Flexion Therapeutics Inc
Form 10-Q
November 09, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 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	**26-1388364**
(State or Other Jurisdiction of	**(I.R.S. Employer**
Incorporation or Organization)	**Identification No.)**
10 Mall Road, Suite 301	
Burlington, Massachusetts	**01803**
(Address of Principal Executive Offices)	**(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 x 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 x No ¨

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 x (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 x No

As of November 2, 2015, the registrant had 21,539,396 shares of Common Stock ($0.001 par value) outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Flexion Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 73,507,121	$ 103,097,522
Marketable securities	58,658,480	48,527,156
Accounts receivable	46,443	
Prepaid expenses and other current assets	802,635	485,814
Total current assets	133,014,679	152,110,492
Property and equipment, net	4,153,389	1,109,391
Restricted cash	80,000	128,000
Total assets	$ 137,248,068	$ 153,347,883
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 1,917,540	$ 1,584,822
Accrued expenses and other current liabilities	4,668,377	3,213,704
Current portion of long-term debt		1,983,500
Total current liabilities	6,585,917	6,782,026
Long-term debt	14,942,401	1,580,958
Other long-term liabilities	13,459	43,008
Total liabilities	21,541,777	8,405,992
Commitments and contingencies		
Preferred Stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2015 and December 31, 2014 and 0 shares issued and outstanding at September 30, 2015 and December 31, 2014		
Stockholders equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized; 21,539,396 and 21,440,058 shares issued and outstanding, at September 30, 2015 and December 31, 2014, respectively	21,539	21,440
Additional paid-in capital	241,905,674	238,402,514

Accumulated other comprehensive income	2,430	(5,240)
Accumulated deficit	(126,223,352)	(93,476,823)
Total stockholders equity	115,706,291	144,941,891
Total liabilities and stockholders equity	$ 137,248,068	$ 153,347,883

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

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Flexion Therapeutics, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$	$	$	$
Operating expenses:				
Research and development	7,828,927	4,658,293	23,724,055	12,423,733
General and administrative	3,196,698	2,304,026	8,860,332	6,822,171
Total operating expenses	11,025,625	6,962,319	32,584,387	19,245,904
Loss from operations	(11,025,625)	(6,962,319)	(32,584,387)	(19,245,904)
Other income (expense):				
Interest income	273,679	153,122	882,001	318,524
Interest expense	(202,399)	(96,926)	(405,867)	(314,630)
Other income (expense), net	(182,067)	(129,484)	(638,276)	(266,443)
Total other income (expense)	(110,787)	(73,288)	(162,142)	(262,549)
Net loss	$ (11,136,412)	$ (7,035,607)	$ (32,746,529)	$ (19,508,453)
Net loss per share basic and diluted	$ (0.52)	$ (0.45)	$ (1.52)	$ (1.50)
Weighted average common shares outstanding, basic and diluted	21,506,721	15,624,963	21,477,830	13,007,892
Other comprehensive (loss) income:				
Unrealized gains from available-for-sale securities, net of tax of $0	8,879	(2,468)	7,670	782
Total other comprehensive (loss) income	8,879	(2,468)	7,670	782
Comprehensive loss	$ (11,127,533)	$ (7,038,075)	$ (32,738,859)	$ (19,507,671)

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

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Flexion Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	
	2015	**2014**
Cash flows from operating activities		
Net loss	$ (32,746,529)	$ (19,508,453)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	130,369	84,943
Stock-based compensation expense	3,099,092	1,752,234
Amortization of premium (discount) on marketable securities	637,208	226,834
Other non-cash charges	31,177	12,374
Changes in operating assets and liabilities:		
Accounts receivable	(46,443)	
Prepaid expenses, other current and long-term assets	(242,642)	(350,534)
Accounts payable	388,905	296,331
Accrued expenses and other current and long-term liabilities	830,030	671,891
Other	(44,458)	
Net cash used in operating activities	(27,963,291)	(16,814,380)
Cash flows from investing activities		
Purchases of property and equipment	(2,415,380)	(326,571)
Change in restricted cash	24,000	
Purchases of marketable securities	(106,465,361)	(72,359,552)
Sale and redemption of marketable securities	95,704,499	20,160,000
Net cash used in investing activities	(13,152,242)	(52,526,123)
Cash flows from financing activities		
Payment of public offering costs	(224,648)	(1,282,785)
Payments on debt	(3,500,000)	(1,000,001)
Payment of debt issuance costs	(107,741)	
Proceeds from the issuance of common stock		69,517,500
Proceeds from the issuance of notes payable	15,003,533	
Proceeds from the exercise of stock options	216,454	282,545
Proceeds from Employee Stock Purchase Plan	137,534	
Net cash provided by financing activities	11,525,132	67,517,259
Net decrease in cash and cash equivalents	(29,590,401)	(1,823,244)
Cash and cash equivalents at beginning of period	103,097,522	16,188,254

