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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 June 30, 2017
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, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

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

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

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

As of July 28, 2017, there were 17,971,816 shares of common stock outstanding.

FLEX PHARMA, INC.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

Forward-looking statements are not guarantees of future performance and our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, the status, timing, costs, results and interpretation of our clinical trials; the uncertainties inherent in conducting clinical trials; results from our ongoing and planned pre-clinical development; expectations of our ability to make regulatory filings and obtain and maintain regulatory approvals; our ability to develop and commercialize our consumer products; anticipated 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, 2016 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)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 39,126,801	$ 22,416,040
Marketable securities	7,996,199	38,658,933
Accounts receivable	34,735	12,181
Inventory	688,185	454,132
Prepaid expenses and other current assets	1,209,192	925,983
Total current assets	49,055,112	62,467,269
Property and equipment, net	448,102	556,315
Other assets	—	64,800
Restricted cash	126,595	126,595
Total assets	$ 49,629,809	$ 63,214,979
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,806,359	$ 1,192,183
Accrued expenses and other current liabilities	3,130,394	2,587,573
Deferred revenue	96,667	88,344
Deferred rent, current portion	—	21,095
Total current liabilities	5,033,420	3,889,195
Deferred rent, net of current portion	91,878	8,398
Total liabilities	5,125,298	3,897,593
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at June 30, 2017 and December 31, 2016; none issued or outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at June 30, 2017 and December 31, 2016; 17,971,816 and 17,970,590 shares issued at June 30, 2017 and December 31, 2016, and 17,285,926 and 16,773,798 shares outstanding at June 30, 2017 and December 31, 2016, respectively	1,729	1,678
Additional paid-in capital	138,227,029	135,962,935
Accumulated other comprehensive loss	(5,616)	(1,614)
Accumulated deficit	(93,718,631)	(76,645,613)
Total stockholders' equity	44,504,511	59,317,386
Total liabilities and stockholders' equity	$ 49,629,809	$ 63,214,979

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Net product revenue	$ 330,688	$ 112,685	$ 570,980	$ 112,685
Other revenue	4,835	—	7,090	—
Total revenue	335,523	112,685	578,070	112,685
Costs and expenses:				
Cost of product revenue	145,325	110,931	224,431	307,951
Research and development	4,076,220	6,094,921	7,991,194	10,482,000
Selling, general and administrative	4,990,943	5,377,784	9,585,659	10,489,479
Total costs and expenses	9,212,488	11,583,636	17,801,284	21,279,430
Loss from operations	(8,876,965)	(11,470,951)	(17,223,214)	(21,166,745)
Interest income, net	72,342	107,818	150,196	211,151
Net loss	$ (8,804,623)	$ (11,363,133)	$ (17,073,018)	$ (20,955,594)
Net loss attributable to common stockholders	$ (8,804,623)	$ (11,363,133)	$ (17,073,018)	$ (20,955,594)
Net loss per share attributable to common stockholders — basic and diluted	$ (0.51)	$ (0.71)	$ (1.00)	$ (1.31)
Weighted-average number of common shares outstanding — basic and diluted	17,130,264	16,105,555	17,002,597	15,974,544

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Net loss	$ (8,804,623)	$ (11,363,133)	$ (17,073,018)	$ (20,955,594)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	6,737	19,885	(4,002)	64,144
Comprehensive loss	$ (8,797,886)	$ (11,343,248)	$ (17,077,020)	$ (20,891,450)

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Operating activities		
Net loss	$ (17,073,018)	$ (20,955,594)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	171,109	89,958
Stock-based compensation expense	2,262,098	3,506,482
Amortization and accretion on investments	(15,895)	78,751
Changes in operating assets and liabilities:		
Accounts receivable	(22,554)	(11,595)
Inventory	207,063	(274,302)
Prepaid expenses and other current assets	(283,209)	(1,351,291)
Other assets	64,800	(64,800)
Accounts payable	601,646	508,066
Accrued expenses and other current liabilities	101,705	(78,918)
Deferred revenue	8,323	65,115
Deferred rent	62,385	2,363
Other long term liabilities	—	(15,442)
Net cash used in operating activities	(13,915,547)	(18,501,207)
Investing activities		
Purchases of marketable securities	(9,607,390)	(22,074,850)
Proceeds from maturities and sales of marketable securities	40,282,017	13,112,760
Purchases of property and equipment	(53,741)	(290,202)
Proceeds from sales of property and equipment	3,375	—
Net cash provided by (used in) investing activities	30,624,261	(9,252,292)
Financing activities		
Proceeds from exercise of common stock	2,047	8,043
Net cash provided by financing activities	2,047	8,043
Net increase (decrease) in cash and cash equivalents	16,710,761	(27,745,456)
Cash and cash equivalents at beginning of period	22,416,040	66,686,695
Cash and cash equivalents at end of period	$ 39,126,801	$ 38,941,239
Supplemental cash flow information		
Inventory purchases included in accrued expenses at June 30, 2017	$ 441,116	$ —
Property and equipment purchases included in accounts payable at June 30, 2017 and 2016	$ 19,630	$ 161,049
Property and equipment purchases included in accounts payable and accrued expenses at December 31, 2016 and 2015	$ 7,100	$ 106,680

See accompanying notes to condensed consolidated financial statements.

