

Flexion Therapeutics Inc  
Form 10-Q  
May 08, 2015  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2015**

**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: 001-36287**

**Flexion Therapeutics, Inc.**

**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or Other Jurisdiction of**  
**Incorporation or Organization)**

**26-1388364**  
**(I.R.S. Employer**  
**Identification No.)**

**10 Mall Road, Suite 301**

**Burlington, Massachusetts**  
**(Address of Principal Executive Offices)**

**01803**  
**(Zip Code)**

**(781) 305-7777**

**(Registrant's Telephone Number, Including Area Code)**

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 such filing requirements for the past 90 days. Yes  No

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

Edgar Filing: Flexion Therapeutics Inc - Form 10-Q

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

As of May 5, 2015, the registrant had 21,461,419 shares of Common Stock (\$0.001 par value) outstanding.

**Table of Contents**

**FLEXION THERAPEUTICS, INC.**

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

Consolidated Balance Sheets as of March 31, 2015 (Unaudited) and December 31, 2014 3

Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2015 and 2014 (Unaudited) 4

Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014 (Unaudited) 5

Notes to Financial Statements (Unaudited) 6

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations** 12

**Item 3. Quantitative and Qualitative Disclosures about Market Risk** 20

**Item 4. Controls and Procedures** 20

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings** 21

**Item 1A. Risk Factors** 21

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds** 21

**Item 3. Defaults Upon Senior Securities** 21

**Item 4. Mine Safety Disclosures** 22

**Item 5. Other Information** 22

**Item 6. Exhibits** 22

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****Flexion Therapeutics, Inc.****Consolidated Balance Sheets****(Unaudited)**

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 26,963,175	\$ 103,097,522
Marketable securities	105,381,958	48,527,156
Accounts receivable	403,209	
Prepaid expenses and other current assets	1,489,269	502,314
<b>Total current assets</b>	<b>134,237,611</b>	<b>152,126,992</b>
Property and equipment, net	1,663,980	1,109,391
Marketable securities	5,016,200	
Other assets		12,375
Restricted cash	104,000	128,000
<b>Total assets</b>	<b>\$ 141,021,791</b>	<b>\$ 153,376,758</b>
<b>Liabilities, and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,183,842	\$ 1,584,822
Accrued expenses and other current liabilities	1,975,832	3,213,704
Current portion of long-term debt		2,000,000
<b>Total current liabilities</b>	<b>4,159,674</b>	<b>6,798,526</b>
Long-term debt		1,593,333
Other long-term liabilities	28,234	43,008
<b>Total liabilities</b>	<b>4,187,908</b>	<b>8,434,867</b>
Commitments and contingencies		
Preferred Stock, \$.001 par value; 10,000,000 shares authorized at March 31, 2015 and December 31, 2014 and 0 shares issued and outstanding at March 31, 2015 and December 31, 2014		
Stockholders equity:		
	21,461	21,440

Edgar Filing: Flexion Therapeutics Inc - Form 10-Q

Common stock, \$0.001 par value; 100,000,000 shares authorized; 21,461,419 and 21,440,058 shares issued and outstanding, at March 31, 2015 and December 31, 2014, respectively		
Additional paid-in capital	239,447,573	238,402,514
Accumulated other comprehensive income	15,195	(5,240)
Accumulated deficit	(102,650,346)	(93,476,823)
<b>Total stockholders' equity</b>	<b>136,833,883</b>	<b>144,941,891</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 141,021,791</b>	<b>\$ 153,376,758</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents**Flexion Therapeutics, Inc.****Consolidated Statements of Operations and Comprehensive Loss****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Revenue</b>	<b>\$</b>	<b>\$</b>
<b>Operating expenses:</b>		
Research and development	6,255,111	4,150,847
General and administrative	2,759,832	2,283,913
Total operating expenses	9,014,943	6,434,760
<b>Loss from operations</b>	<b>(9,014,943)</b>	<b>(6,434,760)</b>
<b>Other income (expense):</b>		
Interest income	168,363	30,758
Interest expense	(203,468)	(111,667)
Other income (expense), net	(123,475)	(26,575)
Total other income (expense)	(158,580)	(107,484)
<b>Net loss</b>	<b>\$ (9,173,523)</b>	<b>\$ (6,542,244)</b>
Net loss per share basic and diluted	\$ (0.43)	\$ (0.86)
Weighted average common shares outstanding, basic and diluted	21,451,317	7,632,786
<b>Other comprehensive (loss) income:</b>		
Unrealized gains from available-for-sale securities, net of tax of \$0	20,435	842
Total other comprehensive income	20,435	842
<b>Comprehensive loss</b>	<b>\$ (9,153,088)</b>	<b>\$ (6,541,402)</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Table of Contents****Flexion Therapeutics, Inc.****Consolidated Statements of Cash Flows****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (9,173,523)	\$ (6,542,244)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	39,680	27,344
Stock-based compensation expense	1,008,250	436,495
Amortization of premium (discount) on marketable securities	109,330	9,271
Other non-cash charges	12,375	4,125
Changes in operating assets and liabilities:		
Accounts receivable	(403,209)	
Prepaid expenses, other current and long-term assets	(986,955)	(663,202)
Accounts payable	592,786	671,763
Accrued expenses and other current and long-term liabilities	(1,082,972)	(430,366)
Other	(93,333)	
Net cash used in operating activities	(9,977,571)	(6,486,814)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(533,060)	(44,875)
Change in restricted cash	24,000	
Purchases of marketable securities	(89,424,898)	(42,731,544)
Redemption of marketable securities	27,465,000	250,000
Net cash used in investing activities	(62,468,958)	(42,526,419)
<b>Cash flows from financing activities</b>		
Payment of public offering costs	(224,648)	(1,096,588)
Payments on debt	(3,500,000)	
Proceeds from the issuance of common stock		69,517,500
Proceeds from the exercise of stock options	36,830	193,312
Net cash (used in) provided by financing activities	(3,687,818)	68,614,224
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(76,134,347)</b>	<b>19,600,991</b>
Cash and cash equivalents at beginning of period	103,097,522	16,188,254
Cash and cash equivalents at end of period	\$ 26,963,175	\$ 35,789,245

