information with respect to the facilities and methods of the Company, trade secrets, Inventions, systems, patents and patent applications, procedures, manuals, confidential reports, financial information, business plans, prospects, or opportunities, personnel information, lists of customers and suppliers, and information of third parties provided by the Company to Advisor. Confidential Information does not include information which (i) is in the public domain or which becomes part of the public domain through no wrongful act on Advisor's part but only after it becomes so publicly known, or (ii) that becomes known to Advisor through disclosure by a third party having the right to disclose the information, as evidenced by written or electronic records.

b) **Obligations of Confidentiality**. Advisor will not directly or indirectly publish, disseminate or otherwise disclose, use for Advisor's own benefit or for the benefit of a third party, deliver or make available to any third party, any Confidential Information, other than in furtherance of the purposes of this Agreement, and only then with the prior written consent of the Company, and it is understood that all Confidential Information shall remain the sole property of the Company. If required, Advisor may disclose the Confidential Information to a governmental authority or by order of a court of competent jurisdiction, provided that such disclosure is subject to all applicable governmental or judicial protection available for like material and reasonable advance notice is given to the Company. Advisor will exercise all reasonable precautions to physically protect the integrity and confidentiality of the Confidential Information and will not remove any Confidential Information or copies thereof from the Company' premises except to the extent necessary to fulfill the Advisory Services, and then only with the Company's prior consent.

c) **Third Party Confidential Information**. Advisor recognizes that the Company has received and in the future will receive from third parties confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Advisor agrees that Advisor owes the Company and such third parties, during the term of this Agreement and thereafter, a duty to hold all such confidential or proprietary information in the strictest confidence in accordance with the Company's obligations to such third party, and not to disclose it to any person, firm or corporation or to use it except in carrying out the Advisory Services for the Company consistent with the Company's agreement with such third party.

5. **Representations and Warranties.** Advisor represents and warrants that: (a) Advisor is under no contractual or other obligation or restriction which is inconsistent with Advisor's execution of this Agreement or the performance of the Advisory Services; (b) Advisor has the full right and authority to enter into this Agreement and perform Advisor's obligations hereunder; (c) Advisor has the right and unrestricted ability to assign the Work Product pursuant hereto; and (d) Advisor's performance of all the terms of this Agreement and as a provider of services to the Company does not and will not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by Advisor in confidence or in trust prior to or during this Agreement.

6. **Nondisparagement.** Advisor agrees not to disparage the Company, and the Company's attorneys, directors, managers, partners, employees, agents and affiliates, in any manner likely to

be harmful to them or their business, business reputation or personal reputation. The Company agrees that the members of its senior management team and that of its parent (including its chief executive officer, general counsel, chief operating officer, vice president of finance, chief medical officer, and senior vice president, investor relations & corporate communications) will not disparage Advisor in any manner likely to be harmful to her or her business, business reputation or personal reputation. Further, the Company agrees to direct Veronica Kelly Cash, Mariah Faulhaber, Christina Hsu, and Selena Roberts not to disparage Advisor in any manner likely to be harmful to her or her business, business reputation or personal reputation. Notwithtanding the foregoing, any person or entity may respond accurately and fully to any question, inquiry or request for information when required by legal process.

7. **Term and Termination**

a) **Term**. This Agreement will commence on the Effective Date and continue until terminated in accordance with the terms hereof.

b) **Termination**. Either party may terminate this Agreement at any time without cause upon not less than fifteen (15) days' prior written notice to the other party.

c) **Effect of Expiration/Termination.** Upon termination of this Agreement, neither the Company nor Advisor will have any further obligations under this Agreement, except (a) the liabilities accrued through the date of termination, and (b) the obligations under sections 2(b), 3, 4, 5, 6, 7 and 8 will survive. Upon expiration or termination, and in any case upon the Company's request, Advisor will return immediately to the Company all tangible Confidential Information, including all copies and reproductions thereof, except for one (1) copy which may be retained solely for archival purposes, and shall delete any such Company Confidential Information from Advisor's computer storage or any other media (including, but not limited to, online and off-line libraries). Upon termination of this Agreement, Advisor may retain the laptop computer previously provided to her by the Company, provided that she shall make such laptop computer available for inspection by the Company to ensure that all Confidential Information has been removed.

8. **Miscellaneous**

a) **Independent Contractor**. All Advisory Services will be rendered by Advisor as an independent contractor and this Agreement does not create an employer-employee relationship between the Company and Advisor. Advisor will not in any way represent herself to be an employee, partner, joint venturer, or agent of the Company. Advisor is not authorized to make any representation, contract, or commitment on behalf of the Company or incur any liabilities or obligations of any kind in the name of or on behalf of the Company.