FLEX PHARMA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Organization and operations

The Company

Flex Pharma, Inc. (the "Company") is a biotechnology company that is developing innovative and proprietary treatments for muscle cramps and spasticity associated with severe neurological conditions and exercise-associated muscle cramps. In August 2017, the Company initiated a Phase 2 clinical trial in the United States of its lead drug product candidate, FLX-787, in patients with motor neuron disease, or MND, primarily with amyotrophic lateral sclerosis, or ALS, who suffer from cramps. The Company also expects to initiate an additional Phase 2 clinical trial in third quarter of 2017 in patients with Charcot-Marie-Tooth disease, or CMT, who suffer from cramps. FLX-787 is currently in an exploratory Phase 2 spasticity study in Australia in patients with multiple sclerosis, or MS. In 2016, the Company launched its consumer product, HOTSHOT®, to prevent and treat exercise-associated muscle cramps, or EAMCs.

FLX-787, HOTSHOT and the Company's other product candidates are based on the potential mechanism of action the Company describes as chemical neurostimulation, which is the process by which a chemical signal, acting topically, induces a neuronal sensory signal that produces a beneficial effect. The Company's product candidates activate certain receptors in primary sensory neurons, which then act via neuronal circuits to reduce hyperexcitability, which can result in the repetitive firing of alpha-motor neurons in the spinal cord, thereby preventing or reducing the frequency and intensity of muscle cramps and spasms.

The Company operates as two reportable segments, Consumer Operations and Drug Development. See Note 11 for additional discussion and information on the reportable segments.

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

Liquidity

The Company has incurred an accumulated deficit of $93,718,631 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 $47,123,000 at June 30, 2017. The Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to allow the Company to fund its current operating plan for at least 12 months from the date the financial statements are issued. Management expects the Company to incur a loss for the foreseeable future. The Company's ability to achieve profitability in the future is dependent upon the successful development, approval and commercialization of its drug product candidates and successful commercialization of HOTSHOT and future consumer products, and achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through additional private or public debt or equity offerings, and may seek additional capital through arrangements with collaborators or from other sources. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

2. Summary of significant accounting policies 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 June 30, 2017, 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, 2016 (the “2016 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. The Company issues refunds to e-commerce customers, upon request, within 30 days of delivery. As the Company currently does not have adequate history to accurately estimate refunds, all e-commerce sales, and their related costs, are deferred and revenue is recognized once the refund period lapses. This deferral represents total deferred revenue presented on the Company's consolidated balance sheet. For specialty retailers and sports teams, the Company does not offer a right of return or refund and revenue is recognized at the time products are delivered to customers.

Discounts provided to customers are accounted for as a reduction of 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 six months ended June 30, 2017. The vast majority of 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 June 30, 2017.

Advertising expense

Advertising expense consists of media and production costs related to print and digital advertising. All advertising is expensed as incurred. Total advertising expenses are included in selling, general and administrative expenses in the condensed consolidated statement of operations, and were approximately $1,250,000 and $1,915,000 for the three and six months ended June 30, 2017 and approximately $916,000 and $1,426,000 for the three and six months ended June 30, 2016.

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 $47,000 and $81,000 for the three and six months ended June 30, 2017, and approximately $28,000 for both the three and six months ended June 30, 2016, as the product launched during the second quarter of 2016.

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 2016 10-K.

The condensed consolidated financial statements as of June 30, 2017, for the three and six months ended June 30, 2017 and 2016, 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 June 30, 2017, and the statements of operations, comprehensive loss and cash flows for the three and six month periods ended June 30, 2017 and 2016. The results for the three

and six months ended June 30, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017, or any other future annual or interim periods.

Basis of presentation and use of estimates

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

Principles of consolidation

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

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 No. 2016-08, *Revenue from Contracts with Customers, Principal versus Agent Considerations (Reporting Revenue Gross versus Net),* clarifying the implementation guidance on principal versus agent considerations. Specifically, an entity is required to determine whether the nature of a promise is to provide the specified good or service itself (that is, the entity is a principal) or to arrange for the good or service to be provided to the customer by the other party (that is, the entity is an agent). The determination influences the timing and amount of revenue recognition. The effective date and transition requirements for ASU No. 2016-08 are the same as the effective date and transition requirements for ASU No. 2014-09.

The Company is currently evaluating the adoption impact of the guidance related to the Company's sales of HOTSHOT. The Company plans to adopt the amendment retrospectively to all prior reporting periods presented. Based on evaluation of the Company's current revenue streams, the Company does not expect the new guidance to change the total amount of revenue recognized, but may accelerate the timing of when revenue is recognized. The Company expects that the guidance will impact the consolidated statement of operations and balance sheet, but

cannot yet quantify those impacts at this time. The Company has completed an initial impact analysis, including reviewing the terms and conditions of its contracts. The Company is in the process of finalizing its accounting policy, and, once finalized, the Company will design and implement necessary changes to processes and controls to allow for proper recognition, presentation and disclosure upon adoption effective in the beginning of fiscal year 2018. The FASB has issued, and may issue in the future, interpretive guidance which may cause the Company's evaluation to change.

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

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The ASU requires lessees to recognize assets and liabilities on their balance sheet for the right of use ("ROU") and obligations created by most leases, and to 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. While the Company is currently evaluating the effect this standard will have on its consolidated financial statements and timing of adoption, the Company expects that upon adoption, it will recognize ROU assets and lease liabilities and those amounts could be material.

In March 2016, the FASB issued ASU No. 2016-09 *Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This ASU simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. The Company adopted this standard as of March 31, 2017 and the following summarizes the effects of the adoption on the Company's unaudited condensed consolidated financial statements:

Forfeitures - Prior to adoption, share-based compensation expense was recognized on a straight-line basis, net of estimated forfeitures, such that expense was recognized only for share-based awards that were expected to vest. A forfeiture rate was estimated annually and revised, if necessary, in subsequent periods if actual forfeitures differed from initial estimates. Upon adoption, the Company no longer applies a forfeiture rate and instead will account for forfeitures as they occur. As the Company previously estimated forfeitures to determine stock-based compensation expense, this change resulted in a cumulative-effect adjustment as of January 1, 2017 to increase retained earnings by approximately $2,000.