**Supplemental disclosures of cash flow information:**



Cash paid for interest	\$ 292,037	\$ 100,000
<b>Supplemental disclosures of non-cash financing activities:</b>		
Initial public offering costs included in accounts payable or accrued expenses		\$ 158,029
Conversion of convertible preferred stock into common stock		\$ 74,806,213

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Table of Contents**

**Flexion Therapeutics, Inc.**

**Notes to Financial Statements (Unaudited)**

**1. Overview and Nature of the Business**

Flexion Therapeutics, Inc. ( Flexion or the Company ) was incorporated under the laws of the state of Delaware on November 5, 2007. Flexion is a specialty pharmaceutical company focused on the development and commercialization of novel, injectable pain therapies. The Company is targeting anti-inflammatory and analgesic therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a type of degenerative arthritis ( OA ) and post-operative pain. Flexion s broad and diversified portfolio of product candidates addresses the OA pain treatment spectrum, from moderate to severe pain, and provides the Company with multiple opportunities to achieve its goal of commercializing novel, patient-focused pain therapies.

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical industry, including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance reporting capabilities. The Company s product candidates are all in the development stage. There can be no assurance that development efforts, including clinical trials, will be successful. Even if the Company s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The accompanying condensed consolidated financial statements as of March 31, 2015, and for the three months ended March 31, 2015 and 2014, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the SEC ) and Generally Accepted Accounting Principles ( GAAP ) for consolidated financial information including the accounts of the Company and its wholly-owned subsidiary after elimination of all significant intercompany accounts and transactions. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these condensed consolidated financial statements reflect all adjustments which are necessary for a fair statement of the Company s financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company s Annual Report on Form 10-K filed with the SEC on March 24, 2015.

The information presented in the condensed consolidated financial statements and related notes as of March 31, 2015, and for the three months ended March 31, 2015 and 2014, is unaudited. The December 31, 2014 consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2015, or any future period.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. As of March 31, 2015 and December 31, 2014, the Company had cash and cash equivalents and marketable securities of \$137,361,333 and \$151,624,678, respectively. Management believes that current cash, cash equivalents and marketable securities on hand at March 31, 2015 should be sufficient to fund operations for at least the next twelve months. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations and to fund increased research and development costs in order to seek approval for commercialization of its product candidates. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies as this capital is necessary for the Company to perform the research and development activities required to develop the Company's product candidates in order to generate future revenue streams.

## **Table of Contents**

### ***Consolidation***

The accompanying condensed consolidated financial statements include the Company and its wholly-owned subsidiary, Flexion Securities Corporation, Inc. The Company has eliminated all intercompany transactions for the three months ended March 31, 2015 and the year ended December 31, 2014, the year Flexion Securities Corporation, Inc. was established.

### ***U.S. Government Grant***

The Company performs research and development for a U.S. Government agency under a cost reimbursable grant for clinical development of FX006. The related costs incurred under the grant are included in research and development expense in the statements of operations. The Company is reimbursed and offsets research and development expenses in the statement of operations when invoices for allowable costs are prepared and submitted to the U.S. Government agency. Payments under cost reimbursable grants with agencies of the U.S. Government are provisional payments subject to adjustment upon audit by the U.S. government. When the final determination of the allowable costs for any year has been made, research and development expenses may be adjusted accordingly. The grant also provides the U.S. government agency the ability to terminate the grant for various reasons, including if we fail to meet our obligations as set forth in the grant.

### ***Accounts Receivable***

Accounts receivable represents allowable costs under the Company's U.S. Government agency grant for which the Company has not yet received reimbursement. The Company invoices the government on a quarterly basis for reimbursable costs under the grant. Reimbursable costs that have not been invoiced on the last day of the quarter are recorded as unbilled accounts receivable.

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that may affect the reported amounts of assets and liabilities, expenses and related disclosures. The Company bases estimates and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. The most significant estimates in these condensed consolidated financial statements include useful lives with respect to long-lived assets, such as property and equipment and leasehold improvements, accounting for stock-based compensation, and accrued expenses, including clinical research costs. The Company's actual results may differ from these estimates under different assumptions or conditions. The Company evaluates its estimates on an ongoing basis. Changes in estimates are reflected in reported results in the period in which they become known by the Company's management.

### **3. Fair Value of Financial Assets**

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014 and indicate the level of the fair value hierarchy utilized to determine such fair value:

#### **Fair Value Measurements as of March 31, 2015 Using:**

Edgar Filing: Flexion Therapeutics Inc - Form 10-Q

	Level 1		Level 2		Level 3		Total
<b>Assets:</b>							
Cash equivalents	\$	\$	24,628,158	\$	\$	24,628,158	
Marketable securities			110,398,158			110,398,158	
	\$	\$	135,026,316	\$	\$	135,026,316	

7

**Table of Contents**

	Fair Value Measurements as of December 31, 2014 Using:			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash equivalents	\$	\$ 101,687,995	\$	\$ 101,687,995
Marketable securities		48,527,156		48,527,156
	\$	\$ 150,215,151	\$	\$ 150,215,151

As of March 31, 2015 and December 31, 2014, the Company's cash equivalents and marketable securities that were invested primarily in U.S. treasury bills, corporate bonds, money market funds, commercial paper and U.S. Government agency holdings were valued based primarily on Level 2 inputs. The Company measures the fair value of marketable securities using Level 2 inputs and primarily relies on quoted prices in active markets for similar marketable securities. During the three months ended March 31, 2015 and year ended December 31, 2014, there were no transfers between Level 1, Level 2 and Level 3.

The carrying values of accounts receivable, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these balances.

