

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

Flex Pharma, Inc.
Form 10-Q
November 05, 2018
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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 September 30, 2018

OR

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

For the Transition Period from _____ to _____

Commission File Number: 001-36812

FLEX PHARMA, INC.

(Exact name of Registrant as specified in its charter)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer <input type="checkbox"/>	Accelerated Filer <input type="checkbox"/>	Non-accelerated Filer <input checked="" type="checkbox"/>	Smaller Reporting Company <input checked="" type="checkbox"/>	Emerging Growth Company <input type="checkbox"/>
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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

As of October 31, 2018, there were 18,069,476 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, expectations regarding the timing and outcome of the strategic review process, the expectations regarding our research and development efforts, the commercial prospects of our consumer product, and the plans and objectives of management, are forward looking statements. These factors also include, but are not limited to, those factors set forth in the sections entitled "Risk Factors," "Legal Proceedings," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Quantitative and Qualitative Disclosures about Market Risk," and "Controls and Procedures" in this Quarterly Report on Form 10-Q, all of which you should review carefully. 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 outcome of the evaluation of our strategic alternatives, including any perceived benefits of our restructuring plan; the costs associated with our pending litigation; our ability to raise funds for our operations, our ability to continue to sell our consumer product; availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements; ability to attract, retain and motivate qualified personnel; the status, timing, costs, results and interpretation of our clinical trials; the uncertainties inherent in conducting clinical trials; results from our ongoing and planned clinical development; expectations of our ability to make regulatory filings and obtain and maintain regulatory approvals; results of early clinical studies as indicative of the results of future trials; other matters that could affect the availability or commercial potential of our drug product candidates; the inherent uncertainties associated with intellectual property; and other factors discussed in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2017 and other filings with the Securities and Exchange Commission, or SEC.

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

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

FLEX PHARMA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,961,126	\$ 19,186,036
Marketable securities	—	14,129,723
Accounts receivable	20,993	10,385
Inventory	223,519	431,891
Prepaid expenses and other current assets	478,746	777,102
Total current assets	13,684,384	34,535,137
Property and equipment, net	127,090	331,040
Restricted cash	126,595	126,595
Total assets	\$ 13,938,069	\$ 34,992,772
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,279,258	\$ 2,004,440
Accrued expenses and other current liabilities	1,554,679	3,712,221
Deferred revenue	—	72,188
Deferred rent, current portion	53,919	58,821
Total current liabilities	2,887,856	5,847,670
Deferred rent, net of current portion	—	39,214
Total liabilities	2,887,856	5,886,884
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at September 30, 2018 and December 31, 2017; none issued or outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized at September 30, 2018 and December 31, 2017; 18,069,476 and 17,972,166 shares issued at September 30, 2018 and December 31, 2017, and 18,066,767 and 17,797,178 shares outstanding at September 30, 2018 and December 31, 2017, respectively	1,807	1,780
Additional paid-in capital	142,000,936	140,184,630
Accumulated other comprehensive loss	—	(1,247)
Accumulated deficit	(130,952,530)	(111,079,275)
Total stockholders' equity	11,050,213	29,105,888
Total liabilities and stockholders' equity	\$ 13,938,069	\$ 34,992,772

See accompanying notes to condensed consolidated financial statements.

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FLEX PHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Net product revenue	\$247,284	\$407,241	\$664,955	\$978,221
Other revenue	3,707	6,360	10,120	13,450
Total revenue	250,991	413,601	675,075	991,671
Costs and expenses:				
Cost of product revenue	91,937	148,756	355,816	373,187
Research and development	865,765	4,739,360	11,720,535	12,730,554
Selling, general and administrative	1,959,872	4,934,937	8,651,808	14,520,596
Total costs and expenses	2,917,574	9,823,053	20,728,159	27,624,337
Loss from operations	(2,666,583)	(9,409,452)	(20,053,084)	(26,632,666)
Interest income, net	28,210	77,339	139,612	227,535
Net loss	\$(2,638,373)	\$(9,332,113)	\$(19,913,472)	\$(26,405,131)
Net loss attributable to common stockholders	\$(2,638,373)	\$(9,332,113)	\$(19,913,472)	\$(26,405,131)
Net loss per share attributable to common stockholders — basic and diluted	\$(0.15)	\$(0.54)	\$(1.11)	\$(1.54)
Weighted-average number of common shares outstanding — basic and diluted	18,066,548	17,386,249	17,999,877	17,131,887

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 September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Net loss	\$(2,638,373)	\$(9,332,113)	\$(19,913,472)	\$(26,405,131)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	—	4,305	1,247	303
Comprehensive loss	\$(2,638,373)	\$(9,327,808)	\$(19,912,225)	\$(26,404,828)

See accompanying notes to condensed consolidated financial statements.

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FLEX PHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Operating activities		
Net loss	\$(19,913,472)	\$(26,405,131)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	176,954	250,563
Stock-based compensation expense	1,698,323	3,266,879
Amortization and accretion on investments	11,537	(38,551)
Other non-cash items	22,274	—
Changes in operating assets and liabilities:		
Accounts receivable	(3,848)	(22,953)
Inventory	191,380	(79,864)
Prepaid expenses and other current assets	283,463	(130,196)
Other assets	—	64,800
Accounts payable	(725,182)	(274,525)
Accrued expenses and other current liabilities	(2,161,081)	1,309,611
Deferred revenue	—	9,227
Deferred rent	(44,116)	83,247
Net cash used in operating activities	(20,463,768)	(21,966,893)
Investing activities		
Purchases of marketable securities	(1,997,751)	(23,364,721)
Proceeds from maturities and sales of marketable securities	16,117,184	43,286,118
Purchases of property and equipment	—	(98,100)
Proceeds from sales of property and equipment	1,415	4,233
Net cash provided by investing activities	14,120,848	19,827,530
Financing activities		
Proceeds from exercise of common stock	118,010	2,047
Net cash provided by financing activities	118,010	2,047
Net decrease in cash, cash equivalents and restricted cash	(6,224,910)	(2,137,316)
Cash, cash equivalents and restricted cash at beginning of period	19,312,631	22,542,635
Cash, cash equivalents and restricted cash at end of period	\$13,087,721	\$20,405,319
Supplemental cash flow information		
Property and equipment purchases included in accounts payable at September 30, 2017	\$—	\$8,472
Property and equipment purchases included in accounts payable and accrued expenses at December 31, 2016	\$—	\$7,100

See accompanying notes to condensed consolidated financial statements.

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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 was focused on developing innovative and proprietary treatments for muscle cramps, spasms and spasticity associated with severe neurological conditions. In June 2018, the Company announced that it was ending its ongoing Phase 2 clinical trials of FLX-787 in patients with motor neuron disease ("MND"), primarily with amyotrophic lateral sclerosis ("ALS"), and in patients with Charcot-Marie-Tooth disease ("CMT"), due to oral tolerability concerns observed in both studies.

Additionally, in June 2018, the Company initiated a process to explore a range of strategic alternatives for enhancing stockholder value, including the potential sale or merger of the Company. Wedbush PacGrow has been engaged to act as the Company's strategic financial advisor. The Company also announced the restructuring of the organization to reduce its cost structure in order to preserve liquidity. In connection with the restructuring plan, the Company reduced its workforce by approximately 60%, with the reduction completed as of September 30, 2018. While the strategic assessment is ongoing, the Company will continue to operate with a reduced internal team that will focus their efforts on limited research and development activities and operating its consumer business, which sells HOTSHOT®, the Company's consumer product launched in 2016 to prevent and treat exercise-associated muscle cramps.

The Company's evaluation of strategic alternatives and its restructuring plans entails significant risks and uncertainties, including the risks and uncertainties set forth in Item 1A under the heading "Risk Factors" and Item 2 under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Quarterly Report on Form 10-Q and in the Company's Annual Report on Form 10-K. There can be no assurance that the Company's evaluation of potential strategic alternatives will result in any transaction.

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

Liquidity

The Company incurred a loss of \$2,638,373 for the three months ended September 30, 2018, a loss of \$19,913,472 for the nine months ended September 30, 2018 and had an accumulated deficit of \$130,952,530 as of September 30, 2018. The Company had unrestricted cash and cash equivalents of \$12,961,126 at September 30, 2018. The Company's operating plan assumes limited research and development activities and that the Consumer Operations segment will continue to sell HOTSHOT.

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

Based on the Company's operating plan, the Company believes that its existing cash and cash equivalents will be sufficient to allow the Company to fund its current operating plan for at least 12 months from the date the financial statements are issued.

The Company cannot predict the outcome of its strategic assessment or whether and to what extent it will resume drug development activities for FLX-787 or other drug product candidates and to what extent it will promote and sell HOTSHOT or other consumer products in the future. Accordingly, it is difficult to predict future cash needs.