Cash and cash equivalents at end of period	$ 73,507,121	$ 14,365,010
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 369,719	$ 287,370
Supplemental disclosures of non-cash financing activities:		
Conversion of convertible preferred stock into common stock	$	$ 74,806,213
Purchases of property and equipment in accounts payable and accrued expenses	$ 810,998	$ 52,011

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

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Flexion Therapeutics, Inc.

Notes to Condensed Consolidated 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 September 30, 2015, and for the three and nine months ended September 30, 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 September 30, 2015, and for the three and nine months ended September 30, 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 and nine months ended September 30, 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 September 30, 2015 and December 31, 2014, the Company had cash and cash equivalents and marketable securities of $132,165,601 and $151,624,678, respectively. Management believes that current cash, cash equivalents and marketable securities on hand at September 30, 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.

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In April 2015, the FASB issued ASU 2015-03, *Interest Imputation of Interest*, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. The update requires retrospective application and represents a change in accounting principle. The update is effective for fiscal years beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. The Company elected to early adopt this standard in the period ending September 30, 2015, accordingly debt issuance costs of $112,309 were deducted from the carrying amount of the debt liabilities at September 30, 2015. In accordance with ASU 2015-03, during the three months ended September 30, 2015, we reclassified $28,875 of our debt issuance costs related to our 2013 term loan from an asset to a reduction of the carrying amount of the 2013 term loan as of December 31, 2014.

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 and nine months ended September 30, 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 the Company fails to meet its 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. As of September 30, 2015 there were no 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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization expense is recognized using the straight-line method over the following estimated useful lives:

	Estimated Useful Life (Years)
Computers, software and office equipment	3
Manufacturing equipment	7
Furniture and fixtures	5

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Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Costs of major additions and improvements are capitalized and depreciated on a straight-line basis over their useful lives. Repairs and maintenance costs are expensed as incurred. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to income. Construction-in-progress, which represents direct costs related to the construction of manufacturing equipment, is not depreciated until the asset is ready for its intended use.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company s assets that are measured at fair value on a recurring basis as of September 30, 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 September 30, 2015 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$	$ 58,760,286	$	$ 58,760,286
Marketable securities		58,658,480		58,658,480
	$	$ 117,418,766	$	$ 117,418,766

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

As of September 30, 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 nine months ended September 30, 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.

The 2013 term loan with MidCap Financial SBIC, LP (2013 term loan) and 2015 term loan with MidCap Financial Trust (2015 term loan), outstanding under the Company s credit and security agreements are reported at their carrying value in the accompanying balance sheet. The Company determined the fair value of the term loans using an income

approach, that utilizes 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 loans were valued using Level 2 inputs as of September 30, 2015 and December 31, 2014. The result of the calculations yielded fair values that approximate carrying value.

4. Marketable Securities

As of September 30, 2015 and December 31, 2014, the fair value of available-for-sale marketable securities by type of security was as follows:

	September 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 44,916,443	$ 8,301	$ (11,341)	$ 44,913,403
Commercial paper	13,744,467	610		13,745,077
	$ 58,660,910	$ 8,911	$ (11,341)	$ 58,658,480

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	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 September 30, 2015 and December 31, 2014, marketable securities consisted of investments that mature within twelve months.