Income taxes - Upon adoption of this standard, all excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) are recognized as income tax expense or benefit in the consolidated statement of operations. The tax effects of exercised or vested awards are treated as discrete items in the reporting period in which they occur. The Company did not recognize any discrete adjustments to income tax expense for the three months ended March 31, 2017, the first quarter of adoption, as the Company was in a full valuation allowance position. The Company has applied the modified retrospective adoption approach beginning in 2017. This cumulative-effect adjustment related to tax assets that had previously arisen from tax deductions for equity compensation expenses that were greater than the compensation recognized for financial reporting. These assets had been excluded from the deferred tax assets and liabilities totals on the balance sheet as a result of certain realization requirements previously included in ASC 718. The Company recorded a cumulative-effect adjustment of approximately $50,000 through retained earnings and deferred tax assets. However, due to the full valuation allowance, the only impact of the retrospective adoption is footnote presentation which will be presented in the December 31, 2017 year-end notes to the consolidated financial statements.

Upon adoption, no other aspects of ASU 2016-09 had a material effect on the Company's consolidated financial statements or related footnote disclosures.

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

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 June 30, 2017 and December 31, 2016:

	Level 1	Level 2	Level 3	Balance as of June 30, 2017
Cash equivalents	$ 26,029,665	$ —	$ —	$ 26,029,665
Marketable securities:				
U.S. government agency securities	—	7,996,199	—	7,996,199
	$ 26,029,665	$ 7,996,199	$ —	$ 34,025,864

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

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. The majority of the Company's cash equivalents consist of money market funds that are valued based on publicly available quoted market prices for identical securities as of June 30, 2017. After completing its validation procedures, the Company did not adjust or override any fair value carrying amounts as of June 30, 2017.

The carrying amounts reflected in the condensed consolidated balance sheets for cash, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair values at June 30, 2017 and December 31, 2016, due to their short-term nature.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the six months ended June 30, 2017 or the year ended December 31, 2016. The Company had no financial assets or liabilities that were classified as Level 3 at any time during the six months ended June 30, 2017 or the year ended December 31, 2016.

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 June 30, 2017 and December 31, 2016 consisted of money market funds.

Marketable securities as of June 30, 2017 consisted of U.S. government agency securities. Marketable securities as of December 31, 2016 consisted of U.S. government agency securities, commercial paper and corporate debt securities. Management determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company classifies its marketable securities as available-for-sale pursuant to ASC 320, *Investments – Debt and Equity Securities*. Marketable securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity and a component of total comprehensive income (loss) in the condensed consolidated statement of comprehensive income (loss), until realized. Realized gains and losses are included in investment income on a specific-identification basis. There were no realized gains on marketable securities during the three and six months ended June 30, 2017, and there were immaterial realized gains on marketable securities during the three and six months ended June 30, 2016.

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

Marketable securities at June 30, 2017 and December 31, 2016 consisted of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
As of June 30, 2017				
Current (due within 1 year):				
U.S. government agency securities	$ 8,001,815	$ —	$ (5,616)	$ 7,996,199
Total	$ 8,001,815	$ —	$ (5,616)	$ 7,996,199

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

The Company held three and six debt securities that were in an unrealized loss position at June 30, 2017 and December 31, 2016, 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 $7,996,199 and $16,519,620 at June 30, 2017 and December 31, 2016, respectively. There were no individual securities that were in a significant unrealized loss position as of June 30, 2017 or December 31, 2016. The Company evaluated its securities for other-than-temporary impairment and no marketable securities were considered to be other-than-temporarily impaired as of June 30, 2017.

At June 30, 2017 and December 31, 2016, all investments held by the Company were classified as current. Investments classified as current have maturities of less than one year. Investments classified as noncurrent are those that (i) have a maturity greater than one year and (ii) management does not intend to liquidate within the next year, although these funds are available for use and therefore classified as available-for-sale.

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 June 30, 2017 and December 31, 2016. Costs capitalized at June 30, 2017 and December 31, 2016 relate to HOTSHOT finished goods, as well as raw materials available to be used for future production runs.

The following table presents inventory:

	June 30, 2017	December 31, 2016
Raw materials	$ 10,441	$ 19,888
Finished goods	677,744	434,244
Total inventory	$ 688,185	$ 454,132

In the second quarter of 2017, the Company completed a production run of HOTSHOT, and wrote off raw materials purchased for the production run that are not expected to be used in future production runs. In the prior year, the Company wrote off raw materials purchased for production runs of HOTSHOT that were not expected to be used in future production runs, as well as finished goods not expected to be sold based upon projected sales, estimated product shelf life, the number of units produced and production level requirements.

Write-offs totaled $17,767 for the three and six months ended June 30, 2017, and $40,652 and $225,950 for the three and six months ended June 30, 2016, respectively, and were 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:

	June 30, 2017	December 31, 2016
Research and development costs	$ 1,858,526	$ 938,665
Consumer product-related costs	507,691	42,024
Payroll and employee-related costs	505,489	1,453,665
Professional fees	208,688	153,219
Other	50,000	—
Total	$ 3,130,394	$ 2,587,573

7. Common stock

As of June 30, 2017, the Company had authorized 100,000,000 shares of common stock, $0.0001 par value per share. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors. The Company does not intend to declare dividends for the foreseeable future.