Management does expect the Company to incur losses for the foreseeable future. The Company's ability to achieve profitability in the future is dependent upon achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. If the Company raises funds through the issuance of additional equity, whether through private placements or additional public offerings, such an issuance would dilute the stockholders' ownership in the Company. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

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2. Summary of significant accounting policies and recent accounting pronouncements

The accompanying unaudited condensed consolidated financial statements reflect the application of certain significant accounting policies as described below and elsewhere in these notes to the condensed consolidated financial statements. As of September 30, 2018, the Company's significant accounting policies, which are detailed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (the "2017 10-K"), have not changed, other than as noted below.

Accounts receivable and allowance for doubtful accounts

Accounts receivable are stated at their carrying values, net of any allowances for doubtful accounts. Accounts receivable consist primarily of amounts due from specialty retailers and sports teams, for which collection is probable based on the customer's intent and ability to pay. Receivables are evaluated for collection probability on a regular basis and an allowance for doubtful accounts is recorded, if necessary. No allowance for doubtful accounts was deemed necessary at September 30, 2018 or December 31, 2017.

Restricted cash

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

Advertising expense

Advertising expense consists of media and production costs related to print and digital advertising. All advertising is expensed as incurred. Total advertising expenses are included in selling, general and administrative expenses in the condensed consolidated statement of operations, and were approximately \$20,000 and \$792,000 for the three and nine months ended September 30, 2018 and approximately \$1,158,000 and \$3,073,000 for the three and nine months ended September 30, 2017.

Shipping and handling costs

Shipping and handling costs related to the movement of inventory to the Company's co-packer and from the co-packer to the Company's third-party warehousing and fulfillment partners are capitalized as inventory and expensed as cost of product revenue when revenue is recognized. Shipping and handling costs to move finished goods from the Company's third-party warehousing and fulfillment partners to customer locations are included in selling, general and administrative expenses in the condensed consolidated statement of operations, and were approximately \$27,000 and \$81,000 for the three and nine months ended September 30, 2018, and approximately \$64,000 and \$145,000 for the three and nine months ended September 30, 2017.

Restructuring-related costs

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

Restructuring-related costs are recorded within research and development expenses and selling, general and administrative expenses on the Company's condensed consolidated statement of operations. Liabilities associated with the Company's restructuring activities are recorded as a component of accrued expenses and other current liabilities on its condensed consolidated balance sheet. See Note 7 for additional information on the Company's current restructuring plan.

Unaudited interim financial information

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

The condensed consolidated financial statements as of September 30, 2018, for the three and nine months ended September 30, 2018 and 2017, and the related information contained within the notes to the condensed consolidated financial statements, are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as annual audited consolidated financial statements, and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's condensed consolidated financial position as of September 30, 2018, and the statements of operations, comprehensive loss and cash flows for the three and nine month periods ended September 30, 2018 and 2017. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, or any other future annual or interim periods.

Basis of presentation and use of estimates

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

Principles of consolidation

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

Recent accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers ("ASC 606"). ASC 606 supersedes the revenue recognition requirements in ASC Topic 605, Revenue Recognition ("ASC 605") and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted ASC 606 as of January 1, 2018 using the modified retrospective transition method. See Note 3 for further details.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The ASU requires lessees to recognize the assets and liabilities on their balance sheet for the rights and obligations created by most leases and continue to recognize expenses on their income statements over the lease term. It will also require disclosures designed to give financial statement users information on the amount, timing and uncertainty of cash flows arising from leases. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases. This ASU is intended to clarify or correct unintended application of the guidance outlined in ASU No. 2016-02. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements. This ASU is intended to address comparative reporting requirements for initial adoption. The guidance is effective for annual reporting periods

beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted. While the

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Company is currently evaluating the impact this standard will have on its consolidated financial statements, the Company expects that upon adoption, it will recognize right-of-use assets and lease liabilities and those amounts could be material.

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

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows, which amends ASU Topic 230. This update requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities are no longer required to present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. When cash, cash equivalents, restricted cash and restricted cash equivalents are presented in more than one line item on the balance sheet, the new guidance requires a reconciliation of the totals in the statement of cash flows to the related captions in the balance sheet. The Company adopted ASU No. 2016-18 in the first quarter of 2018, retrospectively, resulting in a change to the presentation of restricted cash on the condensed consolidated statement of cash flows.

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

	September 30, 2018	December 31, 2017
Cash and cash equivalents	\$12,961,126	\$19,186,036
Restricted cash	126,595	126,595
Cash, cash equivalents and restricted cash shown on the condensed consolidated statement of cash flows	\$13,087,721	\$19,312,631

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

In June 2018, the FASB issued ASU No. 2018-07, Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU No. 2018-07"). This ASU is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within that year. Early adoption is permitted, but not before an entity has adopted ASC 606, and the guidance should be applied using a modified retrospective transition approach. The Company early adopted ASU No. 2018-07 on July 1, 2018 and revalued its unvested nonemployee awards as of the July 1, 2018 adoption date. The adoption did not have a material impact on the condensed consolidated financial statements and therefore a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year was not required.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement. This ASU modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. The guidance is effective for

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annual reporting periods beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted. The Company is currently evaluating the impact of ASU No. 2018-13 on its consolidated financial statements and disclosures.

The Company believes that the impact of other recently issued standards that are not yet effective will not have a material effect on its consolidated financial position or results of operations upon adoption.

3. Revenue from contracts with customers

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

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

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

The cumulative effect of applying the new guidance to all contracts that were not completed as of January 1, 2018 was recorded as an adjustment to accumulated deficit of approximately \$40,000 as of the adoption date, which was primarily the result of reducing deferred revenue by approximately \$70,000 and deferred cost of product revenue and selling fees by approximately \$30,000, that were recorded on the consolidated balance sheet at December 31, 2017. The Company would have recognized approximately \$1,000 and \$29,000 of additional total revenue during the three and nine months ended September 30, 2018, respectively, if the Company had continued to recognize revenue under ASC 605.

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

Revenue recognition

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

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

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

1. Identify the contract with a customer

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

2. Identify the performance obligations in the contract

Performance obligations promised in a contract are identified based on the goods that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract, whereby the transfer

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of the goods is separately identifiable from other promises in the contract. The Company has concluded the sale of bottled finished goods and related shipping and handling are accounted for as a single performance obligation.

3. Determine the transaction price

The transaction price is determined based on the consideration to which the Company will be entitled to receive in exchange for transferring goods to the customer. For sales through June 18, 2018, the Company offered refunds to e-commerce customers, upon request, within 30 days of delivery. For sales subsequent to June 18, 2018, the Company now offers refunds to e-commerce customers, upon request, within 14 days of delivery. The Company estimates the amount of potential refunds at each reporting period using a portfolio approach of historical data, adjusted for changes in expected customer experience, including seasonality and changes in economic factors, as necessary. For specialty retailers and sports teams, the Company does not offer a right of return or refund and revenue is recognized at the time products are delivered to customers.

Discounts provided to customers are accounted for as an element of the transaction price and as a reduction to revenue, and were approximately \$2,000 and \$19,000 for the three and nine months ended September 30, 2018, respectively, and approximately \$82,000 and \$202,000 for the three and nine months ended September 30, 2017, respectively.

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

4. Determine the satisfaction of performance obligation

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

Concentrations of credit risk

The Company had no customers that represented greater than 10% of total revenue during the three and nine months ended September 30, 2018 or the three and nine months ended September 30, 2017. The vast majority of revenue was generated from sales within the United States.

4. Fair value measurements

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

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

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

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

The following tables summarize the cash equivalents and marketable securities measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017:

			Balance as
Level 1	Level 2	Level 3	Level of September 30, 2018
Cash equivalents	\$2,321,614	\$ —	—\$2,321,614
	\$2,321,614	\$ —	—\$2,321,614

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	Level 1	Level 2	Level of 3	Balance as December 31, 2017
Cash equivalents	\$5,046,205	\$—	\$	—\$5,046,205
Marketable securities:				
U.S. government agency securities	—	8,986,259	—	8,986,259
Commercial paper	—	4,440,689	—	4,440,689
Corporate debt securities	—	702,775	—	702,775
	\$5,046,205	\$14,129,723	\$	—\$19,175,928

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services or other market observable data. The third-party pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. The Company's cash equivalents consist of money market funds that are valued based on publicly available quoted market prices for identical securities as of September 30, 2018. After completing its validation procedures, the Company did not adjust or override any fair value carrying amounts as of September 30, 2018.

The carrying amounts reflected in the condensed consolidated balance sheets for cash, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair values at September 30, 2018 and December 31, 2017, due to their short-term nature.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the nine months ended September 30, 2018 or the year ended December 31, 2017. The Company had no financial assets or liabilities that were classified as Level 3 at any time during the nine months ended September 30, 2018 or the year ended December 31, 2017.

5. Cash equivalents and marketable securities

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. Cash equivalents as of September 30, 2018 and December 31, 2017 consisted of money market funds.