5. Property and Equipment, Net

Property and equipment as of September 30, 2015 and December 31, 2014 consisted of the following:

	September 30, 2015	December 31, 2014
Computer and office equipment	$ 350,345	$ 229,980
Manufacturing equipment	153,140	153,140
Furniture and fixtures	236,810	181,366
Software	274,142	77,454
Leasehold improvements	239,456	134,573
Construction in progress	3,298,304	601,317
	4,552,197	1,377,830
Less: Accumulated depreciation	(398,808)	(268,439)
Total property and equipment, net	$ 4,153,389	$ 1,109,391

Depreciation expense for the three months ended September 30, 2015 and 2014 was $47,945 and $31,897, respectively. Depreciation expense for the nine months ended September 30, 2015 and 2014 was $130,369 and $84,943, respectively. During the nine months ended September 30, 2015 and 2014, there were no disposals of property and equipment. Construction-in progress is primarily comprised of amounts related to the construction of new manufacturing equipment for use by our contract manufacturers.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2015	December 31, 2014

Clinical research	$ 1,145,600	$ 1,035,510
Contract manufacturing services	1,349,875	294,900
Payroll and other employee-related expenses	1,392,377	1,172,978
Preclinical services	103,000	119,500
Consultant fees and expenses	203,750	26,900
Professional services fees	329,568	439,874
Interest expense	78,125	24,111
Other	66,082	99,931
Total accrued expenses and other current liabilities	$ 4,668,377	$ 3,213,704

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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, the Company 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 nine months ended September 30, 2015 and 2014 are as follows:

	Nine months ended September 30,	
	2015	2014
Risk-free interest rates	1.49-1.92%	1.54-2.04%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.0	6.0
Expected volatility	76.4-81.4%	61.9-67.9%

The following table summarizes stock option activity for the nine months ended September 30, 2015:

	Shares Issuable Under Options	Weighted Average Exercise Price
Outstanding as of December 31, 2014	1,289,082	$ 10.26
Granted	556,550	22.81
Exercised	(88,371)	3.03
Canceled	(179,636)	18.42
Outstanding as of September 30, 2015	1,577,625	$ 14.15
Options vested and expected to vest at September 30, 2015	1,363,360	
Options exercisable at September 30, 2015	666,984	

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 88,371 options were exercised during the nine months ended September 30, 2015. The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2015 was

$1,530,551.

At September 30, 2015 and 2014, the Company had options for the purchase of 1,577,625 and 1,238,973 shares of common stock outstanding, respectively, with a weighted average remaining contractual term of 8.1, and 8.3 years, respectively, and with a weighted average exercise price of $10.32 and $9.78 per share, respectively.

The weighted average grant date fair value of options granted during the nine months ended September 30, 2015 and 2014 was $15.67 and $10.15, respectively.

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Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options for the three and nine months ended September 30, 2015 and 2014 as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Research and development	$ 331,551	$ 170,668	$ 940,698	$ 466,465
General and administrative	789,432	504,141	2,158,394	1,285,769
	$ 1,120,983	$ 674,809	$ 3,099,092	$ 1,752,234

As of September 30, 2015, unrecognized stock-based compensation expense for stock options outstanding was $11,499,534, which is expected to be recognized over a weighted average period of 2.7 years. As of September 30, 2014, unrecognized stock-based compensation expense for stock options outstanding was $7,822,984, which was expected to be recognized over a weighted average period of 3.0 years.

8. Net Loss Per Share

Basic and diluted net loss per share was calculated as follows for the three and nine months ended September 30, 2015 and 2014:

	For the three months ended September 30,		For the nine months ended September 30,	
	2015	2014	2015	2014
Numerator:				
Net loss	$ (11,136,412)	$ (7,035,607)	$ (32,746,529)	$ (19,508,453)
Net loss:	$ (11,136,412)	$ (7,035,607)	$ (32,746,529)	$ (19,508,453)
Denominator:				
Weighted average common shares outstanding, basic and diluted	21,506,721	15,624,963	21,477,830	13,007,892
Net loss per share, basic and diluted	$ (0.52)	$ (0.45)	$ (1.52)	$ (1.50)

Stock options for the purchase of 1,715,837 and 1,234,199 weighted average shares of common stock were excluded from the computation of diluted net loss per share for the three months ended September 30, 2015 and 2014, respectively, and 1,658,292 and 1,130,000 weighted average shares of common stock were excluded from the computation of diluted net loss per share for the nine months ended September 30, 2015 and 2014, respectively. These options were excluded from the computations because the options had an anti-dilutive impact due to the net loss

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 (2013 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 approximated carrying value.