Restricted common stock to founders

In March 2014, the Company sold 4,553,415 shares of restricted common stock to the founders of the Company ("recipients"), for $0.0004 per share, for total proceeds of $1,950. In April 2014, based upon anti-dilution provisions granted to the founders, an additional 867,314 shares of restricted common stock were sold to the same founders, after which the anti-dilution provisions were terminated. The restricted common stock vested 25% upon issuance, and the remaining 75% vests ratably over four years, during which time the Company has the right to repurchase the unvested shares held by a recipient if the relationship between such recipient and the Company ceases. If the relationship terminates, the Company has 90 days to repurchase unvested shares at $0.0004 per share. Such shares are not accounted for as outstanding until they vest. There were 4,742,923 shares of restricted common stock outstanding as of June 30, 2017. Unvested restricted common stock awards to non-employees are re-measured at each vest date and each financial reporting date.

The following is a summary of restricted common stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2016	1,185,958	$ 0.10
Issued	—	—
Vested	(508,152)	0.10
Forfeited	—	—
Unvested at June 30, 2017	677,806	$ 0.10

Restricted common stock to consultants

In 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 10,110 shares of restricted common stock issued to consultants outstanding as of June 30, 2017. Unvested restricted common stock awards to non-employees are re-measured at each vest date and each financial reporting date.

The following is a summary of restricted common stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2016	10,834	$ 9.72
Issued	—	—
Vested	(2,750)	8.95
Forfeited	—	—
Unvested at June 30, 2017	8,084	$ 9.98

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 June 30, 2017, there were 771,983 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 six months ended June 30, 2017:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2016	2,156,250	$ 8.66	7.94	$ 1,605,684
Granted	792,500	4.27		
Exercised	(1,226)	1.67		
Cancelled or forfeited	(279,337)	9.81		
Outstanding at June 30, 2017	2,668,187	$ 7.24	7.97	$ 939,484
Exercisable at June 30, 2017	1,226,720	$ 7.67	6.90	$ 654,967
Vested or expected to vest at June 30, 2017	2,668,187	$ 7.24	7.97	$ 939,484

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 June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Research and development	$ 391,602	$ 684,695	$ 786,019	$ 1,280,161
Selling, general and administrative	681,744	1,303,626	1,476,079	2,226,321
Total	$ 1,073,346	$ 1,988,321	$ 2,262,098	$ 3,506,482

As of June 30, 2017, there was approximately $7,132,098 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 2.38 years.

Employee stock purchase plan

In 2015, the Company's board of directors adopted, and the Company's stockholders approved, the 2015 Employee Stock Purchase Plan (the "ESPP"). As of June 30, 2017, no shares of 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 six months ended June 30, 2017 or 2016.

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.

As the Company has reported a net loss for the periods presented, diluted net loss per common share is the same as basic net loss per common share.

The following potentially dilutive securities outstanding, prior to the use of the treasury stock method or if-converted method, have been excluded from the computation of diluted weighted-average shares outstanding for the periods indicated, because including them would have had an anti-dilutive impact:

	June 30, 2017	June 30, 2016
Options to purchase common stock	2,668,187	2,425,017
Unvested restricted common stock	685,890	1,707,694
Total	3,354,077	4,132,711

11. Segment Information

The Company operates as two reportable segments:

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

The Company discloses information about its reportable segments based on the way that the Company's Chief Operating Decision Maker, who the Company has identified as the Chief Executive Officer, and management, organize segments within the Company for making operating decisions and assessing financial performance. The Company evaluates the performance of its reportable segments based on revenue and operating income or loss. The accounting policies of the segments are the same as those described herein as well as those described in Note 2 to the audited consolidated financial statements in the 2016 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 June 30, 2017 and 2016 are as follows:

Three months Ended June 30, 2017	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	$ 335,523	—	—	$ 335,523
Interest income, net	$ —	—	72,342	$ 72,342
Loss from operations	$ 2,760,496	3,960,335	2,156,134	$ 8,876,965

Three months Ended June 30, 2016	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	$ 112,685	—	—	$ 112,685
Interest income, net	$ —	—	107,818	$ 107,818
Loss from operations	$ 2,841,848	5,907,774	2,721,329	$ 11,470,951

Information for the Company's reportable segments for the six months ended June 30, 2017 and 2016 are as follows:

Six Months Ended June 30, 2017	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	$ 578,070	—	—	$ 578,070
Interest income, net	$ —	—	150,196	$ 150,196
Loss from operations	$ 4,748,306	7,788,616	4,686,292	$ 17,223,214

Six Months Ended June 30, 2016	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	$ 112,685	—	—	$ 112,685
Interest income, net	$ —	—	211,151	$ 211,151
Loss from operations	$ 5,771,202	9,966,817	5,428,726	$ 21,166,745

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, 2016. 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, 2016, 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 six months ended June 30, 2017 to the three and six months ended June 30, 2016.

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 muscle cramps and spasticity associated with severe neurological conditions and exercise-associated muscle cramps. In August 2017, we initiated a Phase 2 clinical trial in the United States of our lead drug product candidate, FLX-787, in patients with

motor neuron disease, or MND, primarily with amyotrophic lateral sclerosis, or ALS, who suffer from cramps. We also expect to initiate an additional Phase 2 clinical trial in third quarter of 2017 in patients with Charcot-Marie-Tooth disease, or CMT, who suffer from cramps. FLX-787 is currently in an exploratory Phase 2 spasticity study in Australia in patients with multiple sclerosis, or MS. In 2016, we launched our consumer product, HOTSHOT®, to prevent and treat exercise-associated muscle cramps, or EAMCs.