**4. Marketable Securities**

As of March 31, 2015 and December 31, 2014, the fair value of available-for-sale marketable securities by type of security was as follows:

	March 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 23,719,268	\$ 26,992	\$	\$ 23,746,260
U.S. Government Obligations	13,080,203	644	(198)	13,080,649
Corporate bonds	73,583,492	8,966	(21,209)	73,571,249
	\$ 110,382,963	\$ 36,602	\$ (21,407)	\$ 110,398,158

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 8,991,820	\$ 7,570	\$	\$ 8,999,390
U.S. Government Obligations	28,300,921	181	(5,101)	28,296,001
Corporate bonds	11,239,655	2	(7,892)	11,231,765
	\$ 48,532,396	\$ 7,753	\$ (12,993)	\$ 48,527,156

At March 31, 2015 and December 31, 2014, marketable securities consisted of investments that mature within 14 months and twelve months, respectively. The estimated fair value and amortized cost of the Company's marketable

debt securities available-for-sale by contractual maturity are summarized as follows:

	As of March 31, 2015		As of December 31, 2014	
	Fair Value	Amortized Cost	Fair Value	Amortized Cost
Due in one year or less	\$ 105,381,958	\$ 105,370,385	\$ 48,527,156	\$ 48,532,396
Due after one year through 5 years	5,016,200	5,012,578		
<b>Total available-for-sale securities</b>	<b>\$ 110,398,158</b>	<b>\$ 110,382,963</b>	<b>\$ 48,527,156</b>	<b>\$ 48,532,396</b>

**Table of Contents****5. Property and Equipment**

Property and equipment as of March 31, 2015 and December 31, 2014 consisted of the following:

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Computer and office equipment	\$ 251,386	\$ 229,980
Manufacturing equipment	153,140	153,140
Furniture and fixtures	181,366	181,366
Software	98,869	77,454
Leasehold improvements	134,573	134,573
Construction in Progress	1,152,765	601,317
	1,972,099	1,377,830
Less: Accumulated depreciation	(308,119)	(268,439)
<b>Total property and equipment, net</b>	<b>\$ 1,663,980</b>	<b>\$ 1,109,391</b>

Depreciation expense for the three months ended March 31, 2015 and, 2014, was \$39,680 and \$27,344, respectively. During the three months ended March 31, 2015 and 2014, there were no disposals of property and equipment.

**6. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following:

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Clinical research	\$ 582,650	\$ 1,035,510
Contract manufacturing services	270,000	294,900
Payroll and other employee-related expenses	649,205	1,172,978
Preclinical services		119,500
Consultant fees and expenses	74,150	26,900
Professional services fees	325,333	439,874
Interest expense		24,111
Other	74,494	99,931
<b>Total accrued expenses and other current liabilities</b>	<b>\$ 1,975,832</b>	<b>\$ 3,213,704</b>



**Table of Contents****7. Stock-Based Compensation**  
**Stock Option Valuation**

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to the IPO, the Company was a private company and therefore lacked company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of its publicly-traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the simplified method for awards that qualify as plain vanilla options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The relevant data used to determine the value of the stock option grants for the three months ended March 31, 2015 and 2014 are as follows:

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
Risk-free interest rates	1.51-1.83%	1.54-1.87%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.0	6.0
Expected volatility	78.4-81.4%	64.3-66.9%

The following table summarizes stock option activity for the three months ended March 31, 2015:

	<b>Shares</b>	<b>Weighted</b>
	<b>Issuable</b>	<b>Average</b>
	<b>Under</b>	<b>Exercise</b>
	<b>Options</b>	<b>Price</b>
<b>Outstanding as of December 31, 2014</b>	1,289,082	\$ 10.26
Granted	397,425	23.27
Exercised	(21,361)	1.74
Canceled	(28,336)	17.23
<b>Outstanding as of March 31, 2015</b>	1,636,810	\$ 13.41
<b>Options vested and expected to vest at March 31, 2015</b>	1,387,913	
<b>Options exercisable at March 31, 2015</b>	581,956	

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. A total of 21,361 options were exercised during the three months ended March 31,

2015. The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2015 was \$456,078.

At March 31, 2015 and 2014 the Company had options for the purchase of 1,636,810 and 1,190,704 shares of common stock outstanding, respectively, with a weighted average remaining contractual term of 8.4, and 8.7 years, respectively, and with a weighted average exercise price of \$13.41 and \$9.54 per share, respectively.

The weighted average grant date fair value of options granted during the three months ended March 31, 2015 and 2014 was \$23.27 and \$10.49, respectively.

**Table of Contents****Stock-based Compensation**

The Company recorded stock-based compensation expense related to stock options for the three months ended March 31, 2015 and 2014 as follows:

	<b>Three months ended,</b>	
	<b>2015</b>	<b>2014</b>
Research and development	\$ 321,749	\$ 113,518
General and administrative	686,501	322,977
	<b>\$ 1,008,250</b>	<b>\$ 436,495</b>

As of March 31, 2015, unrecognized stock-based compensation expense for stock options outstanding was \$12,643,020, which is expected to be recognized over a weighted average period of 3.2 years. As of March 31, 2014, unrecognized stock-based compensation expense for stock options outstanding was \$7,717,771, which was expected to be recognized over a weighted average period of 3.3 years.

**8. Net Loss Per Share**

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three months ended March 31, 2015 and 2014:

	<b>2015</b>	<b>2014</b>
<b>Numerator:</b>		
Net loss	\$ (9,173,523)	\$ (6,542,244)
Net loss:	\$ (9,173,523)	\$ (6,542,244)
<b>Denominator:</b>		
Weighted average common shares outstanding, basic and diluted	21,451,317	7,632,786
Net loss per share, basic and diluted	\$ (0.43)	\$ (0.86)

Stock options for the purchase of 1,548,014 and 942,165 weighted average shares of common stock were excluded from the computation of diluted net loss per share attributable to common stockholders for the three months ended March 31, 2015 and 2014, respectively, because those options had an anti-dilutive impact due to the net loss incurred for those periods. These options were excluded from the computations because they had an anti-dilutive impact to diluted net loss attributable to common stockholders incurred for those periods.

**9. Long-term Debt**

On January 3, 2013, the Company entered into a credit and security agreement with MidCap Financial SBIC, LP ( MidCap ) under which it immediately borrowed \$5,000,000 as a term loan. The term loan accrued interest monthly at an interest rate of 8.0% per annum and had a term of 45 months. As the term loan had a 15-month interest-only period, the term loan principal balance, along with any accrued interest, was to be paid in 30 equal monthly installments beginning April 1, 2014 and ending September 1, 2016. In addition to these principal payments, the Company was required to make a payment of \$175,000 to the lender on September 1, 2016, which amount was accreted to the carrying value of the debt using the effective interest rate method. On March 31, 2015, the Company paid MidCap \$3,236,019, representing the outstanding principal of the debt along with accrued interest as of that date, the \$175,000 final payment, a prepayment fee of \$30,000 and associated legal expenses to satisfy the Company's obligation under the credit and security agreement.