The Company held no marketable securities as of September 30, 2018. Marketable securities as of December 31, 2017 consisted of U.S. government agency securities, commercial paper and corporate debt securities. Management determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company classifies its marketable securities as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities. Marketable securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity and a component of total comprehensive income (loss) in the condensed consolidated statement of comprehensive loss, until realized. Realized gains and losses are included in investment income on a specific-identification basis. There were no realized gains on marketable securities during the three and nine months ended September 30, 2018, or during the three and nine months ended September 30, 2017.

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

The Company held no marketable securities at September 30, 2018. Marketable securities at December 31, 2017 consisted of the following:

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	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
As of December 31, 2017				
Current (due within 1 year):				
U.S. government agency securities	\$8,987,254	\$ 38	\$ (1,033)	\$8,986,259
Commercial paper	4,440,689	—	—	4,440,689
Corporate debt securities	703,027	—	(252)	702,775
Total	\$14,130,970	\$ 38	\$ (1,285)	\$14,129,723

At December 31, 2017, the Company held six debt securities that were in an unrealized loss position, all of which had been in a continuous loss position for less than 12 months. The aggregate fair value of debt securities in an unrealized loss position was \$8,191,315 at December 31, 2017. There were no individual securities that were in a significant unrealized loss position as of December 31, 2017.

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

6. Inventory

Inventory has been recorded at cost as of September 30, 2018 and December 31, 2017. Costs capitalized at September 30, 2018 and December 31, 2017 relate to HOTSHOT finished goods, as well as raw materials available to be used for future production runs.

The following table presents inventory:

	September 30, 2018	December 31, 2017
Raw materials	\$7,240	\$17,411
Finished goods	216,279	414,480
Total inventory	\$223,519	\$431,891

In the second quarter of 2018, the Company wrote off raw materials that are not expected to be used in future production runs, as well as finished goods inventory no longer expected to be used for product sampling. In the prior year, the Company wrote off raw materials not expected to be used in future production runs and expiring finished goods not anticipated to be sold.

There were no inventory write-offs during the three months ended September 30, 2018. Write-offs totaled approximately \$85,000 for the nine months ended September 30, 2018, and approximately \$15,000 and \$34,000 for the three and nine months ended September 30, 2017, respectively, and were included in cost of product revenue in the accompanying condensed consolidated statement of operations.

7. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

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	September 30, 2018	December 31, 2017
Phase 2 MND and CMT clinical trial-related costs	\$609,222	\$1,850,115
Payroll and other employee-related costs	430,560	874,246
Professional fees	284,725	227,980
Restructuring-related costs	189,927	—
Other research and development-related costs	23,808	652,285
Consumer product-related costs	16,437	107,595
Total	\$1,554,679	\$3,712,221

Phase 2 MND and CMT clinical trial-related costs

In June 2018, the Company announced that it was ending its ongoing Phase 2 clinical trials of FLX-787 in MND and CMT due to oral tolerability concerns observed in both studies.

The close out of the studies resulted in increased expense during the second quarter of 2018, with the remainder of close out costs occurring in the third quarter of 2018. Accrued costs as of September 30, 2018 totaled approximately \$610,000. All work for the studies was complete as of September 30, 2018. Previously, the Company expected work for the studies to take place through mid-2019.

Restructuring-related costs

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

Also, in June 2018, the Board approved employee retention arrangements and certain increased severance payments related to the corporate restructuring plan, to incentivize certain employees to remain with the Company through a potential sale or merger. Cash retention benefits totaling approximately \$1,210,000 will be payable to these employees upon the occurrence of a change in control event, including a sale or merger of the Company. Of this total, \$500,000 relates to amounts payable only upon a change in control event, and \$710,000 relates to amounts payable upon a change in control event or at certain timepoints through early 2019 if the individuals are employed by the Company and in good standing at the date of payment, even if a change in control event has not occurred. Upon a change in control event and termination without cause, these employees will be eligible for up to approximately \$1,125,000, in the aggregate, of severance benefits.

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

During the three months ended September 30, 2018, the Company recognized expense for restructuring-related activities of approximately \$212,000, which is comprised of approximately \$77,000 of one-time termination benefit costs for terminated employees and approximately \$147,000 in retention benefits for seven retained employees who have retention bonuses not contingent on a change in control event, partially offset by approximately \$12,000 recorded as a credit to termination benefits under ongoing benefit arrangements for terminated employees as certain benefit payments are no longer expected to occur. During the nine months ended September 30, 2018, the Company

recognized expense for restructuring-related activities of approximately \$1,130,000 which is comprised of approximately \$851,000 recorded as termination benefits under ongoing benefit arrangements for terminated

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employees, approximately \$99,000 as one-time termination benefit costs for terminated employees, approximately \$165,000 in retention benefits for seven retained employees who have retention bonuses not triggered by a change in control event and approximately \$15,000 of other restructuring related costs including consulting and legal fees. There are currently no assurances a change in control event will take place. The Company does not consider the payment of severance benefits for retained employees or the payment of retention benefits only payable upon a change in control to be probable for accounting purposes as of September 30, 2018. Unless and until the Company's Board has approved a specific transaction, the Company's probability assessment regarding a change in control event is not expected to change.

The Company expects to incur between approximately \$1,173,000 and \$3,353,000 in total costs for its restructuring-related activities, including approximately \$1,130,000 that was recorded during the second and third quarters of 2018. Approximately \$50,000 is expected to be recorded during the fourth quarter of 2018, based on the Company's current probability assessment regarding a change in control event and termination of retained employees. The range noted above includes approximately \$500,000 related to retention benefits only payable upon a change in control event and \$1,125,000 of severance benefits only payable upon a change in control event and termination under certain circumstances.

The following table outlines the Company's restructuring activities for the nine months ended September 30, 2018:

Opening balance	\$—
Charges:	
Employee termination benefits	950,637
Employee retention benefits	164,813
Other	14,995
Payments	(940,518)
Accrued restructuring balance as of September 30, 2018	\$ 189,927

The Company's accrued restructuring balance as of September 30, 2018 is included as a component of accrued expenses and other current liabilities on the Company's condensed consolidated balance sheet as of September 30, 2018. For the three months ended September 30, 2018, approximately \$133,000 of the restructuring-related charges are included in research and development expenses and approximately \$79,000 are included in selling, general and administrative expenses in the Company's condensed consolidated statement of operations. For the nine months ended September 30, 2018, approximately \$837,000 of the restructuring-related charges are included in research and development expenses and approximately \$293,000 are included in selling, general and administrative expenses in the Company's condensed consolidated statement of operations.

For the three months ended September 30, 2018, approximately \$19,000 of the restructuring-related charges were incurred by our Consumer Operations segment, approximately \$133,000 were incurred by our Drug Development segment and the remaining charges of approximately \$60,000 related to corporate costs. For the nine months ended September 30, 2018, approximately \$75,000 of the restructuring-related charges were incurred by our Consumer Operations segment, approximately \$837,000 were incurred by our Drug Development segment and the remaining charges of approximately \$218,000 related to corporate costs. The Company may incur total restructuring-related charges of up to approximately \$113,000 and \$1,048,000 within our Consumer Operations and Drug Development segments, respectively. The Company may incur up to \$2,192,000 of corporate costs that do not relate to a reportable segment.

Litigation

On June 19, 2018, a putative class action lawsuit was filed against the Company and certain of its current executive officers in the United States District Court for the Southern District of New York, captioned Teofilina Rumaldo v. Flex Pharma, Inc., et al., Case No. 1:18-cv-05493. The complaint purports to be brought on behalf of stockholders

who

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purchased the Company's common stock between November 6, 2017 and June 12, 2018. The complaint generally alleges that the Company and certain of its current officers violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder by making allegedly false and misleading statements or omissions regarding the Company's business, operational and compliance policies. Specifically, the complaint alleges that the Company overstated the viability and approval prospects for its product candidate FLX-787 for the treatment of MND and CMT and, as a result, the Company's public statements were materially false and misleading at all relevant times. The complaint seeks unspecified damages, attorneys' fees and other costs. The court-appointed lead plaintiff has until December 10, 2018, to file an amended complaint. The Company denies any allegations of wrongdoing and intends to vigorously defend against this lawsuit. The Company is unable, however, to predict the outcome of this matter at this time and has not accrued any expense related to this lawsuit as of September 30, 2018.

8. Common stock

As of September 30, 2018, the Company had authorized 100,000,000 shares of common stock, \$0.0001 par value per share. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors. The Company does not intend to declare dividends for the foreseeable future.