FLX-787, HOTSHOT and our other product candidates are based on the potential mechanism of action we describe as chemical neurostimulation, which is the process by which a chemical signal, acting topically, induces a neuronal sensory signal that produces a beneficial effect. Our product candidates activate certain receptors in primary sensory neurons, which then act via neuronal circuits to reduce hyperexcitability, which can result in the repetitive firing of alpha-motor neurons in the spinal cord, thereby preventing or reducing the frequency and intensity of muscle cramps and spasms.

HOTSHOT is our consumer beverage that prevents and treats EAMCs. We market HOTSHOT to endurance athletes, who drink it before, during and after exercise to prevent and treat muscle cramps. The majority of HOTSHOT sales are generated through our branded website and third-party websites. We also engage in sales and marketing efforts in a limited number of geographic areas with strong endurance sports markets.

We operate as the following two reportable segments:

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

We disclose information about our reportable segments based on the way that we organize segments within the Company for making operating decisions and assessing financial performance. See Note 11 to our condensed consolidated financial statements for certain financial information related to our reportable segments.

We have incurred an operating loss since our inception and we anticipate that we will continue to incur operating losses for at least the next several years. Our net loss was $8.8 million and $17.1 million for the three and six months ended June 30, 2017, respectively, and $11.4 million and $21.0 million for the three and six months ended June 30, 2016, respectively. Our accumulated deficit was $93.7 million as of June 30, 2017. To date, we have financed our operations with net proceeds from the private placement of our preferred stock and our initial public offering. We expect to continue incurring significant research and development expenses related to the development of our drug product candidates and significant selling, general and administrative expenses as we continue to commercialize HOTSHOT. As a result, we will need additional capital to fund our future operations.

Recent Developments

In April 2017, we announced the appointment of William McVicar, Ph.D., as our President of Research and Development. In June 2017, we announced that Dr. McVicar had been appointed our Interim President and Chief Executive Officer and in July 2017, we announced that Dr. McVicar had been appointed as our permanent President and Chief Executive Officer. Dr. McVicar replaced Christoph Westphal, M.D., Ph.D., who transitioned from his role as Chief Executive Officer and remains the Chairman of our Board of Directors. Prior to joining the Company, Dr. McVicar served in various leadership roles at Inotek Pharmaceuticals Corporation, most recently as its Executive Vice President and Chief Scientific Officer.

Also in April 2017, we announced our investigational new drug application, or IND, for FLX-787 for the treatment of cramps associated with MND had become effective. In July 2017, we announced that the U.S. Food and Drug Administration, or FDA, granted Fast Track designation for the development of FLX-787 to treat severe muscle cramps in patients with ALS. Fast Track designation allows for a more frequent dialogue with the Neurology Division at FDA on the company's drug development plan, data requirements and clinical trial design, throughout the drug development and review process.

In early August 2017, we announced the initiation of a Phase 2 clinical trial in the United States, referred to as the COMMEND trial. The COMMEND trial is a Phase 2 clinical trial designed to evaluate FLX-787 in patients with MND, focused on ALS, who suffer from cramps. This randomized, controlled, double-blinded, parallel design trial will include a run-in period to establish a baseline in cramp frequency. Patients will then be randomized to 30 mg of FLX-787 administered three times a day, or to a control, for 28 days. Patients will be evaluated for changes in

cramp frequency as the primary endpoint, with a number of secondary endpoints. We expect to report topline results from this clinical trial in the middle of 2018.

We believe the COMMEND trial has certain advantages to our ongoing exploratory ALS clinical study in Australia, including a longer FLX-787 treatment period, increased dosage and a parallel design. As a result, in July 2017, we announced that we will end our ongoing ALS exploratory study in Australia, with roughly a dozen patients.

We intend to initiate a Phase 2 clinical trial in patients that suffer from cramps associated with CMT, referred to as the COMMIT trial, in the third quarter of 2017. In June 2017, we announced that the Inherited Neuropathies Consortium, or the INC, voted to endorse the COMMIT trial. The INC is an integrated group of academic medical centers, patient support organizations, and clinical research resources dedicated to conducting clinical research in CMT and to improving the care of patients. The COMMIT trial is a Phase 2 clinical trial designed to evaluate FLX-787 in patients with CMT who suffer from cramps. This randomized, controlled, double-blinded, parallel design trial in the United States will include a run-in period to establish a baseline in cramp frequency. Patients will then be randomized to 30 mg of FLX-787 administered three times a day or to a control, for 28 days. Patients will be evaluated for changes in cramp frequency as the primary endpoint, with a number of secondary endpoints.

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. 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. As we currently do not have adequate history to accurately estimate refunds, all e-commerce sales, and their related costs, are deferred and revenue is recognized once the refund period lapses. Specialty retailers and sports team are not offered a right of return or refund and revenue is recognized at the time products are delivered to these 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 continue to be generated through our branded website. We also sell HOTSHOT via third-party e-commerce websites, including a retailer that offers international shipping. Generally, we realize higher revenue per bottle from our own e-commerce sales as opposed to third-party website, team and specialty retailer sales. HOTSHOT is generally sold to specialty retailers and sports teams in multi-pack cases.

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

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

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

Research and Development Expenses

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

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

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

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

Selling, General and Administrative Expenses

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

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

Our selling, general and administrative expenses may increase as we support the efforts of our Consumer Operations and Drug Development segments 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 June 30, 2017 Compared to the Three Months Ended June 30, 2016

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 June 30, 2017 compared to the three months ended June 30, 2016.

