

Edgar Filing: Flex Pharma, Inc. - Form 10-Q

Flex Pharma, Inc.
Form 10-Q
August 03, 2016
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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, 2016

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

For the Transition Period from _____ to _____

Commission File Number: 001-36812

FLEX PHARMA, INC.
(Exact name of Registrant as specified in its charter)
Delaware 46-5087339
(State or Other Jurisdiction of (I.R.S. Employer
Incorporation or Organization) Identification Number)
800 Boylston Street, 24th Floor, Boston, MA 02199
(Address of principal executive offices)(Zip Code)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to the filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of July 29, 2016, there were 17,968,475 shares of common stock outstanding.

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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, potential indications for our drug product candidates, expectations regarding the development of our drug product candidates and the launch of our consumer product, the expected timing for the reporting of data from ongoing and future studies, prospects, plans and objectives of management, are forward looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements are not guarantees of future performance and our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, the status, timing, costs, results and interpretation of our clinical studies; the uncertainties inherent in conducting clinical studies; results from our ongoing and planned preclinical development; expectations of our ability to make regulatory filings and obtain and maintain regulatory approvals; our ability to develop and commercialize our consumer products; anticipated positioning and attributes of our consumer products; results of early clinical studies as indicative of the results of future trials; availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of our consumer or drug product candidates; the inherent uncertainties associated with intellectual property; and other factors discussed in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2015 and other filings with the Securities and Exchange Commission, or SEC.

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

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

FLEX PHARMA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$38,941,239	\$66,686,695
Marketable securities	35,912,780	24,652,348
Accounts receivable	11,595	—
Inventory	274,302	—
Prepaid expenses and other current assets	2,259,865	908,574
Total current assets	77,399,781	92,247,617
Marketable securities	—	2,312,949
Property and equipment, net	637,050	382,437
Other assets	64,800	—
Restricted cash	126,835	126,835
Total assets	\$78,228,466	\$95,069,838
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$1,544,760	\$875,646
Accrued expenses and other current liabilities	1,761,777	1,947,374
Deferred revenue	65,115	—
Deferred rent, current portion	25,675	24,381
Total current liabilities	3,397,327	2,847,401
Deferred rent, net of current portion	15,656	14,587
Other long term liabilities	—	15,442
Total liabilities	3,412,983	2,877,430
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at June 30, 2016 and December 31, 2015; none issued or outstanding at June 30, 2016 and December 31, 2015	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized at June 30, 2016 and December 31, 2015; 17,968,475 and 17,943,880 shares issued at June 30, 2016 and December 31, 2015, respectively, and 16,260,781 and 15,741,618 shares outstanding at June 30, 2016 and December 31, 2015, respectively	1,626	1,574
Additional paid-in capital	132,882,451	129,367,978
Accumulated other comprehensive income (loss)	39,490	(24,654)
Accumulated deficit	(58,108,084)	(37,152,490)
Total stockholders' equity	74,815,483	92,192,408
Total liabilities and stockholders' equity	\$78,228,466	\$95,069,838

See accompanying notes to condensed consolidated financial statements.

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FLEX PHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Net revenue	\$ 112,685	\$ —	\$ 112,685	\$ —
Costs and expenses:				
Cost of revenue	110,931	—	307,951	—
Research and development	6,094,921	3,190,178	10,482,000	5,995,124
Selling, general and administrative	5,377,784	3,904,403	10,489,479	7,120,615
Total costs and expenses	11,583,636	7,094,581	21,279,430	13,115,739
Loss from operations	(11,470,951)	(7,094,581)	(21,166,745)	(13,115,739)
Interest income, net	107,818	16,183	211,151	19,760
Net loss	\$(11,363,133)	\$(7,078,398)	\$(20,955,594)	\$(13,095,979)
Net loss attributable to common stockholders	\$(11,363,133)	\$(7,078,398)	\$(20,955,594)	\$(13,095,979)
Net loss per share attributable to common stockholders — basic and diluted	\$(0.71)	\$(0.47)	\$(1.31)	\$(1.04)
Weighted-average number of common shares outstanding — basic and diluted	16,105,555	15,034,764	15,974,544	12,620,771

See accompanying notes to condensed consolidated financial statements.

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FLEX PHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Net loss	\$(11,363,133)	\$(7,078,398)	\$(20,955,594)	\$(13,095,979)
Other comprehensive gain:				
Unrealized gain on available-for-sale securities	19,885	—	64,144	—
Comprehensive loss	\$(11,343,248)	\$(7,078,398)	\$(20,891,450)	\$(13,095,979)

See accompanying notes to condensed consolidated financial statements.