Restricted common stock to founders

In March 2014, the Company sold 4,553,415 shares of restricted common stock to the founders of the Company ("recipients"), for \$0.0004 per share, for total proceeds of \$1,950. In April 2014, based upon anti-dilution provisions granted to the 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% vested ratably over four years, during which time the Company had the right to repurchase the unvested shares held by a recipient if the relationship between such recipient and the Company ceased. Such shares were not accounted for as outstanding until they vested. Unvested restricted common stock awards to non-employees were re-measured at each vest date and each financial reporting date. All restricted common stock sold to recipients had vested as of September 30, 2018, and is no longer subject to re-valuation or eligible for repurchase.

The following is a summary of restricted common stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2017	169,654	\$ 0.10
Issued	—	—
Vested	(169,654)	0.10
Forfeited	—	—
Unvested at September 30, 2018	—	\$ —

Restricted common stock to consultants

During 2016, the Company issued 18,194 shares of restricted common stock to non-employee consultants and advisors. Such shares are not accounted for as outstanding until they vest. There were 15,485 shares of restricted common stock issued to consultants outstanding as of September 30, 2018. Prior to July 1, 2018, unvested restricted common stock awards to non-employees were re-measured at each vest date and each financial reporting date. On July 1, 2018, the Company adopted ASU No. 2018-07 using a modified retrospective transition approach. As a result, the Company permanently revalued all unvested stock awards granted to non-employees as

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of July 1, 2018. The adoption-date fair value did not materially change from the fair value as of June 30, 2018 and therefore, a cumulative-effect adjustment was not required.

The following is a summary of restricted common stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2017	5,334	\$ 10.51
Issued	—	—
Vested	(2,625)	9.95
Forfeited	—	—
Unvested at September 30, 2018	2,709	\$ 11.05

9. Stock-based compensation

In March 2014, the Company adopted the Flex Pharma, Inc. 2014 Equity Incentive Plan (the "2014 Plan"), under which it had the ability to grant incentive stock options ("ISOs"), non-qualified stock options, restricted stock awards, restricted stock units and stock appreciation rights to purchase up to 116,754 shares of common stock. In April 2014, the Company amended the 2014 Plan to reserve for the issuance of up to 1,451,087 shares of common stock pursuant to equity awards. In September 2014, the Company further amended the 2014 Plan to reserve for the issuance of up to 2,070,200 shares of common stock pursuant to equity awards. Terms of stock award agreements, including vesting requirements, were determined by the Board, 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 on the date of grant. No further awards will be granted under the 2014 Plan.

In January 2015, the Company's Board adopted, and the Company's stockholders approved, the 2015 Equity Incentive Plan (the "2015 Plan"), which became effective immediately prior to the closing of the Company's initial public offering ("IPO"). The 2015 Plan provides for the grant of ISOs, nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights, performance-based stock awards and other stock-based awards. Additionally, the 2015 Plan provides for the grant of performance-based cash awards. ISOs may be granted only to the Company's employees. All other awards may be granted to the Company's employees, including officers, and to non-employee directors and consultants. As of September 30, 2018, there were 1,480,758 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. Prior to July 1, 2018, unvested awards to non-employees were re-measured at each vest date and at each financial reporting date. On July 1, 2018, the Company adopted ASU No. 2018-07 using a modified retrospective transition approach. As a result, the Company permanently revalued all unvested stock options granted to non-employees as of July 1, 2018. The adoption-date fair value did not materially change from the fair value as of June 30, 2018 and therefore, a cumulative-effect adjustment was not required.

The following table summarizes stock option activity for employees and non-employees for the nine months ended September 30, 2018:

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	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	2,580,491	\$ 6.65	7.55	\$ 803,600
Granted	1,517,544	2.74		
Exercised	(97,310)	1.21		
Forfeited	(714,699)	5.96		
Expired	(705,387)	8.35		
Outstanding at September 30, 2018	2,580,639	\$ 4.28	8.07	\$ —
Exercisable at September 30, 2018	1,126,248	\$ 5.92	6.55	\$ —
Vested or expected to vest at September 30, 2018	2,580,639	\$ 4.28	8.07	\$ —

Total stock-based compensation expense recognized for employee and non-employee restricted common stock, and stock options granted to employees and non-employees is included in the Company's condensed consolidated statements of operations as follows:

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Research and development	\$ 43,369	\$ 386,636	\$ 674,775	\$ 1,172,655
Selling, general and administrative	235,021	618,145	1,023,548	2,094,224
Total	\$ 278,390	\$ 1,004,781	\$ 1,698,323	\$ 3,266,879

As of September 30, 2018, there was approximately \$2,481,000 of total unrecognized compensation cost related to unvested equity awards. Total unrecognized compensation cost will be adjusted for future changes in employee and non-employee forfeitures, if any. The Company expects to recognize that cost over a remaining weighted-average period of 2.90 years.

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

On June 14, 2018, the Company granted 654,544 stock options, in the aggregate, to seven employees as part of the Company's retention arrangements with these employees. These awards vest monthly over 48 months as the employees provide continuous service, and expense is being recognized over this period. The awards are exercisable for one to three-years post termination depending on the employee to which the stock options were granted. The awards vest in full upon a change in control event and termination of the employees under certain circumstances. A change in control event is not currently considered probable for accounting purposes. Unless and until the Company's Board has approved a specific transaction, the Company's probability assessment regarding a change in control event is not expected to change.

Employee stock purchase plan

In 2015, the Company's Board adopted, and the Company's stockholders approved, the 2015 Employee Stock Purchase Plan (the "ESPP"). As of September 30, 2018, no shares of common stock have been purchased under the ESPP.

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10. Income taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Based upon the Company's history of operating losses and the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets. There was no significant income tax provision or benefit for the nine months ended September 30, 2018 or 2017.

In March 2018, the FASB issued ASU No. 2018-05, Income Taxes (Topic 740), Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118. The ASU adds various Securities and Exchange Commission ("SEC") paragraphs pursuant to the issuance of the December 2017 SEC Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which was effective immediately. The SEC issued SAB 118 to address concerns about a reporting entity's ability to timely comply with the accounting requirements to recognize all of the effects of the Tax Cuts and Jobs Act in the period of enactment. SAB 118 allows disclosure that timely determination of some or all of the income tax effects from the Tax Cuts and Jobs Act are incomplete by the due date of the financial statements and, if possible, to provide a reasonable estimate. The Company's accounting for certain income tax effects is incomplete, but it has determined reasonable estimates for those effects and has included provisional amounts in its condensed consolidated financial statements as of September 30, 2018 and December 31, 2017.

11. Net loss per share

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

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

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

	September 30, 2018	September 30, 2017
Options to purchase common stock	2,580,639	2,701,922
Unvested restricted common stock	2,709	430,439
Total	2,583,348	3,132,361

12. Segment Information

The Company operates as two reportable segments:

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

The Drug Development segment, which reflects the costs and expenses related to the Company's efforts to develop innovative and proprietary drug products; previously to treat muscle cramps, spasms and spasticity associated with severe neurological conditions.

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The Company discloses information about its reportable segments based on the way that the Company's Chief Operating Decision Maker, who the Company has identified as the Chief Executive Officer, and management, organize segments within the Company for making operating decisions and assessing financial performance. The Company evaluates the performance of its reportable segments based on revenue and operating income or loss. The accounting policies of the segments are the same as those described herein as well as those described in Note 2 to the audited consolidated financial statements in the 2017 Form 10-K. Corporate and unallocated amounts that do not relate to a reportable segment have been allocated to "Corporate". No asset information has been provided for the Company's reportable segments as management does not measure or allocate such assets on a reportable segment basis.

Information for the Company's reportable segments for the three months ended September 30, 2018 and 2017 are as follows:

Three Months Ended September 30, 2018	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	\$ 250,991	—	—	\$ 250,991
Interest income, net	\$ —	—	28,210	\$ 28,210
Loss from operations	\$ 18,293	864,934	1,783,356	\$ 2,666,583
Three Months Ended September 30, 2017	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	\$413,601	—	—	\$ 413,601
Interest income, net	\$ —	—	77,339	\$ 77,339
Loss from operations	\$2,323,919	4,683,533	2,402,000	\$ 9,409,452

Information for the Company's reportable segments for the nine months ended September 30, 2018 and 2017 are as follows:

Nine Months Ended September 30, 2018	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	\$675,075	—	—	\$ 675,075
Interest income, net	\$ —	—	139,612	\$ 139,612
Loss from operations	\$1,921,286	11,699,499	6,432,299	\$ 20,053,084
Nine Months Ended September 30, 2017	Consumer Operations	Drug Development	Corporate	Consolidated
Total revenue	\$991,671	—	—	\$ 991,671
Interest income, net	\$ —	—	227,535	\$ 227,535
Loss from operations	\$7,072,225	12,472,149	7,088,292	\$ 26,632,666

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

The following discussion and analysis should be read in conjunction with the unaudited financial information and the notes thereto included herein, as well as our audited consolidated financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2017. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" discussed in our Annual Report on Form 10-K for the year ended December 31, 2017, in other subsequent filings with the SEC, and elsewhere in this Quarterly Report on Form 10-Q. These

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statements, like all statements in this report, speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

Introduction

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

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

Results of Operations - An analysis of our financial results comparing the three and nine months ended September 30, 2018 to the three and nine months ended September 30, 2017.