Prior to the debt repayment, the term loan outstanding under the Company's credit and security agreement with MidCap was reported at its carrying value in the accompanying balance sheet. The Company determined the fair value of the term loan using an income approach, utilizing a discounted cash flow analysis based on current market interest rates for debt issuances with similar remaining years to maturity, adjusted for credit risk. The term loan was valued using Level 2 inputs as of December 31, 2014. The result of the calculation yielded a fair value that approximates carrying value.

#### **10. Subsequent Events**

There were no subsequent events that require disclosure in the financial statements for the period ended March 31, 2015.

---

**Table of Contents**

**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 our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2014 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report of Form 10-K filed by us with the Securities and Exchange Commission, or SEC, on March 24, 2015.*

***Forward-Looking Statements***

*This discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Such forward looking statements, which represent our intent, belief, or current expectations, involve risks and uncertainties. We use words such as may, will, expect, anticipate, estimate, intend, plan, predict, potential, believe, should and similar expressions to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. As a result of many factors, including without limitation those set forth under Risk Factors under Item 1A of Part II below, and under Item 1A of our Annual Report on Form 10-K, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.*

**Overview**

We are a specialty pharmaceutical company focused on the development and commercialization of novel, injectable pain therapies. We are developing anti-inflammatory and analgesic therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a type of degenerative arthritis, referred to as OA. Our broad and diversified portfolio of product candidates addresses the OA pain treatment spectrum, from moderate to severe pain, and provides us with multiple opportunities to achieve our goal of commercializing novel, patient-focused pain therapies. Our pipeline consists of three proprietary product candidates: FX006, a sustained-release, intra-articular, or IA, steroid; FX007, a TrkA receptor antagonist for the post-operative pain setting; and FX005, a sustained-release intra-articular p38 MAP kinase inhibitor. We retain the exclusive worldwide rights to our product candidates.

We were incorporated in Delaware in November 2007, and to date we have devoted substantially all of our resources to our development efforts relating to our product candidates, including conducting clinical trials with our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. From our inception through March 31, 2015, we have funded our operations primarily through the sale of our common stock and convertible preferred stock and, to a lesser extent, debt financing. From our inception through March 31, 2015, we have raised \$244.4 million from such transactions, including from our initial and follow-on public offerings. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or third-party funding, and licensing or collaboration arrangements.

## Product Candidates and Recent Developments

A current summary of our significant research and development programs and recent developments with respect to our related product candidates follows:

Product Candidate	Development Phase	Indication
FX006 Intra-articular injectable steroid	Phase 2b/ Phase 3	OA of the knee
FX007 TrkA receptor antagonist	Preclinical	Post-operative pain
FX005 p38 MAP kinase inhibitor	Phase 2a	End-Stage OA pain

---

**Table of Contents**

**FX006 Front Line IA Therapy for Patients with Moderate to Severe OA Pain**

FX006 is a steroid, triamcinolone acetonide, or TCA, formulated for sustained-release, delivered via IA injection and designed to treat moderate to severe OA pain. FX006 combines commonly administered TCA with our poly lactic-co-glycolic acid, referred to as PLGA, formulation technology, which is the cornerstone of our injectable IA sustained-release technology.

OA is a type of degenerative arthritis that is caused by the progressive breakdown and eventual loss of cartilage in one or more joints. Arthritis is the most common cause of disability in the United States and OA is the most common joint disease, affecting 27 million Americans, with numbers expected to grow as a result of aging, obesity and sports injuries. Recent data suggest that OA accounts for over \$185 billion of annual healthcare expenditures in the United States, which does not include loss of productivity costs. We estimate that by 2030, 45 million people will have OA, and that approximately 24 million of those people will have knee OA. OA commonly affects large weight-bearing joints like the knees and hips, but also occurs in the shoulders, hands, feet and spine. Patients with OA suffer from joint pain, tenderness, stiffness and limited movement. As the disease progresses, it becomes increasingly painful and debilitating, culminating, in many cases, in the need for total joint arthroplasty, or TJA. According to IMS Health, each year approximately ten million patients in the United States receive IA steroid injection treatments in the knee, hip, shoulder, hand and foot. Our clinical trials to date have treated patients with knee OA, which represents the most common joint treated with IA therapies for OA. In 2012, the number of patients that received steroid injections in the knee, the most commonly injected OA joint, increased approximately 12.0% to 3 million patients. We estimate that approximately 1.3 million patients received knee injections of HA in 2012. Sales of HA in the United States in 2013 were approximately \$700 million, with a cost to the patient per treatment ranging from \$500 to \$1000. Worldwide, HA sales were approaching \$2 billion as of 2012, however, recent negative guidance from specialty societies questioning the overall effectiveness of HA therapy (e.g. the American Academy of Orthopedic Surgeons (AAOS), and the Osteoarthritis Research Society International (OARSI) may have put downward pressure on HA sales. We believe that FX006 has the potential to be a superior front line injectable treatment for OA pain management compared to existing therapies by providing safe, more effective and sustained pain relief to patients. We believe the following attributes make FX006 an attractive development candidate:

A first-in-class injectable, IA, sustained-release treatment for patients with moderate to severe OA pain that to date has demonstrated in clinical trials:

clinically meaningful and significantly better pain relief;

persistent therapeutic concentrations of drug in the joint and durable efficacy;

an attractive safety profile with limited systemic exposures and the potential for fewer side effects;

Amongst the largest analgesic effects seen in OA clinical trials;

Strong proprietary position through a combination of patents, trade secrets and proprietary know-how, as well as eligibility for marketing exclusivity;

Well-defined Section 505(b)(2) of the Federal Food Drug and Cosmetic Act, or FDCA, regulatory pathway seeking approval for a novel formulation of the same dose of the already approved immediate-release steroid used by orthopedists and rheumatologists;

Potential for pharmacoeconomic benefits due to superior efficacy and durability and the potential to delay costly and invasive total joint replacement, also referred to as total joint arthroplasty, or TJA.