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FLEX PHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Operating activities		
Net loss	\$(20,955,594)	\$(13,095,979)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	89,958	20,714
Stock-based compensation expense	3,506,482	3,386,319
Amortization and accretion on investments	78,751	—
Changes in operating assets and liabilities:		
Restricted cash	—	(27)
Accounts receivable	(11,595)	—
Inventory	(274,302)	—
Prepaid expenses and other current assets	(1,351,291)	(439,778)
Other assets	(64,800)	(35,200)
Accounts payable	508,066	558,068
Accrued expenses and other current liabilities	(78,918)	1,008,976
Deferred revenue	65,115	—
Deferred rent	2,363	(8,441)
Other long term liabilities	(15,442)	—
Net cash used in operating activities	(18,501,207)	(8,605,348)
Investing activities		
Purchases of marketable securities	(22,074,850)	—
Proceeds from maturities and sales of marketable securities	13,112,760	—
Purchases of property and equipment	(290,202)	(75,562)
Net cash used in investing activities	(9,252,292)	(75,562)
Financing activities		
Proceeds from IPO, net of offering costs	—	80,435,430
Proceeds from exercise of common stock	8,043	2,999
Proceeds from early exercise of common stock	—	400,000
Net cash provided by financing activities	8,043	80,838,429
Net (decrease) increase in cash and cash equivalents	(27,745,456)	72,157,519
Cash and cash equivalents at beginning of period	66,686,695	33,854,153
Cash and cash equivalents at end of period	\$38,941,239	\$106,011,672
Supplemental cash flow information		
Property and equipment purchases included in accounts payable at June 30, 2016	\$161,049	\$—
Property and equipment purchases included in accrued expense at December 31, 2015 and 2014	\$106,680	\$21,000
IPO issuance costs included in accounts payable and accrued expenses at December 31, 2014	\$—	\$499,549
IPO issuance costs paid in cash through December 31, 2014	\$—	\$575,245

See accompanying notes to condensed consolidated financial statements.

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FLEX PHARMA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Organization and operations

The Company

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

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

In connection with the launch of HOTSHOT, the Company began operating as two reportable segments, Consumer Operations and Drug Development. See Note 11 for additional discussion and information on our reportable segments.

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

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

Liquidity

The Company has incurred an accumulated deficit of \$58,108,084 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 \$74,854,019 at June 30, 2016. The Company believes its existing cash, cash equivalents and marketable securities will be sufficient to allow the Company to fund its current operating plan for at least the next 12 months.

2. Summary of significant accounting policies and recent accounting pronouncements

The accompanying unaudited condensed consolidated financial statements reflect the application of certain significant accounting policies as described below and elsewhere in these notes to the condensed consolidated financial statements. As of June 30, 2016, the Company's significant accounting policies, which are detailed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (the "2015 10-K"), have not changed, other than as noted below.

Net revenue

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 e-commerce customers, upon request, the Company issues refunds within 21 days of shipment. As the Company currently does not have adequate history to accurately estimate refunds, all e-commerce sales, and their related costs, are deferred and revenue is recognized once the refund period lapses. For specialty retailers, 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 revenue.

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

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

Accounts receivable and allowance for doubtful accounts

Accounts receivable are stated at their carrying values, net of any allowances for doubtful accounts. Accounts receivable consist primarily of amounts due from specialty retailers, 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, 2016.

Cost of revenue

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

Inventory

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

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

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

Advertising expense

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

Shipping and handling costs

Shipping and handling costs related to the movement of inventory to the Company's co-packer and from the co-packer to the Company's third party warehousing partner is capitalized as inventory and expensed as a cost of 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 \$28,000 for the three and six months ended June 30, 2016. There were no such costs in 2015 as the Company had not yet launched HOTSHOT. As of June 30, 2016, the Company's customers did not pay separately for shipping and handling costs.

Unaudited interim financial information

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the 2015 10-K.

The condensed consolidated financial statements as of June 30, 2016, for the three and six months ended June 30, 2016 and June 30, 2015, and the related information contained within the notes to the condensed consolidated financial statements, are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as annual audited consolidated financial statements, and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's condensed consolidated financial position as of June 30, 2016, and the statements of operations, comprehensive loss and cash flows for the three and six month periods ended June 30, 2016 and 2015. The results for the three and six months ended June 30, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016, or any other future annual or interim periods.

Initial public offering

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

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

Basis of presentation and use of estimates

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

Principles of consolidation

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

Recent accounting pronouncements

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

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

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

In February 2016, the FASB issued ASU No. 2016-02 Leases. The ASU requires lessees to recognize the assets and liabilities on their balance sheet for the rights and obligations created by most leases and continue to recognize expenses on their income statements over the lease term. It will also require disclosures designed to give financial statement users information on the amount, timing, and uncertainty of cash flows arising from leases. The guidance is

effective for annual reporting periods beginning after December 15, 2018, and interim periods within those years.

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

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

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, 2016 and December 31, 2015:

	Level 1	Level 2	Level of 3	Balance as June 30, 2016
Cash equivalents	\$34,259,641	\$—	\$	—\$34,259,641
Marketable securities:				
Corporate debt securities	—	13,812,453	—	13,812,453
U.S. government agency securities	—	22,100,327	—	22,100,327
	\$34,259,641	\$35,912,780	\$	—\$70,172,421

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

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based

approaches and observable market inputs to determine value. The majority of the Company's cash equivalents consist of money market funds that are valued based on publicly available quoted market prices for identical securities as of June 30, 2016. After completing its validation procedures, the Company did not adjust or override any fair value carrying amounts as of June 30, 2016.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the six months ended June 30, 2016 or the year ended December 31, 2015. The Company had no financial assets or liabilities that were classified as Level 3 at any point during the six months ended June 30, 2016 or the year ended December 31, 2015.

4. Cash equivalents and marketable securities

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. Cash equivalents as of June 30, 2016 and December 31, 2015 consisted of money market funds. Marketable securities as of June 30, 2016 consisted of corporate debt securities and U.S. government agency securities. Marketable securities as of December 31, 2015 consisted of corporate debt securities. Management determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company classifies its marketable securities as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities. Marketable securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity and a component of total comprehensive income (loss) in the condensed consolidated statement of comprehensive income (loss), until realized. Realized gains and losses are included in investment income on a specific-identification basis. There were immaterial realized gains on marketable securities during the three and six months ended June 30, 2016 and 2015.