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On August 4, 2015, the Company entered into a credit and security agreement with MidCap Financial Trust, as agent, MidCap Financial Funding XIII Trust and Silicon Valley Bank, as lenders, (the Lenders), to borrow up to $30,000,000 in term loans, (2015 term loan). The Company concurrently borrowed $15,000,000 under an initial term loan. The remaining $15,000,000 under the facility may be drawn down in the form of a second term loan at the Company s option through September 2016, subject to the Company s receipt of positive Phase 3 FX006 clinical trial data meeting the trial s primary endpoint which is sufficient to file a New Drug Application (NDA) for FX006, as well as other customary conditions for funding. The Company granted the Lenders a security interest in substantially all of its personal property, rights and assets, other than intellectual property, to secure the payment of all amounts owed under the credit facility. The Company also agreed not to encumber any of its intellectual property without the Lenders prior written consent. The Company must maintain a balance in cash or cash equivalents at Silicon Valley Bank equal to the principal balance of the loan plus 5 percent. The credit and security agreement also contains certain representations, warranties, and covenants of the Company as well as a material adverse event clause. As of September 30, 2015, the Company was compliant with all covenants and there were no material adverse events.

Borrowings under the credit facility accrue interest monthly at a fixed interest rate of 6.25 % per annum. Following an interest-only period of 19 months, principal will be due in 36 equal monthly installments commencing March 1, 2017 and ending February 1, 2020 (the maturity date). Upon the maturity date, the Company will be obligated to pay a final payment equal to 9% of the total principal amounts borrowed under the facility. The final payment amount is being accreted to the carrying value of the debt using the effective interest rate method. As of September 30, 2015, the carrying value of the term loan was $14,942,401 the entire balance of which is classified as long-term debt on the balance sheet as of September 30, 2015. In connection with the credit and security agreement, the Company incurred debt issuance costs totaling $112,309. These costs will be amortized over the estimated term of the debt using the straight-line method which approximates the effective interest method.

As of September 30, 2015, annual payments due under the Company s 2015 term loan are as follows (in thousands):

Year	Aggregate Minimum Payments
2015 (remaining three months)	$ 236,979
2016	953,125
2017	5,017,868
2018	5,541,088
2019	5,224,248
2020	840,061
Total	$ 17,813,369

10. Commitments and Contingencies

Leases

On July 13, 2015 the Company entered into a first amendment to its existing lease for approximately 4,700 square feet of additional office space (the Additional Space) in Burlington Massachusetts as well as approximately 6,700 square feet of temporary space to be leased prior to the delivery of the Additional Space (which is anticipated to be delivered

on May 1, 2016). The amendment extends the term of the original lease through October 31, 2019, contemporaneous with the Additional Space, and also provides the Company with an option to lease an additional 5,400 square feet of office space (the Option Space). On September 30, 2015, the Company exercised its option for the Option Space. In addition, the Company has the option to extend the term of a portion or the entire lease space for one additional three-year period. The Company may terminate the amendment for convenience with nine months notice upon the occurrence of certain events connected to its clinical stage programs. The total cash obligation for the base rent from inception through the lease termination date for the office space committed to under the original lease, and the amendment, including the Option Space is approximately $2,900,000. In addition to the base rent, the Company is also responsible for its share of operating expenses and real estate taxes.