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Change $	Change %
Net product revenue	$ 330,688	$ 112,685	$ 218,003	193 %
Other revenue	4,835	—	4,835	N/A
Total revenue	335,523	112,685	222,838	198 %
Costs and expenses:				
Cost of product revenue	145,325	110,931	34,394	31 %
Research and development	4,076,220	6,094,921	(2,018,701)	(33)%
Selling, general and administrative	4,990,943	5,377,784	(386,841)	(7)%
Total costs and expenses	9,212,488	11,583,636	(2,371,148)	(20)%
Loss from operations	(8,876,965)	(11,470,951)	2,593,986	(23)%
Interest income, net	72,342	107,818	(35,476)	(33)%
Net loss	$ (8,804,623)	$ (11,363,133)	$ 2,558,510	(23)%

Total Revenue

Our Consumer Operations segment generated all of our revenue during the three months ended June 30, 2017, totaling $0.3 million as compared to $0.1 million for the three months ended June 30, 2016, through sales of HOTSHOT and expedited shipping and handling purchases. Revenue for the three months ended June 30, 2017 was driven by our HOTSHOT marketing, sales and promotional efforts, including our print and digital media campaign, public relation efforts, field marketing efforts and other sales and promotional activities. In 2016, prior to the formal e-commerce and retail launch of HOTSHOT in June, consumers were offered the opportunity to place a pre-order and receive HOTSHOT upon launch. A significant portion of our revenue generated in the second quarter of 2016 related to these pre-order sales.

Sales via e-commerce represented approximately 81% of our total revenue for the three months ended June 30, 2017 compared to 88% for the three months ended June 30, 2016. During the three months ended June 30, 2017, we sold approximately 83,000 bottles of HOTSHOT at an average total revenue per bottle of $4.04, compared to 24,000 bottles at an average total revenue per bottle of $4.70 during the three months ended June 30, 2016. The decrease in average total revenue per bottle is due to various price promotions that were offered to customers during the second quarter of 2017 to attract new and repeat customers.

Cost of Product Revenue

All costs of product revenue are recorded by our Consumer Operations segment and relate to the production and sale of HOTSHOT. Cost of product revenue was $0.1 million for both the three months ended June 30, 2017 and

June 30, 2016, and included the cost of HOTSHOT sold, royalty expense, inventory write-offs, and depreciation expense related to manufacturing equipment purchased to support production which totaled approximately $35,000 for each quarter. Write-offs for the three months ended June 30, 2017 totaled approximately $17,800 and related to certain raw materials from the most recent production run of HOTSHOT during the second quarter of 2017 that are not expected to be used in future production runs. Write-offs for the three months ended June 30, 2016 totaled approximately $40,700, related to production fees for finished goods from the first production run of HOTSHOT that were not expected to be sold based upon projected sales, a 12 month product shelf life, the number of units produced and production level requirements.

Research and Development Expenses

Our Drug Development segment incurred the majority of our research and development expenses, which were $4.1 million for the three months ended June 30, 2017 compared to $6.1 million for the three months ended June 30, 2016. The 33% decrease of $2.0 million was primarily related to:

- $1.5 million decrease in the level of clinical activities compared to 2016, primarily prior year studies of our extract formulation, studies to identify of our drug product candidate and IND-supporting pre-clinical activities, partially offset by increases related to startup, formulation and production costs for our FLX-787 Phase 2 clinical trials in the United States;
- $0.3 million decrease in stock-based compensation expense, related primarily to the revaluation of non-employee awards and option grants at lower valuations than the prior year due to decreased stock price; and
- $0.2 million decrease related to salaries and benefits as research and development headcount decreased from the prior year.

Selling, General and Administrative Expenses

Selling, general and administrative includes expenses that are incurred by our Consumer Operations segment as well as corporate and unallocated amounts that do not relate to a reportable segment. Selling, general and administrative costs were $5.0 million for the three months ended June 30, 2017 compared to $5.4 million for the three months ended June 30, 2016. The 7% decrease of $0.4 million was primarily related to:

- $0.6 million decrease in stock-based compensation expense, related primarily to the revaluation of non-employee awards and option grants at lower valuations than the prior year due to decreased stock price, as well as a stock option award modification in the prior year;
- $0.3 million decrease related to salaries and benefits as corporate headcount decreased from the prior year;
- $0.3 million increased costs within our Consumer Operations segment for print and digital media campaigns for our consumer brand and HOTSHOT; and
- $0.2 million increase in other costs, including increased consulting expenses to supplement our corporate segment personnel.

Loss from Operations

Our consolidated loss from operations for the three months ended June 30, 2017 totaled $8.9 million. Of this total, $2.8 million of the operating loss was incurred by our Consumer Operations segment, $4.0 million was incurred by our Drug Development segment and the remaining $2.2 million related to corporate and unallocated costs. The operating loss incurred by the Consumer Operations segment was primarily driven by marketing, sales and promotional costs related to HOTSHOT, and personnel-related expenses, including stock-based compensation. These costs were slightly offset by the total revenue generated from HOTSHOT sales in the second quarter of 2017. The operating loss incurred by the Drug Development segment relates to costs incurred for FLX-787 formulation and production and clinical study costs, other clinical study activities as well as personnel-related expenses, including stock-based compensation.

Interest Income, net

Interest income, net, decreased by $35,476 in the three months ended June 30, 2017 compared to the three months ended June 30, 2016 as we had by lower available cash to invest.