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

Marketable securities at June 30, 2016 and December 31, 2015 consisted of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
As of June 30, 2016				
Current (due within 1 year):				
Corporate debt securities	\$13,804,598	\$ 7,855	\$ —	\$13,812,453
U.S. government agency securities	22,068,692	31,635	—	22,100,327
Total	\$35,873,290	\$ 39,490	\$ —	\$35,912,780
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
As of December 31, 2015				
Current (due within 1 year):				
Corporate debt securities		\$24,666,607	\$ 1,878	\$(16,137) \$24,652,348
Noncurrent (due after 1 year through 5 years):				
Corporate debt securities		2,323,344	—	(10,395) 2,312,949
Total		\$26,989,951	\$ 1,878	\$(26,532) \$26,965,297

At June 30, 2016, all investments held by the Company were classified as current. The Company had \$24,652,348 of marketable securities classified as current and \$2,312,949 of marketable securities classified as noncurrent as of December 31, 2015. Investments classified as current have maturities of less than one year. Investments classified as noncurrent are those that (i) have a maturity greater than one year and (ii) management does not intend to

liquidate within the next year, although these funds are available for use and therefore classified as available-for-sale. The Company held zero and eleven debt securities that were in an unrealized loss position at June 30, 2016 and December 31, 2015, respectively, all of which have been in a continuous loss position for less than 12 months. The aggregate fair value of debt securities in an unrealized loss position was zero and \$24,967,915 at June 30, 2016 and December 31, 2015, respectively. There were no individual securities that were in a significant unrealized loss position as of June 30, 2016 or December 31, 2015. The Company evaluated its securities for other-than-temporary impairment and no marketable securities were considered to be other-than-temporarily impaired as of June 30, 2016.

5. Inventory

The Company began capitalizing inventory as of March 31, 2016, when it was determined that the inventory had a probable future economic benefit. Inventory has been recorded at cost as of June 30, 2016. Costs capitalized at June 30, 2016 relate to the initial production run of HOTSHOT. The Company held no inventory at December 31, 2015.

The following table presents inventory:

	June 30, 2016	December 31, 2015
Raw materials	\$38,904	\$ —
Finished goods	235,398	—
Total inventory	\$274,302	\$ —

In the first quarter of 2016, the Company wrote off materials purchased for the initial production run of HOTSHOT finished goods that, upon completion, were not expected to be sold based upon projected sales, a 12 month product shelf life, the number of units produced and production level requirements. The initial production run of HOTSHOT finished goods was completed in the second quarter of 2016, at which time the Company wrote-off production costs incurred for those finished goods that were not expected to be sold. Write-offs totaled \$40,652 and \$225,950 for the three and six months ended June 30, 2016, respectively, and are included in cost of revenue in the accompanying condensed consolidated statement of operations.

The cost of revenue related to deferred revenue is capitalized and recorded as cost of 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, 2016	December 31, 2015
Payroll and employee-related costs	\$1,079,260	\$1,299,248
Research and development costs	502,396	307,666
Professional fees	130,889	129,625
Consumer product-related costs	33,790	198,887
Other	15,442	11,948
Total	\$1,761,777	\$1,947,374

7. Common stock

As of June 30, 2016, the Company had authorized 100,000,000 shares of common stock, \$0.0001 par value per share. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors. The Company does not intend to declare dividends for the foreseeable future.

Restricted common stock to founders

In March 2014, the Company sold 4,553,415 shares of restricted common stock to the founders of the Company ("recipients"), for \$0.0004 per share, for total proceeds of \$1,950. In April 2014, based upon anti-dilution provisions granted to the recipients, an additional 867,314 shares of restricted common stock were sold to the same recipients, after which the anti-dilution provisions were terminated. The restricted common stock vested 25% upon issuance, and the remaining 75% vests ratably over four years, during which time the Company has the right to repurchase the unvested shares held by a recipient if the relationship between such recipient and the Company ceases. If the relationship terminates, the Company has 90 days to repurchase unvested shares at \$0.0004 per share. Such shares are not accounted for as outstanding until they vest. There were 3,726,619 shares of restricted common stock outstanding as of June 30, 2016. Unvested restricted common stock awards to non-employees are re-measured at each vest date and each financial reporting date.

The following is a summary of restricted common stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Non-vested at December 31, 2015	2,202,262	\$ 0.10
Issued	—	—
Vested	(508,152)	0.10
Non-vested at June 30, 2016	1,694,110	\$ 0.10

Restricted common stock to consultants

During the six months ended June 30, 2016, the Company issued 18,194 shares of restricted common stock to non-employee consultants and advisors. The Company has the right to repurchase any unvested shares held by a recipient if the relationship between such recipient and the Company ceases. If the relationship terminates, the Company has 90 days to repurchase unvested shares at \$0.0001 per share. Such shares are not accounted for as outstanding until they vest. There were 4,610 shares of restricted common stock outstanding as of June 30, 2016. Unvested restricted common stock awards to non-employees are re-measured at each vest date and each financial reporting date.