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

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

Overview

We are a biotechnology company that was focused on developing innovative and proprietary treatments for muscle cramps, spasms and spasticity associated with severe neurological conditions. In June 2018, we announced that we were ending our ongoing Phase 2 clinical trials of FLX-787 in patients with motor neuron disease, or MND, primarily with amyotrophic lateral sclerosis, or ALS, and in patients with Charcot-Marie-Tooth disease, or CMT, due to oral tolerability concerns observed in both studies.

In the MND study, 31% of patients randomized to receive the oral disintegrating tablet formulation at 30 mg, taken three times a day, discontinued before the end of the 4-week treatment period due to oral adverse events. A similar proportion of subjects in the CMT study discontinued due to oral adverse events, after being randomized to the 30 mg dose. No patients randomized to the 0.5 mg low-dose control discontinued due to oral adverse events in either study. Additionally, in June 2018, we initiated a process to explore a range of strategic alternatives for enhancing stockholder value, including the potential sale or merger of the Company. Wedbush PacGrow has been engaged to act as our strategic financial advisor. There can be no assurance that the evaluation of potential business alternatives will result in any transaction.

We also announced the restructuring of the organization to reduce our cost structure. In connection with the restructuring plan, we reduced our workforce by approximately 60%, with the reduction completed as of September 30, 2018. While the strategic assessment is ongoing, we will continue to operate with a reduced internal team that will focus their efforts on limited research and development activities and operating the consumer business, which sells HOTSHOT®, our consumer product launched in 2016 to prevent and treat exercise-associated muscle cramps. We cannot predict to what extent we will resume drug development activities for FLX-787 or other drug product candidates.

We operate as the following two reportable segments:

• The Consumer Operations segment, which reflects the total revenue and costs and expense for HOTSHOT and our consumer operations; and

The Drug Development segment, which reflects the costs and expenses related to the Company's efforts to develop innovative and proprietary drug products; previously to treat muscle cramps, spasms and spasticity associated with severe neurological conditions.

We disclose information about our reportable segments based on the way that we organize segments within the Company for making operating decisions and assessing financial performance. See Note 12 to our condensed consolidated financial statements for certain financial information related to our reportable segments.

We have incurred an operating loss since our inception and we anticipate that we will continue to incur operating losses for the foreseeable future. Our net loss was \$2.6 million and \$19.9 million for the three and nine months ended September 30, 2018, respectively, and \$9.3 million and \$26.4 million for the three and nine months ended

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September 30, 2017, respectively. Our accumulated deficit was \$131.0 million as of September 30, 2018. To date, we have financed our operations with net proceeds from the private placement of our preferred stock and our initial public offering. We expect to continue incurring significant expenses as we incur costs to complete our strategic assessment, operate as a public company, support our research and development efforts and continue to sell HOTSHOT. As a result, we will need additional capital to fund our future operations. There can be no assurance that we will be able to secure additional funds or, if such funds are available, whether the terms or conditions will be acceptable to us.

Components of Operating Results

Revenue

We adopted ASC Topic 606, Revenue from Contracts with Customers, or ASC 606, on January 1, 2018 using the modified retrospective method. The primary impact of the adoption of ASC 606 related to the timing of revenue recognized for e-commerce sales, due to e-commerce refund rights. Under ASC 606, we recognize revenue when control of the promised good is transferred to the customer, and it reflects the consideration to which we expect to be entitled to receive in exchange for the good. This has resulted in accelerated revenue recognition for e-commerce sales, as under ASC Topic 605, Revenue Recognition, all revenue and related costs were deferred and recognized once the refund period lapsed. Please refer to Note 3 in the accompanying financial statements for a discussion of the impact of adoption of ASC 606 on our condensed consolidated financial statements.

Revenue includes sales of HOTSHOT finished goods to e-commerce customers, specialty retailers and sports teams, including professional and collegiate teams. Revenue also consists of payments made by customers for expedited shipping and handling. Revenue is recognized when control of the promised goods is transferred to the customer. Control of the promised goods is transferred upon delivery to the customer. For sales through June 18, 2018, we offered refunds to e-commerce customers, upon request, within 30 days of delivery. For sales subsequent to June 18, 2018, we now offer refunds to e-commerce customers, upon request, within 14 days of delivery. We do not offer a right of return or refund to specialty retailers or sports teams. Discounts provided to customers are accounted for as a reduction of product revenue. Total revenue is presented net of any taxes collected from customers and remitted to governmental authorities.

When purchasing via our branded website, customers may purchase HOTSHOT in packs of 3, 6, 12 or 24 bottles, and are offered a first-time purchase discount for a 3 pack. Prior to 2018, we offered a first-time purchase discount for a 6 pack. We also sell HOTSHOT via third-party e-commerce websites, including a retailer that offers international shipping. Generally, we realize higher revenue per bottle from our e-commerce sales as opposed to third-party website, sports team and specialty retailer sales. HOTSHOT is generally sold to specialty retailers and sports teams in multi-pack cases.

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

We cannot predict to what extent we will generate revenue in the future. Additionally, we cannot predict to what extent we will resume drug development activities for FLX-787 or other drug product candidates or to what extent we will promote and sell HOTSHOT or other consumer products in the future. Accordingly, future revenue will fluctuate from quarter to quarter and may come 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.

Cost of Product Revenue

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

Cost of product revenue includes write-offs of inventory that becomes obsolete, that has a cost basis in excess of its estimated realizable value, or that exceeds projected sales. The amount of inventory write-offs will vary based upon factors such as inventory levels, production levels, projected sales of HOTSHOT and shelf-lives of our

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inventory components. If we are not successful in generating sufficient levels of revenue from HOTSHOT or if our other estimates prove to be inaccurate, future inventory write-offs may be required.

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

Research and Development Expenses

Our research and development expenses to date have included the costs incurred related to the development and testing of our extract formulation and expenses related to the testing and development of our drug product candidates, including FLX-787, and more recently, costs related to ending our Phase 2 clinical studies in MND and CMT.

Research and development costs include salaries and other compensation-related costs, such as stock-based compensation for research and development employees and termination benefits, costs of clinical studies of our extract formulation and drug product candidates, drug substance production costs, formulation and production costs of clinical supply, including FLX-787, to support clinical studies, costs for consultants who we 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 have been central to our business model. Drug product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to decrease as a result of ending the Phase 2 clinical trials in MND and CMT, and the related drug development efforts, and the reduction of research and development staff. We cannot predict to what extent we will resume drug development activities for FLX-787 or other drug product candidates.

The probability of success for a drug product candidate that we may decide to pursue in the future will depend on numerous factors, including competition, product safety and efficacy, patent protection, regulatory approval, manufacturing capability and commercial viability. The decision to pursue a drug development program in the future will be dependent upon how much is required to fund each program in response to the scientific and clinical success of a drug product candidate, the ability to obtain regulatory approval as well as an assessment of each product candidate's commercial potential.

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

Selling, General and Administrative Expenses

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

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

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

Interest Income, Net

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

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Results of Operations

Three Months Ended September 30, 2018 Compared to the Three Months Ended September 30, 2017

The following table sets forth the condensed consolidated results of our operations, including information related to our Consumer Operations and Drug Development segments, for the three months ended September 30, 2018 compared to the three months ended September 30, 2017.

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Change	
			\$	%
Net product revenue	\$247,284	\$407,241	\$(159,957)	(39)%
Other revenue	3,707	6,360	(2,653)	(42)%
Total revenue	250,991	413,601	(162,610)	(39)%
Costs and expenses:				
Cost of product revenue	91,937	148,756	(56,819)	(38)%
Research and development	865,765	4,739,360	(3,873,595)	(82)%
Selling, general and administrative	1,959,872	4,934,937	(2,975,065)	(60)%
Total costs and expenses	2,917,574	9,823,053	(6,905,479)	(70)%
Loss from operations	(2,666,583)	(9,409,452)	6,742,869	(72)%
Interest income, net	28,210	77,339	(49,129)	(64)%
Net loss	\$(2,638,373)	\$(9,332,113)	\$6,693,740	(72)%

Total Revenue

Our Consumer Operations segment generated all of our revenue during the three months ended September 30, 2018, totaling \$0.3 million as compared to \$0.4 million for the three months ended September 30, 2017, through sales of HOTSHOT and expedited shipping and handling purchases. The decrease in revenue of \$0.2 million relates to decreased marketing spend and activity during the three months ended September 30, 2018 compared to the three months ended September 30, 2017, as we have reduced our Consumer Operations spending while we have been evaluating strategic alternatives for the business.

Sales via e-commerce represented approximately 84% of our total revenue for the three months ended September 30, 2018 compared to 80% for the three months ended September 30, 2017.