Six Months Ended June 30, 2017 Compared to the Six Months Ended June 30, 2016

The following table sets forth the condensed consolidated results of operations, including information related to our Consumer Operations and Drug Development segments, for the six months ended June 30, 2017 compared to the six months ended June 30, 2016.

	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016	Change $	Change %
Net product revenue	$ 570,980	$ 112,685	$ 458,295	407 %
Other revenue	7,090	—	7,090	N/A
Total revenue	578,070	112,685	465,385	413 %
Costs and expenses:				
Cost of product revenue	224,431	307,951	(83,520)	(27)%
Research and development	7,991,194	10,482,000	(2,490,806)	(24)%
Selling, general and administrative	9,585,659	10,489,479	(903,820)	(9)%
Total costs and expenses	17,801,284	21,279,430	(3,478,146)	(16)%
Loss from operations	(17,223,214)	(21,166,745)	3,943,531	(19)%
Interest income, net	150,196	211,151	(60,955)	(29)%
Net loss	$ (17,073,018)	$ (20,955,594)	$ 3,882,576	(19)%

Total Revenue

Our Consumer Operations segment generated all of our revenue in the six months ended June 30, 2017, totaling $0.6 million, through sales of HOTSHOT and expedited shipping and handling purchases. Revenue was driven by our HOTSHOT marketing, sales and promotional efforts, including our print and digital media campaign, public relation efforts, field marketing efforts and other sales and promotional activities. Sales via e-commerce represented approximately 84% of our total revenue for the six months ended June 30, 2017. During the six months ended June 30, 2017, we sold approximately 135,000 bottles of HOTSHOT at an average total revenue per bottle of $4.28.

As HOTSHOT launched in the second quarter of 2016, net revenue for the six months ended June 30, 2016 was equal to the net revenue for the three months ended June 30, 2016, which is described above.

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 six months ended June 30, 2017 compared to $0.3 million for the six months ended June 30, 2016. Cost of product revenue during the six months ended June 30, 2017 includes the cost of HOTSHOT sold, royalty expense, inventory write-offs of $17,800 related to certain raw materials that are not expected to be used in future production runs and depreciation expense of approximately $70,000 related to manufacturing equipment used to support production. Cost of product revenue during the six months ended June 30, 2016 included the cost of HOTSHOT sold, royalty expense, inventory write-offs of $0.2 million related to HOTSHOT finished goods that were not expected to be sold and depreciation expense of approximately $50,000.

Research and Development Expenses

Our Drug Development segment incurred the majority of our research and development expenses, which were $8.0 million for the six months ended June 30, 2017 compared to $10.5 million for the six months ended June 30, 2016. The 24% decrease of $2.5 million was primarily related to:

- $1.7 million decrease in the level of clinical activities compared to 2016, primarily prior year clinical studies of our extract formulation and identification of our drug product candidate, IND-supporting

pre-clinical activities and decreased manufacture of drug substance, partially offset by startup, formulation and production costs for our FLX-787 Phase 2 clinical trials in the United States;

- $0.5 million decrease in stock-based compensation expense, related primarily to the revaluation of non-employee awards and option grants at lower valuations than the prior year due to decreased stock price;
- $0.3 million decrease related to salaries and benefits as research and development headcount decreased from the prior year;
- $0.2 million decrease related to our Consumer Operations segment, as we decreased the number of research studies of our consumer product; and
- $0.2 million increase in consulting expenses to supplement our Drug Development segment personnel, mainly in support of our IND submission.

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 $9.6 million for the six months ended June 30, 2017 compared to $10.5 million for the six months ended June 30, 2016. The 9% decrease of $0.9 million was primarily related to:

- $0.8 million decrease in stock-based compensation expense, related primarily to the revaluation of non-employee awards and option grants at lower valuations than the prior year due to decreased stock price, as well as a stock option award modification in the prior year;
- $0.3 million decrease related to salaries and benefits, as corporate headcount decreased from the prior year;
- $0.3 million decrease in external consulting costs within our Consumer Operations segment due to decreased use of consultants;
- $0.2 million decrease related to our test production run of HOTSHOT in the first quarter of 2016, which was fully expensed and used as samples;
- $0.3 million of increased costs within our Consumer Operations segment for print and digital media campaigns for our consumer brand and HOTSHOT;
- $0.2 million increase in consulting expenses to supplement our corporate segment personnel;
- $0.1 million increase in rent expense due to the extension of the lease agreement at our corporate headquarters; and
- $0.1 million increase related to six months of distributions costs for HOTSHOT sales in 2017, as the product launched during the second quarter of 2016.

Loss from Operations

Our consolidated loss from operations for the six months ended June 30, 2017 totaled $17.2 million. Of this total, $4.7 million of the operating loss was incurred by our Consumer Operations segment, $7.8 million was incurred by our Drug Development segment and the remaining $4.7 million related to corporate and unallocated costs. The operating loss incurred by the Consumer Operations segment was driven by sales, marketing, promotional and distribution costs related to HOTSHOT, and personnel-related expenses, including stock-based compensation. These costs were slightly offset by the total revenue generated from HOTSHOT sales during the six months ended June 30, 2017. The operating loss incurred by the Drug Development segment relates to costs incurred for FLX-787 formulation production and clinical study costs, other clinical study activities and personnel-related expenses, including stock-based compensation, as well as consulting costs.

Interest Income, net

Interest income, net, decreased by $60,955 in the six months ended June 30, 2017 compared to the six months ended June 30, 2016 as we had 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 June 30, 2017, we had $47.1 million in cash, cash equivalents and marketable securities, which were held in bank deposit accounts, money market funds and U.S. government agency securities.