The following is a summary of restricted common stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Non-vested at December 31, 2015	—	\$ —
Issued	18,194	9.51
Vested	(4,610)	9.34
Non-vested at June 30, 2016	13,584	\$ 9.56

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, 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 incentive stock options ("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, 2016, there were 299,671 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, 2016:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	1,824,973	\$ 8.34		
Granted	699,820	9.94		
Exercised	(6,401)	1.26		
Cancelled or forfeited	(93,375)	12.94		
Outstanding at June 30, 2016	2,425,017	\$ 8.64	8.87	\$6,528,784
Exercisable at June 30, 2016	605,959	\$ 7.09	8.24	\$2,864,265
Vested or expected to vest at June 30, 2016	2,115,540	\$ 8.55	8.37	\$6,034,998

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, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Research and development	\$684,695	\$855,083	\$1,280,161	\$1,812,293
Selling, general and administrative	1,303,626	785,476	2,226,321	1,574,026
Total	\$1,988,321	\$1,640,559	\$3,506,482	\$3,386,319

As of June 30, 2016, there was approximately \$13,807,000 of total unrecognized compensation cost related to unvested equity awards. Total unrecognized compensation cost will be adjusted for the re-measurement of non-employee awards as well as future changes in employee and non-employee forfeitures, if any. The Company expects to recognize that cost over a remaining weighted-average period of 2.28 years.

In November 2015, the Company granted 150,000 performance-based stock options to an employee, which are included in the table of stock option activity above. The options will vest based upon the achievement of certain future revenue milestones. As of June 30, 2016, the achievement of these vesting milestones was not considered probable. Unrecognized stock-based compensation expense related to this award was approximately \$1,000,000 as of June 30, 2016. The Company records stock-based compensation expense for stock option grants subject to performance-based vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

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

Employee stock purchase plan

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

9. Income taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Based upon the Company's history of operating losses and the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets. There was no significant income tax provision or benefit for the three or six months ended June 30, 2016 or 2015.

10. Net loss per share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive

common stock equivalents outstanding for the period, determined using the treasury stock method and the if-converted method, for convertible securities, if inclusion of these is dilutive.

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

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

	June 30, 2016	June 30, 2015
Options to purchase common stock	2,425,017	1,363,994
Unvested restricted common stock	1,707,694	2,710,414
Unvested restricted common stock issued upon early exercise of stock options	—	37,064
Total	4,132,711	4,111,472

11. Segment Information

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

The Consumer Operations segment, which reflects the net revenue and costs and expenses related to HOTSHOT and the Company's consumer operations.

The Drug Development segment, which reflects the costs related to the Company's efforts to develop innovative and proprietary drug products to treat nocturnal leg cramps and muscle cramps and spasms associated with severe neuromuscular conditions.

The Company discloses information about its reportable segments based on the way that the Company's Chief Operating Decision Maker (CODM), who the Company has identified as the Chief Executive Officer, and management, organizes segments within the Company for making operating decisions and assessing financial performance. The Company evaluates the performance of its reportable segments based on revenue and operating income or loss. The accounting policies of the segments are the same as those described herein as well as those described in Note 1 to the audited consolidated financial statements in the 2015 Form 10-K. Corporate and unallocated amounts that do not relate to a reportable segment have been allocated to "Corporate". No asset information has been provided for the Company's reportable segments as management does not measure or allocate such assets on a reportable segment basis.

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

Three months Ended June 30, 2016	Consumer Operations	Drug Development	Corporate	Consolidated
Net 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

Three months Ended June 30, 2015	Consumer Operations	Drug Development	Corporate	Consolidated
Net revenue	\$—	—	—	\$—
Interest income, net	\$—	—	16,183	\$ 16,183
Loss from operations	\$1,750,973	3,113,587	2,230,021	\$ 7,094,581

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

Six months Ended June 30, 2016	Consumer Operations	Drug Development	Corporate	Consolidated
Net 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

Six months Ended June 30, 2015	Consumer Operations	Drug Development	Corporate	Consolidated
Net revenue	\$—	—	—	\$—
Interest income, net	\$—	—	19,760	\$ 19,760
Loss from operations	\$2,833,253	5,918,533	4,363,953	\$13,115,739

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

The following discussion and analysis should be read in conjunction with the unaudited financial information and the notes thereto included herein, as well as our audited consolidated financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2015. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" discussed in our Annual Report on Form 10-K for the year ended December 31, 2015, in other subsequent filings with the SEC, and elsewhere in this Quarterly Report on Form 10-Q. These statements, like all statements in this report, speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

Introduction

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

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

Results of Operations - An analysis of our financial results comparing the three and six months ended June 30, 2016 to the three and six months ended June 30, 2015.

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

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

Overview

We are a biotechnology company that is developing innovative and proprietary treatments for nocturnal leg cramps, muscle cramps and spasms associated with severe neuromuscular conditions, and exercise-associated muscle

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

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

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 \$11.4 million and \$21.0 million for the three and six months ended June 30, 2016 and \$7.1 million and \$13.1 million for the three and six months ended June 30, 2015. Our accumulated deficit was \$58.1 million as of June 30, 2016. To date, we have financed our operations with net proceeds from the private placement of our preferred stock and our initial public offering. We expect that our research and development expenses will continue to increase from their current levels as we continue the development of our drug product candidates, and our selling, general and administrative expenses and working capital needs will continue to increase as we continue to commercialize HOTSHOT. As a result, we will need additional capital to fund our future operations.

Recent Developments

Launch of HOTSHOT

In the second quarter of 2016, we launched our consumer brand and cornerstone consumer product, HOTSHOT, which we developed using our extract formulation. HOTSHOT is sold as a 1.7 fluid ounce beverage containing a proprietary formulation of organic transient receptor potential, or TRP, ion channel activators. HOTSHOT is marketed to endurance athletes experiencing EAMCs and is sold on our branded website and to select specialty retailers in Los Angeles, California, Boulder, Colorado and Boston, Massachusetts. We are conducting an extensive print media, digital media and public relations campaign to support the launch of HOTSHOT.