To date, three clinical trials have been completed to test FX006 against immediate-release TCA injection. A total of 302 patients were enrolled in these three clinical trials, of which 236 patients received FX006 and 66 patients received immediate-release TCA. In a completed Phase 2b dose-ranging clinical trial of patients with knee OA, FX006 demonstrated clinically meaningful and significant improvements in pain relief and functional status relative to a commercially available 40 mg immediate-release TCA. Data from this completed 12-week Phase 2b dose-ranging clinical trial show that FX006 has a well-tolerated systemic safety profile that is indistinguishable from the standard of care immediate-release steroid. Further, the local safety profile for FX006 in the completed 12-week Phase 2b dose-ranging clinical trial was attractive and comparable to that seen with the same dose of immediate-release steroid comparator.

Our pharmacokinetic data suggest that IA administration of FX006 produces a more controlled-release of TCA from the site of injection than immediate-release TCA, prolonging local exposure to TCA while reducing systemic exposure. A pharmacodynamic clinical trial has also demonstrated that FX006 avoids the marked suppression of the hypothalamic-pituitary-adrenal, or HPA, axis (which determines the body's ability to make its own naturally occurring steroids) seen with commercially available steroid suspensions. Preclinical data demonstrate that single doses are well tolerated and, in an



---

**Table of Contents**

inflammatory arthritis rat model, have the potential to prevent joint damage more effectively than the immediate-release comparator. We have conducted two pharmacokinetic clinical trials that compared the duration of FX006 to immediate-release TCA in the joint by measuring synovial fluid concentrations in patients with OA following a single IA administration. TCA concentrations in the joint were determined at 6, 12, 16 and 20 weeks following injection depending on the trial design. The data from these clinical trials show that at 6 and 12 weeks, both the FX006 10 mg and 40 mg dose groups had measurable concentrations of drug in synovial fluid. In contrast, the 40 mg immediate-release TCA dose group at 6 and 12 weeks had concentrations of drug that were below the lower limit of quantitation. The FX006 40 mg dose group also demonstrated readily measurable concentrations of drug at 16 weeks, which fell to below the lower limit of quantitation at 20 weeks. These data, in part, will be used to define the dosing interval for repeat injection.

We are conducting a pivotal Phase 2b clinical trial of FX006 and expect to report topline data for the trial in the fourth quarter of 2015. In 2014, the FDA informed us that it will consider our on-going pivotal Phase 2b trial as one of two pivotal efficacy trials required for registration of a single-dose administration of FX006. In addition, the FDA informed us that a second placebo-controlled pivotal trial would be sufficient to support the filing of an NDA for single-dose administration of FX006 and that data from a repeat-dose safety trial would not be required. In February 2015, we initiated the second required pivotal trial for FX006, a placebo-controlled Phase 3 trial and expect to report topline data in the first half of 2016. We expect to develop and file repeat-dose safety data in a supplemental NDA after an approval and launch of FX006 for single-dose administration.

In April 2015, we announced that the U.S. Department of Defense awarded us a grant worth approximately \$2 million to conduct a Phase 2 clinical trial investigating FX006 as a treatment for OA pain in active military and medically retired veterans with post-traumatic OA of the knee. The trial is a single-center, double-blind, randomized, parallel group, proof-of-concept study, in which, we, as the sponsor of the clinical trial, plan to enroll a total of 124 male and female active and medically retired service members between the ages of 20 and 45 and with moderately symptomatic post-traumatic OA of the knee. The primary objective of this study will be to assess the analgesic effect of a single IA injection of 40 mg of FX006 relative to commercially available immediate-release TCA in this population. The primary endpoint is the average change from baseline in the weekly mean of the average daily (24-hour) pain intensity scores over weeks 5 to 10. The study is also designed to assess the effect of FX006 on function, responder status, global impressions of change, stiffness and consumption of analgesic medications and to assess the safety and tolerability of a single IA injection of 40 mg FX006 relative to commercially available immediate-release TCA.

**FX007 For Post-Operative Pain**

FX007 is a small molecule TrkA receptor antagonist that is in development for the persistent relief of post-operative pain. TrkA is the receptor for nerve growth factor, commonly known as NGF, a small peptide that is released following tissue injury. NGF binds to TrkA on the surface of pain sensing neurons and renders these cells more responsive to external stimuli. In recent clinical trials of Pfizer's monoclonal antibody, tanezumab, systemic blockade of NGF demonstrated marked analgesia in a variety of painful conditions. Additionally, human genetic studies demonstrated that patients with a mutation in the TrkA gene have congenital insensitivity to pain. These data indicate that interruption of the NGF-TrkA pathway produces a profound analgesic effect, and in preclinical pharmacology experiments, FX007 has demonstrated both high affinity for the TrkA receptor and analgesic effects in OA and post-operative pain. However, systemic and persistent blockade of NGF with monoclonal antibodies has been associated with rapidly progressive OA requiring TJA. FX007 is being developed for acute, local administration, which has the potential to avoid side effects associated with chronic systemic use.

Post-operative pain is usually most severe in the first few days following the completion of a surgical procedure and is a response to tissue damage during surgery which stimulates peripheral nerves that signal the brain to produce a

sensory and physiological response. Numerous studies reveal that the incidence and severity of post-operative pain is primarily determined by the type of surgery, duration of surgery and the pain treatment choice following surgery.

There are approximately 51 million surgeries performed in the United States each year, and the global post-operative pain market was estimated to be \$5.9 billion in 2010. Despite the size of this market, however, post-operative pain management remains a challenge for healthcare providers, with studies reporting that up to 80% of patients experience inadequate pain relief after surgery. Given the limitations of current post-operative therapies, we are developing FX007 as a superior alternative to manage post-operative pain. The blockade of the NGF-TrkA pathway results in highly effective analgesia. Additionally, acute local administration has the potential to avoid the side-effects associated with systemic and persistent blockade of NGF.

FX007 is being developed to treat post-operative pain with target analgesia of at least 36 to 72 hours and is being formulated to remain in the tissues for a sufficient period of time to provide this duration of pain relief. We are performing preclinical local pharmacology and toxicology experiments and plan to conduct a PoC clinical trial for FX007 following the generation of these data.