Sources of Liquidity

At June 30, 2017, we had $44.0 million of working capital and our cash, cash equivalents and marketable securities totaled $47.1 million. Our cash, cash equivalents and marketable securities balance decreased during the six months ended June 30, 2017, due primarily to our net loss incurred.

Cash Flows

	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Net cash (used in) provided by:		
Operating activities	$ (13,915,547)	$ (18,501,207)
Investing activities	30,624,261	(9,252,292)
Financing activities	2,047	8,043
Net increase (decrease) in cash and cash equivalents	$ 16,710,761	$ (27,745,456)

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2017 was $13.9 million, a decrease of $4.6 million compared to the same period in the prior year. The use of cash for the six months ended June 30, 2017 was primarily related to our net loss for the period of $17.1 million, offset by non-cash charges for stock-based compensation expense of $2.3 million, depreciation expense of $0.2 million and a cash inflow of $0.7 million from changes in operating assets and liabilities.

The $0.7 million cash inflow from changes in operating assets and liabilities was driven by inflows from increases in accounts payable, accrued expenses and other current liabilities, and deferred rent. The increases in accounts payable and accrued expenses and other current liabilities relate to the timing of payments, primarily related to clinical trial startup activities for our MND and CMT Phase 2 clinical trials in the United States. The increase in deferred rent is due to the extension of the lease for our corporate headquarters through 2019. Inventory also generated an inflow for the period as the majority of costs for the Company's second quarter production run were included in accrued expenses at June 30, 2017. These inflows were offset by outflows primarily from an increase in prepaid expenses and other current assets. The increase in prepaid expenses and other current assets relates to the timing of payments for insurance policies.

Net cash used in operating activities for the six months ended June 30, 2016 totaled $18.5 million and was primarily related to our net loss for the period of $21.0 million, offset by non-cash charges of $3.7 million, primarily related to stock-based compensation expense, and a cash outflow of $1.2 million from changes in operating assets and liabilities, primarily related to an increase in prepaid expenses and other current assets.

Investing Activities

Net cash provided by (used in) investing activities for the six months ended June 30, 2017 compared to the six months ended June 30, 2016, increased $39.9 million, primarily related to a $39.6 million increase in net purchases and sales of marketable securities. Property and equipment acquisitions decreased $0.2 million, which primarily related to prior year activity of manufacturing equipment purchased to produce HOTSHOT and development of our branded website for HOTSHOT.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2017 did not change significantly compared to the six months ended June 30, 2016. Cash provided by financing activities during the six months ended June 30, 2017 and 2016 totaled $2,047 and $8,043, respectively, and related to proceeds from exercises of common stock.

As of June 30, 2017, we had no long-term debt.

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

Funding Requirements

We expect that we will require additional funding to 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:

- receiving regulatory approval to conduct clinical trials;
- successfully enrolling, and completing, clinical trials;
- receiving marketing approvals from applicable regulatory authorities;
- establishing arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and

- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others.

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

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

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 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 into early 2019. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect. Additionally, the process of testing drug product candidates in clinical trials is costly, 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, 2016, other than as noted below.

In January 2017, we signed a lease agreement for our corporate headquarters in Boston, MA. Our current sublease will terminate on August 31, 2017, following which time we will lease the same location from September 1, 2017 until August 31, 2019. This resulted in an aggregate increase to future minimum lease payments of $933,186 through 2019.

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, 2016.

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 June 30, 2017, we had cash, cash equivalents and marketable securities of $47.1 million. We invest our cash in a variety of financial instruments, principally money market funds, U.S. government securities, investment-grade corporate notes and commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Available-for-sale securities that we invest in are subject to interest rate risk and may fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

As of June 30, 2017, we have evaluated, under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon our evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

During the six months ended June 30, 2017, 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, 2016.

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, 2016, except as follows:

Risks Related to Our Business Operations and Industry

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

Our future success depends on our ability to retain key executives and to attract, retain motivate qualified personnel. We are highly dependent on William McVicar, our President and Chief Executive Officer, and Thomas Wessel, our Chief Medical Officer. Although we have employment agreements with Drs. McVicar and Wessel, these agreements do not prevent them from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

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 filed with the SEC pursuant to Rule 424(b)(4) on January 28, 2015.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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/ William McVicar

William McVicar, Ph.D.
President and Chief Executive Officer

By: /s/ John McCabe

John McCabe
Chief Financial Officer (Principal Financial and Accounting Officer)

Date: August 2, 2017

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 Company and certain of its stockholders.
10.1	(3)+	Executive Employment Agreement, effective as of April 5, 2017, between the Company and William McVicar.
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 June 30, 2017, 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.

+ Indicates management contract or compensatory plan.

(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.

(3) Incorporated by reference to the Registrant's Current Report on Form 8-K (File No. 001-36812), filed with the SEC on April 5, 2017.

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

/s/ William McVicar

William McVicar, Ph.D.

President and
Chief Executive Officer(Principal Executive Officer)

August 2, 2017

Exhibit 31.2

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

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

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

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

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

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

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

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

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

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

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

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

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

/s/ John McCabe

John McCabe

Chief Financial Officer
(Principal Financial and Accounting Officer)

August 2, 2017

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 June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of their knowledge:

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

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

/s/ William McVicar

William McVicar, Ph.D.

August 2, 2017

President and
Chief Executive Officer(Principal Executive Officer)

/s/ John McCabe

John McCabe

August 2, 2017

Chief Financial Officer
(Principal Financial and Accounting Officer)

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