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As of September 30, 2015, annual aggregate minimum payments due under the Company s lease obligations are as follows (in thousands):

Year	Aggregate Minimum Payments
2015 (remaining three months)	$ 127,999
2016	521,364
2017	736,425
2018	758,299
2019	647,106
Total	$ 2,791,193

Manufacturing and Supply Agreement with Patheon U.K. Limited

On July 31, 2015, the Company and Patheon U.K. Limited (Patheon) entered into a Manufacturing and Supply Agreement (the Manufacturing Agreement) and Technical Transfer and Service Agreement (the Technical Transfer Agreement) for the manufacture of FX006, the Company s lead program, which is an intra-articular (IA), sustained-release steroid for the treatment of osteoarthritis.

Patheon has agreed in the Technical Transfer Agreement to undertake certain technical transfer activities and construction services needed to prepare Patheon s Swindon, United Kingdom facility for the commercial manufacture of FX006 in dedicated manufacturing suites. The Company will provide Patheon with certain equipment and materials necessary to manufacture FX006 and it will pay Patheon a monthly fee for such activities and reimburse Patheon for certain material, equipment and miscellaneous expenses and additional services.

The initial term of the Manufacturing Agreement is 10 years from approval by the U.S. Food and Drug Administration, or FDA, of the Patheon manufacturing suites for FX006. The Company will pay a monthly base fee to Patheon for the operation of the manufacturing suites and a per product fee for each vial based upon a forecast of commercial demand. The Company will also reimburse Patheon for purchases of materials and equipment made on its behalf, certain nominal expenses and additional services. The Company estimates that the aggregate monthly base fees and reimbursement costs for equipment will be approximately 100 million British Pounds (GBP) over the entire term of the Manufacturing Agreement. The Manufacturing Agreement will remain in full effect unless and until it expires or is terminated. Upon termination of the Manufacturing Agreement (other than termination by Flexion in the event that Patheon does not meet the construction and manufacturing milestones or for a breach by Patheon), Flexion will be obligated to pay for the costs incurred by Patheon associated with the removal of our manufacturing equipment and for Patheon s termination costs up to a capped amount.

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 on 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 in our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, 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.

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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 IA 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 September 30, 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 September 30, 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 3	OA of the knee
FX007 TrkA receptor antagonist	Preclinical	Post-operative pain
FX005 Intra-articular p38 MAP kinase inhibitor	Phase 2a	End-Stage OA pain

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 2014, the number of patients that received steroid injections in the knee, the most commonly injected OA joint, increased approximately 7.0% to 3.5 million patients. We estimate that approximately 1.4 million patients received knee injections of hyaluronic, or HA, in 2014. Sales of HA in the United States in 2014 were approximately $750 million, with a cost per treatment ranging from $500 to $1000. Worldwide, HA sales were approximately $1.6 billion as of 2014, however, we believe 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)) has

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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 potential 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, four clinical trials have been completed to test FX006 against either immediate-release TCA injection or placebo (saline). A total of 608 patients were treated in these four clinical trials, of which 442 patients received FX006, 66 patients received immediate-release TCA and 100 patients received placebo. In the initial 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 showed 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 TCA.

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 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.

In September 2015, we reported top-line results from the first of two pivotal clinical trials of FX006 in patients with moderate to severe OA knee pain. In this pivotal Phase 2b trial which enrolled 310 patients, 40 mg of FX006, compared to placebo (saline), demonstrated statistical significance in average pain relief over weeks 1 through 12 ($p = 0.0012$; 2-sided) and over weeks 1 through 24 ($p = 0.0209$; 2-sided). At weekly time points, 40 mg of FX006 also demonstrated superiority to placebo in pain relief beginning at week 1, continuing to week 11 and also at week 13 ($p < 0.05$ at each time point; 2-sided). The primary endpoint of the trial, pain relief at week 12, did not reach statistical significance ($p = 0.0821$; 2-sided). A pre-specified, commonly applied sensitivity analysis (Baseline Observation Carried Forward/Last Observation Carried Forward (BOCF/LOCF)) that addresses missing data due to patient dropouts, however, demonstrated statistical significance for the primary endpoint at week 12 ($p = 0.042$); and at all time points between weeks 1 and 11 and at week 13 significance ($p<0.05$ at each time point; 2-sided). Overall, the 40 mg dose of FX006 performed better than the 20 mg FX006 dose. In particular, the 40 mg dose conferred more durable pain relief. The frequency of treatment-related adverse events across the three groups (FX006 40 mg, FX006 20 mg and placebo) was comparable, and no drug-related serious adverse events were observed in the trial.