---

**Table of Contents****FX005 For End-Stage OA Pain**

FX005 is intended as therapy for patients with end-stage OA pain, particularly those patients awaiting TJA, as an alternative to opioids. FX005 is a p38 MAP kinase inhibitor formulated for sustained-release delivered via IA injection, which is designed to have both analgesic and anti-inflammatory benefits without the systemic side effects of oral p38 MAP kinase inhibitors. p38 MAP kinase is an enzyme in an inflammatory cascade that up regulates in response to stress and culminates in the elaboration of multiple proinflammatory cytokines, including interleukin 1 and tumor necrosis factor, as well as enzymes like matrix metalloproteinases that have the potential to destroy cartilage. In other studies, multiple oral p38 MAP kinase inhibitors have been evaluated in inflammatory diseases and pain and, while efficacy has been demonstrated, serious toxicity affecting multiple organ systems has been frequently observed. For example, a clinical study of an orally administered p38 MAP kinase inhibitor in OA demonstrated pain relief comparable to oxycodone but was associated with concerning side effects, including QTc prolongation which could increase the risk of arrhythmias. Because FX005 leverages the same PLGA technology used in FX006 in order to achieve persistent therapeutic concentrations of drug in the joint while maintaining very low plasma concentrations, it may have the potential to provide durable pain relief while avoiding p38 MAP kinase inhibitor systemic side effects. We believe the preclinical and clinical data we have generated to date support this potential.

In May 2012, FX005 completed a Phase 2a clinical trial in which 70 patients were randomized to FX005 and 70 patients were randomized to placebo. The Phase 2a clinical trial demonstrated positive effects of FX005 on both pain and function. These effects were substantially enhanced in a pre-specified exploratory subset analysis of patients with high baseline pain. FX005 also demonstrated efficacy in responder analysis. Overall, FX005 was well-tolerated systemically and local tolerability was similar to that documented for marketed HA preparations. Repeat-dose toxicology studies demonstrated that FX005 can be associated with synovial inflammation, articular cartilage damage and alterations to joint structure. These findings were not present in animals treated with blank PLGA microspheres, so toxicity appears to be specific to the p38 MAP kinase inhibitor itself. To guide the appropriate future development path for FX005, additional toxicology studies using lower doses of FX005 were conducted to determine the appropriate dose level. These additional toxicology studies showed that at the human equivalent dose of 3 and 1 mg, there was no evidence of the damage to cartilage that had been associated with doses greater than or equal to 10 mg. Based on this, we expect that further development of FX005, if any, would involve a dose substantially lower than the doses studied in the previously-conducted Phase 2a clinical trial. We will continue to evaluate further development of FX005 taking into consideration, among other factors, our available capital resources.

**Financial Overview*****Revenue***

We have not generated any revenue since our inception. We do not have any products approved for sale, and we do not expect to generate any revenue from the sale of products in the near future. In the future, if our research and development efforts result in clinical success and regulatory approval, we may generate revenue from the sales of our product candidates, or we may generate revenue from licensing rights to our product candidates to third parties. If we fail to complete the development of FX006 or our other product candidates, our ability to generate future revenue, and our results of operations and financial position will be adversely affected.

***Operating Expenses***

The majority of our operating expenses to date have been related to in-licensing certain of our product candidates and the development activities of FX006, FX007 and FX005.

***Research and Development Expenses***

Since our inception, we have focused our resources on our development activities, including: preclinical studies and clinical trials and chemistry manufacturing and controls, or CMC. Our development expenses consist primarily of:

expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical studies and clinical trials;

**Table of Contents**

costs of acquiring, developing and manufacturing clinical trial materials;

personnel costs, including salaries, benefits, stock-based compensation and travel expenses for employees engaged in scientific research and development functions;

costs related to compliance with regulatory requirements;

expenses related to the in-license of certain technologies from pharmaceutical companies; and

allocated expenses for rent and maintenance of facilities, insurance and other general overhead.

We expense research and development costs as incurred. Our direct research and development expenses consist primarily of external-based costs, such as fees paid to investigators, consultants, investigative sites, CROs and companies that manufacture our clinical trial materials, and are tracked on a program-by-program basis. We do not allocate personnel costs, facilities or other indirect expenses to specific research and development programs. These indirect expenses are included within the amounts designated as Personnel and other costs in the table below.

The following table summarizes our research and development expenses for the periods presented:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
Direct research and development expenses by program:		
FX006	\$ 3,909,460	\$ 2,811,027
FX007	159,421	228,974
FX005	143,156	71,161
<b>Total direct research and development expenses</b>	<b>4,212,037</b>	<b>3,111,162</b>
Personnel and other costs	2,043,074	1,039,685
<b>Total research and development expenses</b>	<b>\$ 6,255,111</b>	<b>\$ 4,150,847</b>

Related costs incurred under the grant from the U.S. Department of Defense are included in research and development expenses. We are reimbursed and offset research and development expenses when invoices for allowable costs are prepared and submitted to the U.S. Department of Defense. Payments under cost reimbursable grants with agencies of the U.S. government are provisional payments subject to adjustment upon audit by the U.S. government. When the final determination of the allowable costs for any year has been made, research and development expenses may be adjusted accordingly. The grant also provides the U.S. government agency the ability to terminate the grant for various reasons, including if we fail to meet our obligations as set forth in the grant.

Our research and development expenses are expected to increase in the foreseeable future. Specifically, our costs associated with FX006 will increase as we conduct our pivotal Phase 2b and Phase 3 clinical trials, further the manufacturing process in anticipation of validation and commercialization, and otherwise advance our FX006

development program. We cannot determine with certainty the duration of and completion costs associated with future clinical trials of FX006. The duration, costs and timing associated with the development and commercialization of FX006 and our other product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials and our ability to obtain regulatory approval. As it relates to FX005 and FX007, we will decide which development programs to pursue and how much funding to direct to each program on an ongoing basis in response to preclinical and clinical success of each product candidate, as well as ongoing assessments of the commercial potential of each product candidate. As a result of these uncertainties, we are currently unable to estimate with any precision our future research and development expenses for any product candidate, when or if we will achieve regulatory approval, generate revenue from sales of any product candidate or achieve a positive cash flow position.