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

- The Consumer Operations segment, which reflects the net product revenue and costs and expenses for HOTSHOT and our consumer operations.

- The Drug Development segment, which reflects the costs related to our efforts to develop innovative and proprietary drug products to treat nocturnal leg cramps and muscle cramps and spasms associated with severe neuromuscular 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 the condensed consolidated financial statements herein for additional information.

Other Developments

On May 25, 2016, we announced that we initiated a human proof-of-concept efficacy study in nocturnal leg cramps, or NLC, with our chemically synthesized, single molecule, TRP ion channel activator, formulated as an orally disintegrating tablet. The randomized, blinded, controlled, cross-over study is designed to evaluate the safety and efficacy of our single agent in over 50 subjects who suffer from nocturnal leg cramps on a frequent basis. On July 26, 2016, we announced enrollment in this study was complete and that topline results are expected by the end of 2016.

On June 15, 2016, we announced that we initiated a Phase 2 efficacy study in patients with multiple sclerosis, or MS, in Australia. The randomized, controlled, blinded, cross-over study is designed to evaluate the safety and efficacy of FLX-787, our single molecule, chemically synthesized, TRP ion channel activator, in approximately 50 patients who suffer from cramps, spasms and/or spasticity as a consequence of MS. MS is an autoimmune disease

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in which inflammatory processes cause worsening demyelination and cell degeneration over years, resulting in a variety of neurological deficits such as loss of muscle control, sensation and vision. Spasticity is caused by damage to motor systems in the brain and spinal cord. These lesions cause hyperactive muscle stretch reflexes, which result in spasticity. The need to treat spasticity increases as the disease progresses. According to the National Institute of Neurological Disorders and Stroke, between 250,000 and 350,000 people in the United States suffer from MS and approximately 84% of patients with MS experience spasticity.

Components of Operating Results

Net Revenue

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. We issue refunds to e-commerce customers, upon request, within 21 days of shipment. As we do not have adequate history to accurately estimate refunds, all e-commerce sales, and their related costs, are deferred and revenue is recognized once the refund period lapses. For specialty retail sales, revenue is recognized at the time products are delivered to customers. Discounts provided to customers are accounted for as a reduction of revenue. 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 revenue will be generated through our branded website. In the future, we may consider selling HOTSHOT via e-commerce partners or additional websites.

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

Prior to the launch of HOTSHOT, we conducted extensive pre-launch activities, which included, among other things, attending athletic events, providing product samples, gathering feedback, educating potential consumers of our product and launching a print and digital media campaign. The majority of our revenue in the second quarter of 2016 is comprised of revenue generated from customers that were introduced to our product through these pre-launch activities and were offered an opportunity, via an email campaign, to pre-order HOTSHOT and receive it upon launch. To date, we have generated limited revenue from sales of HOTSHOT. Generally, we realize higher revenue per bottle from our e-commerce sales versus specialty retailer sales. Future sales of HOTSHOT are expected to vary from quarter to quarter and will be impacted by the number of visitors attracted to our branded website, those that purchase from the website and the amount of repeat sales that we are able to generate through e-commerce. Future sales will also be impacted by the amount of revenue that we are able to generate through retail channels. Our inability to generate sufficient e-commerce and retail revenues would have a 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 Revenue

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

We began the initial production run of HOTSHOT in the first quarter of 2016, in advance of our planned launch in the second quarter of 2016. In the first quarter of 2016, we wrote-off materials purchased for the initial production run of HOTSHOT finished goods that upon completion were not expected to be sold based upon projected sales, a 12 month

product shelf life, the number of units produced and production level requirements. The initial production

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run of HOTSHOT finished goods was completed in the second quarter of 2016, at which time we wrote-off the production fees associated with those finished goods that were not expected to be sold.

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

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

Research and Development Expenses

Our research and development expenses to date include the costs incurred related to the development and testing of our extract formulation for muscle cramps in the United States. We also incurred research and development expenses related to the testing and development of a single molecule, chemically synthesized, TRP ion channel activator, including FLX-787, our clinical candidate outside the United States. Research and development costs include salaries and other compensation-related costs, such as stock-based compensation, for research and development employees, costs of clinical studies of our extract formulation and drug product candidates including costs of clinical studies outside of the United States, 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 our research and development expenses to increase in the future as we increase personnel and compensation costs, increase our research efforts, conduct larger clinical studies and trials in multiple indications, and perform pre-clinical work on our drug product candidates. It is difficult to determine, with certainty, the duration and completion costs of our current or future pre-clinical programs, clinical studies and clinical trials of our product candidates.

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

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

Selling, General and Administrative Expenses

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

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

As we continue to support the launch and potential growth of HOTSHOT, selling, general and administrative costs are expected to increase as we hire additional personnel to support our selling and marketing activities and incur costs related to distribution, print and digital media and other related sales and promotion activities. In the future, we may also pursue relationships with endurance athletes, figures or teams prominent in the athletic community.