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Also in September 2015, we announced that the FDA had granted Fast Track designation for FX006. The FDA s Fast Track program was designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Drugs with the Fast Track designation generally qualify for priority review if supported by clinical data at the time of NDA filing, thereby expediting the FDA review process. Additionally, Fast Track designation allows a company to submit completed sections of a related NDA on a rolling basis.

In August 2015, we secured a notice of allowance for the trademark Zilretta from the United States Patent and Trademark Office.

In July 2015, we completed enrollment for the Phase 3 trial of FX006 which is a randomized, double-blind trial being conducted at over 40 centers worldwide. A total of 486 enrolled patients have been randomized to one of three treatment groups (1:1:1) and treated with a single IA injection of normal saline (placebo), 40 mg of FX006 or 40 mg of TCA (the current standard of care). Each patient is being evaluated for efficacy and safety at seven outpatient visits over 24 weeks after receiving an injection. The primary objective of this study is to assess the magnitude and duration of pain relief of FX006 at 12 weeks against placebo. The secondary objectives of this study are to assess the effect of FX006 on the magnitude and duration of pain relief relative to immediate-release TCA and the effect of FX006 on function, responder status, global impressions of change, stiffness and consumption of analgesic medications relative to both controls. We expect to release topline data from this trial in February 2016.

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 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 patients between the ages of 20 and 50 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 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.

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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 the development of our product candidates 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;
- costs of acquiring, developing and manufacturing clinical trial materials, as well as scale-up for potential commercial supply;
- 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;

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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 anticipated future commercial supplies, 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Direct research and development expenses by program:				
FX006	$ 5,455,292	$ 3,264,497	$ 15,717,870	$ 8,217,735
FX007	103,199	93,780	383,299	517,580
FX005	78,454	22,535	241,610	99,038
Total direct research and development expenses	5,636,945	3,380,812	16,342,779	8,834,353
Personnel and other costs	2,191,982	1,277,481	7,381,276	3,589,380
Total research and development expenses	$ 7,828,927	$ 4,658,293	$ 23,724,055	$ 12,423,733

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 on-going Phase 3 clinical trial, further the manufacturing process in anticipation of validation and commercialization, including the costs for the build-out of the portion of the dedicated manufacturing facility with our contract manufacturer, Patheon UK Limited, make initial investments for commercial product supply, 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.

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, commercial, 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 and commercial 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.

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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.

On August 4, 2015, we borrowed $15.0 million under a credit facility with MidCap Financial Funding XIII Trust and Silicon Valley Bank, and began to incur interest related to this borrowing at a fixed rate of 6.25% per annum. We expect to incur future interest expense related to this borrowing until February 1, 2020.

Other expense. Other expense consists of the net amortization of premiums and discounts 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 nine months ended September 30, 2015 except for the introduction of accounting for the U.S. Government agency grant.

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RESULTS OF OPERATIONS

Comparison of the three and nine months ended September 30, 2015 and 2014

The following tables summarize our results of operations for the three and nine months ended September 30, 2015 and 2014 (certain items may not sum correctly due to rounding):

	Three Months Ended September 30,			
	2015	2014	Change	% Increase/ (Decrease)
Revenue	$	$	$	
Operating expenses:				
Research and development	7,828,927	4,658,293	3,170,634	68.1%
General and administrative	3,196,698	2,304,026	892,672	38.7%
Total operating expenses	11,025,625	6,962,319	4,063,306	58.4%
Loss from operations	(11,025,625)	(6,962,319)	(4,063,306)	58.4%
Other income (expense):				
Interest income	273,679	153,122	120,557	78.7%
Interest expense	(202,399)	(96,926)	(105,473)	108.8%
Other expense	(182,067)	(129,484)	(52,583)	40.6%
Total other income (expense)	(110,787)	(73,288)	(37,499)	51.2%
Net loss	$ (11,136,412)	$ (7,035,607)	$ (4,100,805)	58.3%