During the three months ended September 30, 2018, we sold approximately 53,000 bottles of HOTSHOT at an average total revenue per bottle of \$4.74, compared to 94,000 bottles at an average total revenue per bottle of \$4.40 during the three months ended September 30, 2017. The increase in average total revenue per bottle is primarily related to specialty retailer promotions during the third quarter of 2017, as well a change to the e-commerce trial pack offer in 2018, resulting in higher revenue per bottle compared to the prior year. The decrease in volume of bottles sold in the comparative periods was primarily due to decreased marketing efforts and resulting demand.

Cost of Product Revenue

All costs of product revenue are recorded by our Consumer Operations segment and relate to the production and sale of HOTSHOT. Cost of product revenue was \$0.1 million for the three months ended September 30, 2018 and \$0.1 million for the three months ended September 30, 2017, and included the cost of HOTSHOT sold, royalty expense, inventory write-offs, and depreciation expense of approximately \$35,000 in each period related to manufacturing equipment used to support production. There were no write-offs of inventory during the three months ended September 30, 2018. Write-offs for the three months ended September 30, 2017 totaled approximately \$15,000 and related to finished goods not expected to be sold due to expiration during the fourth quarter of 2017.

Research and Development Expenses

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Our Drug Development segment incurred the majority of our research and development expenses, which were \$0.9 million for the three months ended September 30, 2018 compared to \$4.7 million for the three months ended September 30, 2017. The 82% decrease of \$3.9 million was primarily related to:

- \$2.3 million decrease in clinical trial costs, primarily related to the decision to end our Phase 2 clinical trials of FLX-787 in MND and CMT, and other supporting studies in the second quarter of 2018;
- \$0.5 million decrease in manufacturing and formulation of drug product to support clinical studies, the majority of which ceased during the second quarter of 2018;
- \$0.3 million decrease in salary and benefit costs due to decreased headcount from prior year, partially offset by restructuring-related charges incurred in the third quarter of 2018;
- \$0.3 million decrease related to stock-based compensation expense, related to decreased headcount compared to the prior year;
- \$0.3 million decrease in consulting expenses due to the winding down of many of our research and development activities due to our ongoing strategic assessment; and
- \$0.2 million decrease in other expenses including employee travel and recruiting costs, related to decreased headcount from the prior year.

Selling, General and Administrative Expenses

Selling, general and administrative includes expenses that are incurred by our Consumer Operations segment as well as corporate and unallocated amounts that do not relate to a reportable segment. Selling, general and administrative expenses were \$2.0 million for the three months ended September 30, 2018 compared to \$4.9 million for the three months ended September 30, 2017. The 60% decrease of \$3.0 million was primarily related to:

- \$1.4 million decrease in marketing and consulting costs within our Consumer Operations segment for HOTSHOT due to decreased marketing efforts;
- \$0.8 million decrease related to salaries and benefits as Consumer Operations and corporate headcount decreased from the prior year, partially offset by restructuring-related charges incurred in the third quarter of 2018;
- \$0.4 million decrease in stock-based compensation expense, related primarily to a decrease in headcount compared to the prior year;
- \$0.3 million decrease in consulting due to cash conservation efforts during strategic assessment;
- \$0.1 million decrease in employee travel and recruiting costs, related to decreased Consumer Operations and corporate headcount from the prior year;
- \$0.1 million decrease in office and other expenses due to cost saving initiatives;
- \$0.1 million decrease in HOTSHOT product sampling within our Consumer Operations segment due to decreased marketing events; and
- \$0.2 million increase in legal and professional expenses to supplement our corporate personnel during strategic assessment.

Loss from Operations

Our consolidated loss from operations for the three months ended September 30, 2018 totaled \$2.7 million. Of this total, \$18.3 thousand of the operating loss was incurred by our Consumer Operations segment, \$0.9 million was incurred by our Drug Development segment and the remaining \$1.8 million related to corporate and unallocated costs. The operating loss incurred by the Consumer Operations segment was primarily driven by marketing, sales, promotional and distribution costs related to HOTSHOT, and personnel-related expenses, including stock-based compensation. These costs were slightly offset by the total revenue generated from HOTSHOT sales during the three months ended September 30, 2018. The operating loss incurred by the Drug Development segment relates to costs incurred to close out the FLX-787 clinical study, other clinical study activities and personnel-related expenses, including stock-based compensation and restructuring-related expenses, as well as consulting costs.

Interest Income, net

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Interest income, net, decreased by \$49,129 in the three months ended September 30, 2018 compared to the three months ended September 30, 2017, as we had lower available cash to invest.

Nine Months Ended September 30, 2018 Compared to the Nine Months Ended September 30, 2017

The following table sets forth the condensed consolidated results of operations, including information related to our Consumer Operations and Drug Development segments, for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017.

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	Change \$	%
Net product revenue	\$664,955	\$978,221	\$(313,266)	(32)%
Other revenue	10,120	13,450	(3,330)	(25)%
Total revenue	675,075	991,671	(316,596)	(32)%
Costs and expenses:				
Cost of product revenue	355,816	373,187	(17,371)	(5)%
Research and development	11,720,535	12,730,554	(1,010,019)	(8)%
Selling, general and administrative	8,651,808	14,520,596	(5,868,788)	(40)%
Total costs and expenses	20,728,159	27,624,337	(6,896,178)	(25)%
Loss from operations	(20,053,084)	(26,632,666)	6,579,582	(25)%
Interest income, net	139,612	227,535	(87,923)	(39)%
Net loss	\$(19,913,472)	\$(26,405,131)	\$6,491,659	(25)%

Total Revenue

Our Consumer Operations segment generated all of our revenue during the nine months ended September 30, 2018, totaling \$0.7 million, as compared to \$1.0 million for the nine months ended September 30, 2017 through sales of HOTSHOT and expedited shipping and handling purchases. The decrease in revenue is due to decreased marketing efforts in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017, as we have reduced spending in our Consumer Operations segment while we have been evaluating strategic alternatives for the business.

Sales via e-commerce represented approximately 85% of our total revenue for the nine months ended September 30, 2018 compared to 82% for the nine months ended September 30, 2017.

During the nine months ended September 30, 2018, we sold approximately 146,000 bottles of HOTSHOT at an average total revenue per bottle of \$4.62, compared to 229,000 bottles at an average total revenue per bottle of \$4.33 during the nine months ended September 30, 2017. The increase in average total revenue per bottle is due to various price promotions that were offered to customers during 2017 to attract new and repeat customers, including a specialty retailer promotion. Additionally, our e-commerce trial pack offer in 2018 generated higher revenue per bottle than the 2017 e-commerce trial pack promotions. The decrease in the number of bottles sold primarily relates to decrease in marketing efforts and resulting demand.

Cost of Product Revenue

All costs of product revenue are recorded by our Consumer Operations segment and relate to the production and sale of HOTSHOT. Cost of product revenue was \$0.4 million for the nine months ended September 30, 2018 compared to \$0.4 million for the nine months ended September 30, 2017. Cost of product revenue during the nine months ended September 30, 2018 includes the cost of HOTSHOT sold, royalty expense, inventory write-offs and depreciation expense of approximately \$105,000 in each period related to manufacturing equipment used to support production. Write-offs for the nine months ended September 30, 2018 totaled approximately \$85,000 and related to raw materials not expected to be used in future production runs, as well as finished goods inventory not

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expected to be used for product sampling. Write-offs for the nine months ended September 30, 2017 totaled approximately \$34,000 and related to raw materials that were not expected to be used in future production runs.

Research and Development Expenses

Our Drug Development segment incurred the majority of our research and development expenses, which were \$11.7 million for the nine months ended September 30, 2018 compared to \$12.7 million for the nine months ended September 30, 2017. The 8% decrease of \$1.0 million was primarily related to:

- \$0.6 million decrease in consulting expenses as we had increased the use of consultants in the prior year to assist with our investigational new drug application and other research activities in 2017;
- \$0.5 million decrease related to stock-based compensation expense, related primarily to the final vesting of restricted common stock issued to the founders in 2014 during the first quarter of 2018, as well as decrease in headcount compared to prior year;
- \$0.2 million decrease in employee travel and recruiting costs, related to decreased Drug Development headcount from the prior year;
- \$0.2 million decrease in research activities related to our Consumer Operations segment, as we conducted a research study of our consumer product in prior year;
- \$0.3 million increase in clinical activities and related work, primarily related to clinical trial costs for our Phase 2 clinical trials of FLX-787 in MND and CMT, which commenced during the first quarter of 2017 with start-up activities, increased in activity from mid-2017 through May 2018, and incurred increased expense in June 2018 through September 2018 due to the decision to end our Phase 2 clinical trials; and
- \$0.2 million increase related to salaries and benefits, mainly due to restructuring-related expenses, including termination benefit expenses, incurred during the second and third quarters of 2018.