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

Interest Income, Net

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

Results of Operations**Three Months Ended June 30, 2016 Compared to the Three Months Ended June 30, 2015**

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

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Change
Net revenue	\$112,685	\$—	\$112,685
Costs and expenses:			
Cost of revenue	110,931	—	110,931
Research and development	6,094,921	3,190,178	2,904,743
Selling, general and administrative	5,377,784	3,904,403	1,473,381
Total costs and expenses	11,583,636	7,094,581	4,489,055
Loss from operations	(11,470,951)	(7,094,581)	(4,376,370)
Interest income, net	107,818	16,183	91,635
Net loss	\$(11,363,133)	\$(7,078,398)	\$(4,284,735)

Net Revenue

Our Consumer Operations segment generated all of our revenue during the three and six months ended June 30, 2016, through sales of HOTSHOT. Net revenue totaled \$0.1 million for the three months ended June 30, 2016. Sales via e-commerce on our branded website represented approximately 88% of our net revenue and we expect that e-commerce will continue to represent a significant portion of our future net revenue. Customers purchase HOTSHOT in 6 or 12 pack configurations via our website and first time purchasers of a 6 pack are offered a one-time discount. Discounts are recorded as a reduction of revenue. Prior to the formal e-commerce and retail launch of HOTSHOT, consumers were offered the opportunity to place a pre-order and receive HOTSHOT upon launch. A significant portion of our e-commerce revenue generated in the second quarter of 2016 related to these pre-order sales.

We issue refunds to e-commerce customers, upon request, within 21 days of shipment. As we 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.

Cost of Revenue

All costs of revenue are recorded by our Consumer Operations segment and relate to the production and sale of HOTSHOT. Cost of revenue was \$0.1 million for the three months ended June 30, 2016 and included the cost of HOTSHOT sold, depreciation expense related to manufacturing equipment purchased to support production and an inventory write-off totaling approximately \$40,700. This write-off related to production fees associated with HOTSHOT finished goods that, upon completion of production, were not expected to be sold based upon projected

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sales, a 12 month product shelf life, the number of units produced and production level requirements. There was no cost of revenue for the three months ended June 30, 2015.

Research and Development Expenses

Our Drug Development segment incurred the majority of our research and development expenses, which were \$6.1 million for the three months ended June 30, 2016 compared to \$3.2 million for the three months ended June 30, 2015. The increase of \$2.9 million was primarily related to:

- \$2.5 million of increased costs primarily related to clinical studies of our single molecule, chemically synthesized, TRP ion channel activator and IND-supporting pre-clinical activities for our drug product candidate;
- \$0.3 million of increased costs for clinical studies of our clinical candidate outside the United States, FLX-787;
- \$0.2 million increase in salaries expense due to headcount additions;
- \$0.1 million increase related to our Consumer Operations segment for continued research of our consumer product; and
- \$0.2 million decrease in stock-based compensation expense, primarily due to the impact of the lower current year stock price on the revaluation of non-employee stock awards.

Selling, General and Administrative Expenses

Selling, general and administrative includes expenses that are incurred by our Consumer Operations segment as well as corporate and unallocated amounts that do not relate to a reportable segment. Selling, general and administrative costs were \$5.4 million for the three months ended June 30, 2016 compared to \$3.9 million for the three months ended June 30, 2015. The increase of \$1.5 million was primarily related to:

- \$0.5 million of increased external costs within our Consumer Operations segment related to preparing for and launching HOTSHOT during the second quarter of 2016, including costs associated with our print and digital media campaign, marketing and promotional costs and pre-launch and launch activities;
- \$0.4 million of increased personnel costs incurred by our Consumer Operations segment, including salaries and other compensation-related costs such as stock-based compensation, as we added personnel to support the launch of our consumer brand and HOTSHOT;
- \$0.4 million of increased corporate personnel costs, including salaries and other compensation-related costs such as stock-based compensation, related to additional administrative personnel hired to support our growth and increased activities; and
- \$0.2 million of increased external consulting costs incurred to supplement our Consumer Operations segment and general and administrative personnel due to increased activity.

Loss from Operations

Our consolidated loss from operations for the three months ended June 30, 2016 totaled \$11.5 million. Of this total, \$2.8 million of the operating loss was incurred by our Consumer Operations segment and \$5.9 million was incurred by our Drug Development segment. The operating loss incurred by the Consumer Operations segment was primarily driven by production costs, marketing, promotional and branding costs related to preparing for, and executing, the launch of HOTSHOT, and personnel related expenses, including stock-based compensation. These costs were slightly offset by the net revenue generated from HOTSHOT sales in the second quarter of 2016. The operating loss incurred by the Drug Development segment relates to costs incurred for preclinical and clinical activities, as well as personnel related expenses, including stock-based compensation.

Six Months Ended June 30, 2016 Compared to the Six Months Ended June 30, 2015

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

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	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Change
Net revenue	\$112,685	\$—	\$112,685
Costs and expenses:			
Cost of revenue	307,951	—	307,951
Research and development	10,482,000	5,995,124	4,486,876
Selling, general and administrative	10,489,479	7,120,615	3,368,864
Total costs and expenses	21,279,430	13,115,739	8,163,691
Loss from operations	(21,166,745)	(13,115,739)	(8,051,006)
Interest income, net	211,151	19,760	191,391
Net loss	\$(20,955,594)	\$(13,095,979)	\$(7,859,615)

Net Revenue

Our Consumer Operations segment generated all of our revenue in the six months ended June 30, 2016 through sales of HOTSHOT. 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 Revenue

All costs of revenue are recorded by our Consumer Operations segment and relate to the production and sale of HOTSHOT. Cost of net product revenue was \$0.3 million for the six months ended June 30, 2016, and included the cost of HOTSHOT sold, depreciation expense related to manufacturing equipment purchased to support production, and inventory write-offs which totaled approximately \$226,000. Of this write-off, \$185,300 was recorded in the first quarter of 2016 and related to an inventory write-off of material purchased for the initial production run of HOTSHOT finished goods that, upon completion of production, 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. In the second quarter of 2016, when the production of HOTSHOT finished goods was complete, we recorded an additional reserve of \$40,700 for production fees incurred for those finished goods that are not expected to be sold. There was no cost of revenue for the six months ended June 30, 2015.