## **Table of Contents**

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of personnel costs, including salaries, related benefits, travel expenses and stock-based compensation of our executive, finance, business development, information technology, legal and human resources functions. Other general and administrative expenses include an allocation of facility-related costs, patent filing expenses, and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase in the future as we continue to build our corporate infrastructure to support the continued development of our product candidates. Additionally, we anticipate increased expenses related to the audit, legal, regulatory, investor relations and tax-related services associated with maintaining compliance with the Securities and Exchange Commission and Nasdaq requirements, director and officer insurance premiums and other costs associated with operating as a publicly-traded company.

### ***Other Income (Expense)***

***Interest income.*** Interest income consists of interest earned on our cash and cash equivalents balances and our marketable securities. The primary objective of our investment policy is capital preservation.

***Interest expense.*** In January 2013, we borrowed \$5.0 million under a credit facility with MidCap Financial SBIC, LP, or MidCap, and began to incur interest related to this borrowing at a fixed rate of 8.0% per annum. On March 31, 2015 we paid MidCap \$3,236,019 to satisfy our obligation related to the credit facility.

***Other expense.*** Other expense consists of the net amortization of premiums related to our marketable securities, and our realized gains (losses) on redemptions of our marketable securities. We will continue to incur expenses related to net amortization of premiums on marketable securities for as long as we hold these investments.

### **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 financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, and the reported revenue and expenses during the reported periods. We evaluate these estimates and judgments, including those described below, on an ongoing basis. We base our estimates on historical experience, known trends and events, contractual milestones and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the estimates, assumptions and judgments involved in the accounting policies described in Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2014 have the greatest potential impact on our financial statements, so we consider them to be our critical accounting policies and estimates. There were no material changes to our critical accounting policies and estimates during the quarter ended March 31, 2015 except for the introduction of accounting for the U.S. Government agency grant.

## **RESULTS OF OPERATIONS**

**Comparison of the three months ended March 31, 2015 and 2014**

The following table summarizes our results of operations for the three months ended March 31, 2015 and 2014 (certain items may not sum correctly due to rounding):

	<b>Three Months Ended March 31,</b>			
	<b>2015</b>	<b>2014</b>	<b>Change</b>	<b>% Change</b>
Revenue	\$	\$		
Operating expenses:				
Research and development	6,255,111	4,150,847	2,104,264	50.7%
General and administrative	2,759,832	2,283,913	475,919	20.8%



**Table of Contents**

	<b>Three Months Ended March 31,</b>			
	<b>2015</b>	<b>2014</b>	<b>Change</b>	<b>% Change</b>
Total operating expenses	9,014,943	6,434,760	2,580,183	40.1%
Loss from operations	(9,014,943)	(6,434,760)	2,580,183	40.1%
<b>Other income (expense):</b>				
Interest income	168,363	30,758	137,605	447.4%
Interest expense	(203,468)	(111,667)	91,801	82.2%
Other expense	(123,475)	(26,575)	96,900	364.6%
<b>Total other income (expense)</b>	<b>(158,580)</b>	<b>(107,484)</b>	<b>51,096</b>	<b>47.5%</b>
Net loss	\$ (9,173,523)	\$ (6,542,244)	2,631,279	40.2%

**Research and Development Expenses**

	<b>Three Months Ended March 31,</b>			
	<b>2015</b>	<b>2014</b>	<b>Change</b>	<b>% Change</b>
	<b>(in thousands)</b>			
<b>Direct research and development expenses by program:</b>				
FX006	\$ 3,909,460	\$ 2,811,027	\$ 1,098,433	39.1%
FX007	159,421	228,974	(69,553)	(30.4%)
FX005	143,156	71,161	71,995	101.2%
<b>Total direct research and development expenses</b>	<b>4,212,037</b>	<b>3,111,162</b>	<b>1,100,875</b>	<b>35.4%</b>
Personnel and other costs	2,043,074	1,039,685	1,003,389	96.5%
<b>Total research and development expenses</b>	<b>\$ 6,255,111</b>	<b>\$ 4,150,847</b>	<b>\$ 2,104,264</b>	<b>50.7%</b>

Research and development expenses were \$6.3 million and \$4.2 million for the three months ended March 31, 2015 and 2014, respectively. The increase in research and development expenses year over year of \$2.1 million was primarily due to \$1.5 million in FX006 program expenses related to the pivotal Phase 2b clinical trial, the preparation and initiation of the Phase 3 trial, and manufacturing expenses related to clinical trial supplies. These costs were partially offset by \$0.4 million in reimbursements due in connection with the U.S. Department of Defense grant. Additionally, there was an increase of \$1.0 million in personnel and other costs primarily related to employee related costs for additional headcount, stock compensation expense and consulting costs.

**General and Administrative Expenses**

General and administrative expenses were \$2.8 million and \$2.3 million for the three months ended March 31, 2015 and 2014, respectively. The increase in general and administrative expenses of \$0.5 million was primarily due to salary and related costs associated with additional headcount and stock compensation expense.

***Other Income (Expense)***

Interest income was \$0.2 and \$0.03 million for the three months ended March 31, 2015 and 2014, respectively. The increase in interest income is primarily due to a larger average investment balance during the first quarter of 2015. Interest expense was \$0.2 and \$0.1 million for the three months ended March 31, 2015 and 2014, respectively. The increase in interest expenses was primarily due to the payment of our debt with MidCap during the first quarter of 2015.

**Liquidity and Capital Resources**

To date, we have not generated any revenue and have incurred losses since our inception in 2007. As of March 31, 2015, we had an accumulated deficit of \$102.7 million. We anticipate that we will continue to incur losses for the foreseeable

**Table of Contents**

future. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt financings, government or other third-party funding, and licensing or collaboration arrangements.

Since our inception through March 31, 2015, we have funded our operations primarily through the sale of our common stock and convertible preferred stock and, to a lesser extent, debt financing. From our inception through March 31, 2015, we have raised \$244.4 million from such transactions, including from our initial and follow-on public offerings during 2014. As of March 31, 2015, we had cash and cash equivalents of \$27.0 million and marketable securities of \$110.4 million.

Based on our current operating plan we anticipate that our existing cash, cash equivalents and marketable securities will fund our operations for at least the next twelve months. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation.