	Nine Months Ended September 30,			
	2015	2014	Change	% Increase/ (Decrease)
Revenue	$	$	$	
Operating expenses:				
Research and development	23,724,055	12,423,733	11,300,322	91.0%
General and administrative	8,860,332	6,822,171	2,038,161	29.9%
Total operating expenses	32,584,387	19,245,904	13,338,483	69.3%
Loss from operations	(32,584,387)	(19,245,904)	(13,338,483)	69.3%
Other income (expense):				
Interest income	882,001	318,524	563,477	176.9%
Interest expense	(405,867)	(314,630)	(91,237)	29.0%
Other expense	(638,276)	(266,443)	(371,833)	139.6%

Total other income (expense)	(162,142)	(262,549)	100,407	(38.2)%
Net loss	$ (32,746,529)	$ (19,508,453)	$ (13,238,076)	67.9%

Research and Development Expenses

	Three Months Ended September 30,			
	2015	**2014**	**Change**	**% Increase/ (Decrease)**
Direct research and development expenses by program:				
FX006	$ 5,455,292	$ 3,264,497	$ 2,190,795	67.1%
FX007	103,199	93,780	9,419	10.0%
FX005	78,454	22,535	55,919	248.1%
Total direct research and development expenses	5,636,945	3,380,812	2,256,133	66.7%
Personnel and other costs	2,191,982	1,277,481	914,501	71.6%
Total research and development expenses	$ 7,828,927	$ 4,658,293	$ 3,170,634	68.1%

	Nine Months Ended September 30,			
	2015	2014	Change	% Increase/ (Decrease)
Direct research and development expenses by program:				
FX006	$ 15,717,870	$ 8,217,735	$ 7,500,135	91.3%
FX007	383,299	517,580	(134,281)	(25.9%)
FX005	241,610	99,038	145,572	144.0%
Total direct research and development expenses	16,342,779	8,834,353	7,508,426	85.0%
Personnel and other costs	7,381,276	3,589,380	3,791,896	105.6%
Total research and development expenses	$ 23,724,055	$ 12,423,733	$ 11,300,322	91.0%

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Research and development expenses were $7.8 million and $4.7 million for the three months ended September 30, 2015 and 2014, respectively. The increase in research and development expenses year over year of $3.2 million was primarily due to $2.2 million in FX006 program expenses related to the recently completed Phase 2b clinical trial and on-going Phase 3 clinical trial and manufacturing expenses related to clinical trial supplies. Additionally, there was an increase of $0.9 million in personnel and other costs primarily related to employee related costs for additional headcount and stock compensation expense.

Research and development expenses were $23.7 million and $12.4 million for the nine months ended September 30, 2015 and 2014, respectively. The increase in research and development expenses year over year of $11.3 million was primarily due to $7.5 million in FX006 program expenses related to the recently completed Phase 2b clinical trial, the preparation and initiation of the Phase 3 clinical trial, and manufacturing expenses related to clinical trial supplies, as well as, an increase of $3.8 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 $3.2 million and $2.3 million for the three months ended September 30, 2015 and 2014, respectively. The increase in general and administrative expenses of $0.9 million was primarily due to salary and related costs associated with additional headcount and stock compensation expense.

General and administrative expenses were $8.9 million and $6.8 million for the nine months ended September 30, 2015 and 2014, respectively. The increase in general and administrative expenses of $2.1 million was primarily due to salary and related costs associated with additional headcount and stock compensation expense.

Other Income (Expense)

Interest income was $0.3 million and $0.2 million for the three months ended September 30, 2015 and 2014, respectively, and $0.9 million and $0.3 million for the nine months ended September 30, 2015 and 2014, respectively. The increase in interest income was primarily due to a larger average investment balance during 2015.

Interest expense was $0.2 million and $0.1 million for the three months ended September 30, 2015 and 2014, respectively, and $0.4 million and $0.3 million for the nine months ended September 30, 2015 and 2014, respectively. The increase in interest expense for the three months ended September 30, 2015 was primarily due to interest incurred on the $15.0 million borrowed under our credit facility with MidCap Financial Funding XIII Trust and Silicon Valley Bank which we entered into on August 4, 2015.