b) **Taxes.** Advisor and the Company agree that the Company will treat Advisor as an independent contractor for purposes of all tax laws (local, state and federal) and file forms consistent with that status. Advisor agrees, as an independent contractor, that Advisor is not entitled to unemployment benefits in the event this Agreement terminates, or workers' compensation benefits in the event that Advisor is injured in any manner while performing obligations under this Agreement. Advisor will be solely responsible to pay any and all local, state, and/or federal income, social security and unemployment taxes for Advisor and Advisor's employees. The Company will not withhold any taxes or prepare W-2 Forms for Advisor, but will provide Advisor with a Form 1099, if required by law. Advisor is solely responsible for, and will timely file all tax returns and payments required to be filed with, or made to, any federal, state or local tax authority with respect to the performance of services and receipt of fees under this Agreement.

c) **Use of Name**. Advisor consents to the use by the Company of Advisor's name and likeness in written materials and oral presentations to current or prospective customers, partners, investors or others, provided that such materials or presentations accurately describe the nature of Advisor's relationship with or contribution to the Company.

d) **Assignability and Binding Effect**. The Advisory Services to be rendered by Advisor are personal in nature. Advisor may not assign or transfer this Agreement or any of Advisor's rights or obligations hereunder except to a corporation of which Advisor is the sole stockholder. In no event will Advisor assign or delegate responsibility for actual performance of the Advisory Services to any other natural person except to Advisor Personnel as provided for under this Agreement. This Agreement will be binding upon and inure to the benefit of the parties and their respective legal representatives, heirs, successors and permitted assigns. The Company may assign this Agreement to any other corporation or entity which acquires (whether by purchase, merger, consolidation or otherwise) all or substantially all of the business and/or assets of the Company.

e) **Notices**. Any notices or other communications from one party to the other will be in writing and will be given by addressing the same to the other at the address or facsimile number set forth in this Agreement. Notices to the Company will be marked "Attention: General Counsel". Notice will be deemed to have been duly given when (a) deposited in the United States mail with proper postage for first class Registered or Certified Mail prepaid, return receipt requested, (b) sent by any reputable commercial courier, delivery confirmation requested, (c) delivered personally, or (d) if promptly confirmed by mail or commercial courier as provided above, when dispatched by facsimile.

f) **Amendment.** This Agreement may be amended or modified only by a writing signed by authorized representatives of both parties.

g) **No. Waiver.** No waiver of any term or condition of this Agreement shall be valid or binding on either party unless the same shall be been mutually assented to in writing by both parties. The failure of either party to enforce at any time any of the provisions of this Agreement, or the failure to require at any time performance by the other party of any of the provisions of this Agreement, shall in no way be construed to be a present or future waiver of such provisions, nor in any way affect the right of either party to enforce each and every such provision thereafter. The express waiver by either party of any provision, condition or requirement of this Agreement shall not constitute a waiver of any future obligation to comply with such provision, condition or requirement.

h) **Severability.** In the event that any one or more of the provisions contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and all other provisions will remain in full force and effect. If any provision of this Agreement is held to be excessively broad, it will be reformed and construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by law.

i) **Entire Agreement.** This Agreement and the 2014 Option Agreement constitute the entire agreement of the parties with regard to its subject matter, and supersede all previous written or oral representations, agreements and understandings between the parties.

j) **Governing Law**. This Agreement will be governed by, and construed and enforced in accordance with, the laws of the State of New York applicable to contracts made and to be performed therein, without giving effect to the principles thereof relating to the conflict of laws,

and any action arising out of or related to this Agreement shall be maintained in a court sitting in the City, County, and State of New York.

k) **Remedies.** Advisor's obligations under this Agreement are of a unique character that gives them particular value; breach of any of such obligations will result in irreparable and continuing damage to the Company for which there will be no adequate remedy at law; and, in the event of such breach, the Company will be entitled to injunctive relief and/or a decree for specific performance, and such other and further relief as may be proper. Advisor and the Company further agree that no bond or other security shall be required in obtaining such equitable relief.

l) **Counterparts**. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

Signature Page Follows]

[***Signature Page to Advisor Agreement***]

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Effective Date.

Flex Innovation Group LLC

By: /s/ Robert Hadfield
Name: Robert Hadfield
Title: General Counsel

Address: 800 Boylston Street, 24th Floor
Boston, MA 02199

Marina Hahn

/s/ Marina Hahn

Address:

ACKNOLWEDGED AND AGREED:

Flex Pharma, Inc.

By: /s/ Robert Hadfield
Name: Robert Hadfield
Title: General Counsel

Address: 800 Boylston Street, 24th Floor
Boston, MA 02199

Exhibit 31.1

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

I, Christoph Westphal, 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.

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/ CHRISTOPH WESTPHAL

Christoph Westphal, M.D., Ph.D.

President and
Chief Executive Officer(Principal Executive Officer)

November 2, 2016

Exhibit 31.2

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

I, John McCabe, Vice President, Finance, 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.

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

Vice President, Finance
(Principal Financial and Accounting Officer)

November 2, 2016

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Flex Pharma, Inc. (the "Company") for the fiscal period ended September 30, 2016 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/ CHRISTOPH WESTPHAL

Christoph Westphal, M.D., Ph.D.

November 2, 2016

President and
Chief Executive Officer(Principal Executive Officer)

/s/ JOHN MCCABE

John McCabe

November 2, 2016

Vice President, Finance
(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.