Research and Development Expenses

Our Drug Development segment incurred the majority of our research and development expenses, which were \$10.5 million for the six months ended June 30, 2016 compared to \$6.0 million for the six months ended June 30, 2015. The increase of \$4.5 million was primarily related to:

\$3.8 million of increased costs related to clinical studies of our single molecule, chemically synthesized, TRP ion channel activator, IND-supporting pre-clinical activities for our drug product candidate and clinical studies of alternate formulations of our extract formulation;

\$0.6 million of increased costs for clinical studies of our clinical candidate outside the United States, FLX-787;

\$0.5 million increase in salaries expense related to headcount;

\$0.1 million increase in consulting expense to supplement Drug Development segment personnel due to increased activities; and

\$0.5 million decrease in stock-based compensation expense, primarily due to the impact of the lower current year stock price on the revaluation of non-employee stock awards.

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

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administrative expenses were \$10.5 million for the six months ended June 30, 2016 compared to \$7.1 million for the six months ended June 30, 2015. The increase of \$3.4 million was primarily related to:

\$1.2 million of increased external costs related to developing our consumer brand and HOTSHOT, including brand development and strategy costs, and marketing and promotional costs for pre-launch and launch activities, as selling commenced in the second quarter of 2016;

\$0.9 million of increased personnel costs incurred by our Consumer Operations segment, including salaries and other compensation-related costs such as stock-based compensation, as we added personnel to support the launch of HOTSHOT;

\$0.9 million of increased corporate personnel costs, including salaries and other compensation-related costs such as stock-based compensation, related to additional administrative personnel hired to support our growth and increased activities;

\$0.3 million of increased external consulting costs incurred to supplement our general and administrative and Consumer Operations segment personnel due to increased activity; and

\$0.1 million increase in other costs, primarily facility and office-expense related.

Loss from Operations

Our consolidated loss from operations for the six months ended June 30, 2016 totaled \$21.2 million. Of this total, \$5.8 million of the operating loss was incurred by our Consumer Operations segment and \$10.0 million was incurred by our Drug Development segment. The operating loss incurred by the Consumer Operations segment was driven by production costs, marketing, promotional and branding costs related to preparing for, and executing, the launch of HOTSHOT, and personnel related expenses, including stock-based compensation. These costs were slightly offset by the net revenue generated from HOTSHOT sales in the second quarter of 2016. The operating loss incurred by the Drug Development segment relates to costs incurred for preclinical and clinical activities, personnel related expenses, including stock-based compensation, as well as consulting costs.

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 the sales of HOTSHOT. We expect that our research and development and selling, general and administrative expenses will continue to increase, as we continue our drug development efforts and incur significant sales and marketing expense associated with the commercialization of 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, 2016, we had \$74.9 million in cash, cash equivalents and marketable securities, which were held in bank deposit accounts, money market funds, corporate debt and U.S. government agency securities.

Sources of Liquidity

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Cash Flows

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Net cash (used in) provided by:		
Operating activities	\$(18,501,207)	\$(8,605,348)
Investing activities	(9,252,292)	(75,562)
Financing activities	8,043	80,838,429
Net (decrease) increase in cash and cash equivalents	\$(27,745,456)	\$72,157,519

Operating Activities

The increase in cash used in operations for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily due to our significant increase in operations. For the six months ended June 30, 2016, we incurred increased costs related to our personnel, increased costs related to our research and development efforts including clinical study costs, increased costs associated with our consumer product development and HOTSHOT launch efforts and increased costs needed to support our operations.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2016 primarily related to \$9.0 million of net purchases and sales of marketable securities. We did not hold any marketable securities during the six months ended June 30, 2015. Property and equipment acquisitions increased \$0.2 million, which primarily related to manufacturing equipment used to produce HOTSHOT, and development of our branded website for e-commerce sales.

Financing Activities

Net cash provided by financing activities was \$8,043 during the six months ended June 30, 2016 compared to \$80.8 million for the six months ended June 30, 2015. During the six months ended June 30, 2015, we completed our IPO, which resulted in net proceeds of \$79.9 million.

As of June 30, 2016, we had no long-term debt.

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

Funding Requirements

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

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

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property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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

Drug Product Candidates

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

- successfully enrolling, and completing, clinical studies and trials;
 - receiving marketing approvals from applicable regulatory authorities;
 - establishing arrangements with third-party manufacturers;
 - obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
 - launching commercial sales of our products, if and when approved, whether alone or in collaboration with others.
- A change in the outcome of any of these variables with respect to the development of any of our drug product candidates would significantly change the costs and timing associated with the development of that drug product candidate.

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

Consumer Brand and Products

The development and growth of our consumer brand, HOTSHOT and future products is uncertain, including the timing and resources needed to support successful commercialization. Our future success depends, in large part, on our ability to implement a growth strategy that establishes distribution and placement of our products, attracts consumers to HOTSHOT and future product offerings and maintains brand loyalty for our consumer products. Our future funding requirements will be impacted by our ability to successfully grow our consumer brand, HOTSHOT and any future products. In addition, delays or unexpected costs related to HOTSHOT and growth plans could significantly change the costs and the timing of such costs associated with our consumer operations.