The following table shows a summary of our cash flows for each of the three months ended March 31, 2015 and 2014:

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Cash flows used in operating activities	\$ (9,977,571)	\$ (6,486,814)
Cash flows used in investing activities	(62,468,958)	(42,526,419)
Cash flows (used in) provided by financing activities	(3,687,818)	68,614,224
Net increase (decrease) in cash and cash equivalents	\$ (76,134,347)	\$ 19,600,991

*Net Cash Used in Operating Activities*

Operating activities used \$10.0 million of cash in the three months ended March 31, 2015. The cash flow used in operating activities resulted primarily from our net loss of \$9.2 million for the period and cash used for changes in our operating assets and liabilities of \$2.0 million, offset by non-cash charges of \$1.2 million. Net cash used for changes in our operating assets and liabilities consisted primarily of a \$1.0 million increase in our prepaid expenses and other current assets due primarily to insurance costs. Additionally, accrued expenses and other current liabilities decreased \$1.1 million, primarily due to an increase in vendor invoices received and processed to accounts payable prior to March 31, 2015, as compared to the previous year, and accounts receivable increased by \$0.4 million related to our U.S. Government grant recorded during the first quarter of 2015. These changes were partially offset by a \$0.6 million increase in our accounts payable due to the timing of our payments to manufacturers, CROs and legal counsel. Our non-cash charges consisted of primarily of \$1.0 million of stock-based compensation expense.

Operating activities used \$6.5 million of cash in the three months ended March 31, 2014. The cash flow used in operating activities resulted primarily from our net loss of \$6.5 million for the period and cash used for changes in our operating assets and liabilities of \$0.4 million, offset by non-cash charges of \$0.5 million. Net cash used for changes in our operating assets and liabilities consisted primarily of a \$0.7 million increase in our prepaid expenses and other current assets due primarily to increased insurance costs. Accrued expenses and other current liabilities decreased \$0.4

million, this decrease was primarily attributable to an increase in vendor invoices received and processed to accounts payable prior to March 31, 2014, as compared to the previous year. These changes were partially offset by a \$0.7 million increase in our accounts payable due to the timing of our payments to manufacturers, CROs and legal counsel, as well as an increase in the timely receipt of invoices from our vendors. Our non-cash charges consisted of primarily of \$0.4 million of stock-based compensation expense.

*Net Cash Used in Investing Activities*

Net cash used in investing activities was \$62.4 million in the three months ended March 31, 2015. Net cash used in investing activities consisted primarily of cash used for the purchase of marketable securities of \$89.4 million, partially offset by cash received from the redemption of marketable securities of \$27.5 million. In addition, \$0.5 million of cash was used to purchase manufacturing equipment.

## **Table of Contents**

Net cash used in investing activities was \$42.5 million in the three months ended March 31, 2014. Net cash used in investing activities consisted primarily of cash used for the purchase of marketable securities of \$42.7 million, partially offset by cash received from the redemption of marketable securities of \$0.3 million.

### *Net Cash Used in and Provided by Financing Activities*

Net cash used in financing activities was \$3.7 million compared to net cash provided by financing activities of \$68.6 million for the three months ended March 31, 2015 and 2014, respectively. Net cash used in financing activities in the three months ended March 31, 2015 consisted of \$3.5 million paid to satisfy our obligation to MidCap and \$0.2 million in financing costs associated with our follow-on financing in late 2014. Net cash provided by financing activities in the three months ended March 31, 2014 primarily consisted of \$69.5 million in proceeds from our initial public offering, and \$0.2 million in proceeds received from the exercise of stock options, offset by the payment of fees incurred in connection with our initial public offering of \$1.1 million.

### *Contractual Obligations*

During the three months ending March 31, 2015, there were no material changes, outside of the ordinary course of business, in our outstanding contractual obligations from those disclosed within Management's Discussion and Analysis of Financial Condition and Results of Operations, as contained in our Annual Report on Form 10-K filed by us with the SEC on March 24, 2015.

### **Off-Balance Sheet Arrangements**

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of a majority of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on our investment portfolio.

We do not believe that our cash, cash equivalents and marketable securities have significant risk of default or illiquidity. While we believe our cash and cash equivalents and certificates of deposit do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Disclosure Controls and Procedures**

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded,

processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of March 31, 2015, the end of the period covered by this report.

## **Table of Contents**

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

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

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

### **ITEM 1A. RISK FACTORS**

*You should carefully consider the following risk factors, and the risk factors included in Item 1A of our Annual Report on Form 10-K, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock would likely decline. You should consider all of the factors described below and in Item 1A of our Annual Report on Form 10-K when evaluating our business. The risk factors set forth below represent new risk factors or those containing changes, including material changes, to the similarly titled risk factors included in Item 1A of our Annual Report on Form 10-K.*

#### **Risks Related to Our Financial Condition and Need for Additional Capital**

*We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.*

We have limited operating history. To date, we have focused primarily on developing our lead product candidate, FX006. We have two additional product candidates, FX007 and FX005. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred significant net losses in each year since our inception, including net losses of \$9.2 million for the three months ended March 31, 2015 and \$27.3 million, \$18.2 million and \$15.0 million for fiscal years 2014, 2013 and 2012, respectively. As of March 31, 2015, we had an accumulated deficit of \$102.7 million.

We have devoted most of our financial resources to product development, including our non-clinical development activities and clinical trials. To date, we have financed our operations exclusively through the sale of equity securities and debt. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. To date, none of our product candidates have been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenue is insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenue is also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success.

We expect to continue to incur substantial and increased expenses as we expand our development activities and advance our clinical programs, particularly with respect to FX006. We also expect a continued increase in our expenses associated with our operations as a publicly-traded company. As a result of the foregoing, we expect to

continue to incur significant and increasing losses and negative cash flows for the foreseeable future.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

**Recent Sales of Unregistered Securities**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.



**Table of Contents****ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS****Exhibit**

<b>number</b>	<b>Description of document</b>
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 the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

**Table of Contents**

**SIGNATURES**

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

Flexion Therapeutics, Inc.

Date: May 8, 2015

By: /s/ Frederick W. Driscoll  
Frederick W. Driscoll  
Chief Financial Officer  
(Principal Financial Officer)