Selling, General and Administrative Expenses

Selling, general and administrative includes expenses that are incurred by our Consumer Operations segment as well as corporate and unallocated amounts that do not relate to a reportable segment. Selling, general and administrative expenses were \$8.7 million for the nine months ended September 30, 2018 compared to \$14.5 million for the nine months ended September 30, 2017. The 40% decrease of \$5.9 million was primarily related to:

- \$2.9 million of decreased marketing and consulting costs within our Consumer Operations segment for HOTSHOT due to decreased activity during the strategic assessment;
- \$1.7 million decrease related to salaries and benefits, as Consumer Operations and corporate headcount decreased from the prior year, including executive level employees, partially offset by restructuring-related expenses, including termination and retention benefit expenses, incurred during the second and third quarters of 2018;
- \$1.1 million decrease in stock-based compensation expense, related primarily to a decrease in headcount compared to the prior year and the final vesting of restricted common stock issued to the founders in 2014 during the first quarter of 2018;
- \$0.4 million decrease in employee travel and recruiting costs, related to decreased Consumer Operations and corporate headcount from the prior year;
- \$0.2 million decrease in HOTSHOT product sampling within our Consumer Operations segment due to decreased marketing events,
- \$0.2 million decrease in rent, office and other expenses due to the termination of our lease agreement for our office in New York, NY in the third quarter of 2017;
- \$0.1 million decrease in distribution cost within our Consumer Operations segment due to decreased sales;
- \$0.1 million decrease in consulting due to cash conservation efforts during strategic assessment; and
- \$0.8 million increase in legal and professional expenses to supplement our corporate personnel.

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Loss from Operations

Our consolidated loss from operations for the nine months ended September 30, 2018 totaled \$20.1 million. Of this total, \$1.9 million of the operating loss was incurred by our Consumer Operations segment, \$11.7 million was incurred by our Drug Development segment and the remaining \$6.4 million related to corporate and unallocated costs. The operating loss incurred by the Consumer Operations segment was driven by sales, marketing, promotional and distribution costs related to HOTSHOT, and personnel-related expenses, including stock-based compensation. These costs were slightly offset by the total revenue generated from HOTSHOT sales during the nine months ended September 30, 2018. The operating loss incurred by the Drug Development segment relates to costs incurred for FLX-787 formulation, production and clinical study costs, including increased costs associated with ending our MND and CMT Phase 2 clinical trials, other clinical study activities and personnel-related expenses, including stock-based compensation and restructuring-related expenses, as well as consulting costs.

Interest Income, net

Interest income, net, decreased by \$87,923 in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017, as we had lower available cash to invest.

Liquidity and Capital Resources

Overview

Since inception, we have incurred operating losses and we anticipate that we will continue to incur losses for the foreseeable future. To date, we have generated limited revenue from sales of HOTSHOT, and have generated no revenue from any of our drug product candidates. In June 2018, we announced that we were ending our ongoing Phase 2 clinical trials of FLX-787 in patients with MND, primarily with ALS, and in patients with CMT. As a result, we initiated a process to explore a range of strategic alternatives for enhancing stockholder value, including the potential sale or merger of the Company. In the event we do not complete a sale or merger, we (i) may elect to pursue a dissolution and liquidation of the Company or (ii) may continue to market HOTSHOT and operate as a consumer business.

We cannot predict to what extent we will resume drug development activities for FLX-787 or other drug product candidates, and we may not be successful in generating significant revenue from HOTSHOT. Our operating plan assumes limited research and development activities and that the Consumer Operations segment will continue to sell HOTSHOT. We expect that our research and development expenses will continue to decrease as a result of ending our Phase 2 clinical trials in MND and CMT and the related drug development efforts, and the reduction of research and development staff. Our selling, general and administrative expenses may increase as we complete our strategic assessment, operate as a public company, support our research and development efforts and continue to sell HOTSHOT. We will need additional capital to fund our operations. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

Sources of Liquidity

At September 30, 2018, we had \$10.8 million of working capital and our cash and cash equivalents totaled \$13.0 million, which were held in bank deposit accounts and money market funds. The Company held no marketable securities at September 30, 2018. Our cash, cash equivalents and marketable securities balance decreased during the nine months ended September 30, 2018, due primarily to our net loss incurred.

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

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Cash Flows

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Net cash (used in) provided by:		
Operating activities	\$(20,463,768)	\$(21,966,893)
Investing activities	14,120,848	19,827,530
Financing activities	118,010	2,047
Net decrease in cash and cash equivalents	\$(6,224,910)	\$(2,137,316)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2018 was \$20.5 million, a decrease of \$1.5 million compared to the same period in the prior year. The use of cash for the nine months ended September 30, 2018 was primarily related to our net loss for the period of \$19.9 million, offset by non-cash charges consisting of stock-based compensation expense of \$1.7 million, as well as depreciation, amortization and accretion on investments and other non-cash items, which totaled \$0.2 million. Cash used in operations also included a cash outflow of \$2.5 million from changes in operating assets and liabilities.

The \$2.5 million cash outflow from changes in operating assets and liabilities was driven primarily by outflows from decreases in accounts payable of \$0.7 million and accrued expenses and other current liabilities of \$2.2 million. The decrease in accounts payable relates to decreased spending at September 30, 2018 compared to December 31, 2017. The decrease in accrued expenses and other current liabilities relates primarily to delayed billings of 2017 invoices at December 31, 2017, primarily related to clinical trial expenses for the MND and CMT Phase 2 clinical trials coupled with decreased activity due to study close out in third quarter of 2018, and decreases in accrued bonus and accrued vacation due to the terminations related to the corporate restructuring, as well as payment of prior year employee-related accruals, partially offset by the accrual for restructuring-related activities as of September 30, 2018. These outflows were offset by inflows from decreases in prepaid expenses and other current assets of \$0.3 million and inventory of \$0.2 million. The decrease to prepaid expenses and other current assets primarily relates to the timing of clinical projects ending, partially offset by the timing of insurance payments in the first quarter of 2018.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 decreased \$5.7 million, related to a \$5.8 million decrease in net purchases and sales of marketable securities. This included a \$21.4 million decrease in purchases of marketable securities and a \$27.2 million decrease in proceeds from maturities and sales of marketable securities. The Company does not have any marketable securities as of September 30, 2018.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 increased \$0.1 million, related to proceeds from exercises for options of common stock. Proceeds from exercises of options for common stock during the nine months ended September 30, 2018 and September 30, 2017 were \$0.1 million and \$2,047, respectively.

As of September 30, 2018, we had no long-term debt.

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

Funding Requirements

Our future funding requirements are difficult to forecast. We expect that our research and development expenses will decrease in the future due to ending our Phase 2 clinical trials in MND and CMT and related drug development, and the reduction in research and development headcount, while our general and administrative costs may increase as we complete our strategic assessment, operate as a public company, support research and

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development activities and continue to sell HOTSHOT. We will need additional capital to fund our operations. There can be no assurances, however, that additional funding will be available on terms we deem to be acceptable, or at all. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Drug Product Candidates

We cannot predict to what extent we will resume drug development activities for FLX-787 or other drug product candidates. To the extent that we pursue drug development activities in the future, the successful development of any drug product candidate is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of future drug product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of drug product candidates. This is due to the numerous risks and uncertainties associated with developing drug products, including the uncertainty of:

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

Consumer Brand and Products

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

Concurrent with our efforts to grow HOTSHOT, on January 22, 2018, we disclosed that we engaged an investment banking firm to assist with the consideration of strategic alternatives for our consumer business segment. Due to the announcement in June 2018 regarding the initiation of our corporate strategic review, we are now assessing the consumer business segment in conjunction with the corporate assessment process.

Outlook

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

Contractual Obligations

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

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In connection with our strategic assessment, we entered into retention and severance agreements with certain employees. Based upon the terms of these agreements, we may be required to pay up to \$2.3 million in retention and severance payments. See Note 7 to the accompanying unaudited condensed consolidated financial statements for more information on our retention and severance arrangements.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Readers should refer to our 2017 Form 10-K under "Management's Discussion and Analysis of Financial Condition and Results of Operation—Critical Accounting Policies and Use of Estimates" and Note 2 to the accompanying financial statements for descriptions of these policies and estimates.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2018, we had cash and cash equivalents of \$13.0 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. As of September 30, 2018, our cash was only invested in money market funds, and we did not have any marketable securities. Therefore, we have minimal market risk related to the fair market value of our portfolio.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

As of September 30, 2018, we have evaluated, under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, the effectiveness of the design and operation of

our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon our evaluation, the

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Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the nine months ended September 30, 2018, there was no significant change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On June 19, 2018, a putative class action lawsuit was filed against us and certain of our current executive officers in the United States District Court for the Southern District of New York, captioned Teofilina Rumaldo v. Flex Pharma, Inc., et al., Case No. 1:18-cv-05493. The complaint purports to be brought on behalf of stockholders who purchased our common stock between November 6, 2017 and June 12, 2018. The complaint generally alleges that we and certain of our current officers violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder by making allegedly false and misleading statements or omissions regarding our business, operational and compliance policies. Specifically, the complaint alleges that we overstated the viability and approval prospects for our product candidate FLX-787 for the treatment of MND and CMT and, as a result, our public statements were materially false and misleading at all relevant times. The complaint seeks unspecified damages, attorneys' fees, and other costs. The court-appointed lead plaintiff has until December 10, 2018 to file an amended complaint.