Outlook

Based on our research and development plans, our consumer brand and HOTSHOT growth plans and our expectations of timing related to the progress of our clinical programs, we expect that our existing cash resources and marketable securities will enable us to fund our costs and expenses, working capital and capital expenditure requirements through mid-2018. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect. Additionally, the process of testing drug product candidates in clinical trials is costly, as are the resources required to commercialize a consumer brand and products, and the timing of progress of these efforts is uncertain.

Contractual Obligations

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K for the year ended December 31, 2015.

Off-Balance Sheet Arrangements

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

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Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the condensed consolidated balance sheet and the reported amounts of expenses during the reporting period. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our consolidated financial statements prospectively from the date of the change in estimate.

There have been no material changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2015, other than as noted below.

Inventory

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

During the three and six months ended June 30, 2016, we recorded inventory write-downs of excess inventory totaling approximately \$40,700 and \$226,000, respectively, based upon our analysis of projected sales, a 12 month product shelf life, the number of units produced and production level requirements.

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

Net revenue

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 e-commerce customers, we issue refunds, upon request, within 21 days of shipment. As we do not currently have adequate history to accurately estimate refunds, all e-commerce sales, and their related costs, are deferred and revenue is recognized once the the refund period lapses. For specialty retail sales, revenue is recognized at the time products are delivered to customers. We do not offer a right of return or refund to specialty retailers.

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

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of June 30, 2016, we had cash, cash equivalents and marketable securities of \$74.9 million. We invest our cash in a variety of financial instruments, principally money market funds, U.S. government securities, investment-grade corporate notes and commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Available for sale securities that we invest in are subject to interest rate risk and may fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments,

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an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

As of June 30, 2016, we have evaluated, under the supervision and with the participation of our management, including the chief executive officer and the principal financial and accounting officer, the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon our evaluation, the chief executive officer and the principal financial and accounting officer concluded that our disclosure controls and procedures were effective. Accordingly, management believes that the condensed consolidated financial statements included in this report fairly present in all material respects our consolidated financial condition, results of operations and cash flow for the periods presented

Changes in Internal Control over Financial Reporting

During the six months ended June 30, 2016, there was no significant change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

You should carefully review and consider the information regarding certain factors that could materially affect our business, financial condition or future results set forth under Item 1A. (Risk Factors) in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

There have been no material changes to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, except as follows:

Risks Related to Our Reliance on Third-Parties

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

We rely on a network of third-party manufacturers to supply materials and produce HOTSHOT. Our supply chain for sourcing raw materials and production is a multi-step endeavor. Third-party contract suppliers provide us with raw

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recent sales of unregistered securities.

None.

Use of Proceeds

In February 2015, we completed our initial public offering pursuant to a registration statement on Form S-1 (File No. 333-201276), which the SEC declared effective on January 28, 2015. In our initial public offering, we issued and sold 5,491,191 shares of common stock (inclusive of 91,191 shares of common stock sold by us pursuant to the

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exercise of an overallotment option granted to the underwriters in connection with the offering) at a public offering price of \$16.00 per share, for aggregate gross offering proceeds of \$87.9 million. The managing underwriters for our initial public offering were Jefferies LLC, Piper Jaffray & Co., JPM Securities LLC, Cantor Fitzgerald & Co., and Roth Capital Partners, LLC.

The aggregate net proceeds received by us from our initial public offering were \$79.9 million, after deducting underwriting discounts and commissions and offering expenses payable by us. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates or to any other persons.

There has been no material change in the use of proceeds from our initial public offering as described in our final prospectus dated January 28, 2015 and filed with the SEC pursuant to Rule 424(b)(4) on January 29, 2015.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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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.

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SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

FLEX PHARMA, INC.

By: /s/ Christoph Westphal
Christoph Westphal, M.D., Ph.D.
President and Chief Executive Officer

By: /s/ John McCabe
John McCabe
Vice President, Finance (Principal Financial and
Accounting Officer)

Date: August 3, 2016

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EXHIBIT INDEX

Exhibit number	Description of Document
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3.1	(1) Amended and Restated Certificate of Incorporation of the Registrant.
3.2	(1) Amended and Restated Bylaws of the Registrant.
4.1	(2) Form of Common Stock Certificate of the Registrant.
4.2	(2) Amended and Restated Investors' Rights Agreement, dated July 23, 2014, by and among the Registrant and certain of its stockholders.
10.1	† Supply Agreement dated May 9, 2016 by and between Trilogy Essential Ingredients Inc. and Flex Innovation Group LLC, a wholly owned subsidiary of the Registrant.
10.2	License Agreement, dated May 1, 2014, by and between the Registrant and ECLDS, LLC, as amended.
10.3	(3)+ Amendment to Offer Letter, dated May 9, 2016, by and between Flex Innovation Group LLC, the Registrant and Marina Hahn
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101	The following materials from Flex Pharma, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, formatted in XBRL (eXtensible Business Reporting Language):(i) Unaudited Condensed Consolidated Balance Sheets, (ii) Unaudited Condensed Consolidated Statements of Operations (iii) Unaudited Condensed Consolidated Statements of Comprehensive Loss, (iv) Unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Unaudited Condensed Consolidated Financial Statements.

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

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

(3) Incorporated by reference to the Registrant's Current Report on Form 8-K K (File No. 001-36812), filed with the SEC on May 13, 2016.

† Confidential treatment requested under 17 C.F.R. §200.80(b)(4) and Rule 24b-2. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been provided separately to the SEC pursuant to the confidential treatment request.

+ Indicates management contract or compensatory plan.