We deny any allegations of wrongdoing and intend to vigorously defend against this lawsuit. We are unable, however, to predict the outcome of this matter at this time. Moreover, any conclusion of this matter in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business. In addition, the litigation could adversely impact our reputation and divert management's attention and resources from other priorities, including the execution of business plans and strategies that are important to our business, any of which could have a material adverse effect on our business.

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 Part I, Item 1A. (Risk Factors) in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, or the Annual Report.

There have been no material changes to the risk factors included in our Annual Report and in item 1A of Part II of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, except as follows:

We recently implemented a plan to reduce our workforce and initiated a process to explore a range of strategic alternatives, including the potential sale or merger of the Company. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our restructuring plans or strategic evaluation. Following our recent announcement that we are ending our ongoing Phase 2 clinical trial investigations of FLX-787 in MND and CMT, we implemented a reduction in force and terminated 10 employees in order to better align our resources with our operational needs going forward. These reductions in force resulted in the loss of numerous long-term employees, the loss of institutional knowledge and expertise and the reallocation of certain job responsibilities, all of which could negatively affect operational efficiencies and increase our operating expenses such that we may not fully realize anticipated savings from the restructuring and could negatively affect our ability to advance our existing drug candidate.

Additionally, we announced that we plan to explore strategic alternatives that may include a potential sale or merger of the Company, among other potential alternatives that could enhance both near and long-term value for our stockholders. The Board has established a Strategic Committee that will work with management to oversee this

process and has retained Wedbush PacGrow to serve as our strategic financial advisor in the process. We do not have a defined timeline for the exploration of strategic alternatives and are not confirming that the process will result

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in any strategic alternative being announced or consummated. We do not intend to discuss or disclose further developments during this process unless and until our Board has approved a specific action or otherwise determined that further disclosure is appropriate. There can be no assurance that this process will result in a transaction, or that if a transaction does occur, that it will successfully enhance stockholder value. If we are unable to identify and execute such strategic alternatives, we may be forced to cease operations.

If we do not successfully identify and execute a strategic transaction, our Board may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the process to identify a strategic transaction will result in a successfully consummated transaction. If no transaction is completed, our Board may decide to pursue a dissolution and liquidation of the company. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic alternatives. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of the company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of the company. If a dissolution and liquidation were pursued, our Board, in consultation with its advisers, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of the company.

We cannot predict to what extent we will resume drug development activities for FLX-787 or any other drug product candidates, which could materially affect our business, results of operations and financial condition.

In June 2018, we announced that we are ending our ongoing Phase 2 clinical trials of FLX-787 in MND and CMT due to oral tolerability concerns observed in both studies. In the MND study, 31% of patients randomized to receive the oral disintegrating tablet formulation at 30 mg, taken three times a day, discontinued before the end of the 4-week treatment period due to oral adverse events. A similar proportion of subjects in the CMT study discontinued due to oral adverse events, after being randomized to the 30 mg dose. No patients randomized to the 0.5 mg low-dose control discontinued due to oral adverse events in either study.

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

Further, we will need substantial additional financing to complete the development of FLX-787 or any other drug product candidates we may develop. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our development of any drug product candidate and research and development activities or to

cease operations.

We are subject to securities class action litigation, which could distract our management and could result in substantial costs or large judgments against us.

In June 2018, we experienced a substantial decline in our stock price following our announcement that we will be ending our ongoing Phase 2 clinical trial investigations of FLX-787 in MND and CMT. As described above in Part II,

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Item 1. (Legal Proceedings), on June 19, 2018, a class action lawsuit was filed against us and certain of our current executive officers in federal district court in the Southern District of New York. Due to the volatility in our stock price, we may be the target of similar litigation in the future. In connection with such litigation, we could incur substantial costs and such costs and any related settlements or judgments may not be covered by insurance. We could also suffer an adverse impact on our reputation and a diversion of management's attention and resources, which could cause serious harm to our business, operating results and financial condition.

If we fail to meet the requirements for continued listing on The Nasdaq Global Market, or Nasdaq, our common stock could be delisted from trading, which would decrease the liquidity of our common stock.

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

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

If we do not regain compliance prior to the expiration of the initial 180-day compliance periods, and if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are not otherwise eligible, Nasdaq will provide us with a written notification that our securities are subject to delisting from Nasdaq. At that time, we may appeal the delisting determination to a Nasdaq hearings panel.

The failure to maintain our listing on Nasdaq could have an adverse effect on the market price and liquidity of our shares of common stock and reduce our ability to raise additional capital.

In addition, if our common stock is delisted from Nasdaq and the trading price is below \$5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a "penny stock" (generally, any equity security not listed on a national securities exchange or quoted on Nasdaq that has a market price of less than \$5.00 per share, subject to certain exceptions). These requirements may affect the ability of broker-dealers to sell our common stock, thereby limiting liquidity and the ability of stockholders to resell their shares of common stock in the secondary market.

Our share price has been and could remain volatile.

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 2018 through October 31, 2018, the market price of our common stock has fluctuated from a high of \$8.98 per share on March 15, 2018, to a low of \$0.39 per share on September 20, 2018. The outcome of the evaluation of our strategic alternatives, including any perceived benefits of our restructuring plan, the costs associated with our pending litigation; our progress in research and development, the potential sale of a large volume of our common stock by stockholders, our quarterly operating results, changes in general conditions in the economy or the financial markets and other developments affecting us or our competitors could cause the market price of our common stock to fluctuate substantially with significant market losses. If our stockholders sell a substantial number of shares of common stock, especially if those sales are made during a short period of time, those sales could adversely affect the market price of our common stock and could impair our ability to raise capital. In addition, in recent years, the stock

market has experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies for reasons unrelated to their operating performance and may adversely affect the price of our common stock. In addition, we recently became subject to a securities class action litigation, which could result in substantial costs and diversion of management's attention and resources and could materially effect our stock price, business, results of operations and financial condition.

Due to our consumer business, we may be subject to foreign privacy directives and regulations.

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Through our promotional efforts for HOTSHOT®, we may be subject to laws governing the collection, use, disclosure and transmission of personal and/or patient information. In December 2015, the European Union approved a General Data Protection Regulation, or GDPR, to replace the current data protection directive, Directive 95/46/EC, which took effect May 25, 2018. The GDPR governs the use and transfer of personal data and imposes enhanced penalties for noncompliance. We are currently evaluating how to adjust our operations so as to comply with the GDPR.

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

Recent sales of unregistered securities; repurchases of equity securities

None.

Use of Proceeds

In February 2015, we completed our initial public offering pursuant to a registration statement on Form S-1 (File No. 333-201276), which the SEC declared effective on January 28, 2015. In our initial public offering, we issued and sold 5,491,191 shares of common stock (inclusive of 91,191 shares of common stock sold by us pursuant to the exercise of an overallotment option granted to the underwriters in connection with the offering) at a public offering price of \$16.00 per share, for aggregate gross offering proceeds of \$87.9 million. The managing underwriters for our initial public offering were Jefferies LLC, Piper Jaffray & Co., JPM Securities LLC, Cantor Fitzgerald & Co., and Roth Capital Partners, LLC.

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

The remaining use of proceeds from our initial public offering are expected to be used to fund a reduced internal team that will focus their efforts on limited research and development activities and operating our consumer business, which sells HOTSHOT® while we assess strategic business alternatives, which may include a potential sale or merger of the Company.

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

Exhibit
number Description of Document

3.1 (1) Amended and Restated Certificate of Incorporation of the Registrant.

3.2 (2) Amended and Restated Bylaws of the Registrant.

4.1 (3) Form of Common Stock Certificate of the Registrant.

4.2 (4) Amended and Restated Investors' Rights Agreement, dated July 23, 2014, by and among the Company and certain of its stockholders.

31.1 Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.

31.2 Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.

32.1 Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.

101 The following materials from Flex Pharma, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Unaudited Condensed Consolidated Balance Sheets, (ii) Unaudited Condensed Consolidated Statements of Operations (iii) Unaudited Condensed Consolidated Statements of Comprehensive Loss, (iv) Unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Unaudited Condensed Consolidated Financial Statements.

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

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

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

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

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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/ William McVicar
William McVicar, Ph.D.
President and Chief Executive Officer (Principal Executive Officer)

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

Date: November 5, 2018