Liquidity and Capital Resources

To date, we have not generated any revenue and have incurred losses since our inception in 2007. As of September 30, 2015, we had an accumulated deficit of $126.2 million. We anticipate that we will continue to incur losses for the foreseeable 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 September 30, 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 September 30, 2015, we have raised $244.4 million from such transactions, including amounts from our initial and

follow-on public offerings during 2014. As of September 30, 2015, we had cash and cash equivalents of $73.5 million and marketable securities of $58.7 million.

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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 nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,	
	2015	2014
Cash flows used in operating activities	$ (27,963,291)	$ (16,814,380)
Cash flows used in investing activities	(13,152,242)	(52,526,123)
Cash flows (used in) provided by financing activities	11,525,132	67,517,259
Net decrease in cash and cash equivalents	$ (29,590,401)	$ (1,823,244)

Net Cash Used in Operating Activities

Operating activities used $28.0 million of cash in the nine months ended September 30, 2015. The cash flow used in operating activities resulted primarily from our net loss of $32.7 million for the period partially offset by cash provided by changes in our operating assets and liabilities of $0.9 million, and non-cash charges of $3.9 million. Net cash provided by changes in our operating assets and liabilities consisted primarily of a $0.4 million increase in our accounts payable, and an increase of $0.8 million in accrued expenses. The increase in accounts payable, accrued expenses and other current liabilities was primarily attributable to increased expenses related to clinical research and contract manufacturing services. These changes were partially offset by an increase in accounts receivable and other current assets of $0.3 million. Our non-cash charges consisted primarily of $3.1 million of stock-based compensation expense and $0.8 million in depreciation expense and amortization and accretion related to our investments.

Operating activities used $16.8 million of cash in the nine-months ended September 30, 2014. The cash flow used in operating activities resulted primarily from our net loss of $19.5 million, partially offset by net cash provided by changes in our operating assets and liabilities of $0.6 million, and non-cash charges of $2.1 million. The increase in accounts payable, accrued expenses and other current liabilities was primarily attributable to increased expenses related to clinical research and contract manufacturing services. Net cash used for changes in our operating assets and liabilities consisted primarily of a $0.4 million increase in prepaid expenses and other current assets. The increase in our prepaid expenses and other current assets was primarily due to prepayments we made for insurance. Our non-cash charges consisted of depreciation expense and amortization of premiums on marketable securities, as well as stock based compensation expense.

Net Cash Used in Investing Activities

Net cash used in investing activities was $13.2 million in the nine months ended September 30, 2015. Net cash used in investing activities consisted primarily of cash used for the purchase of marketable securities of $106.5 million, partially offset by cash received from the redemption and sale of marketable securities of $95.7 million. In addition, $2.4 million of cash was used to purchase property and equipment.

Net cash used in investing activities was $52.5 million in the nine months ended September 30, 2014. Net cash used in investing activities consisted primarily of cash used for the purchase of marketable securities of $72.4 million, partially offset by cash received from the redemption of marketable securities of $20.2 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $11.5 million for the nine months ended September 30, 2015 compared to $67.5 million for the nine months ended September 30, 2014. Net cash provided by financing activities in the nine months ended September 30, 2015 consisted of $15.0 borrowed under our credit facility with MidCap Financial Funding XIII Trust and Silicon Valley Bank in August 2015, offset by $3.5 million paid to satisfy our 2013 term loan obligation. In addition, we received $0.4 million in proceeds from the exercise of stock options and the issuance of common stock related to our employee stock purchase plan that was partially offset by $0.2 million in financing costs associated with our follow-on financing in late 2014 and $0.1 million in issuance costs associated with our long-term loan obligation.

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Net cash provided by financing activities in the nine months ended September 30, 2014 consisted of $69.5 million in proceeds from our initial public offering, and $0.3 million in proceeds received from the exercise of stock options, partially offset by the payment of fees incurred in connection with our initial public offering of $1.3 million and the repayment of principal on our term loan of $1.0 million.

Contractual Obligations

In July 2015, we amended the lease for our primary office space which increased the size of our leased premises and extended the lease term through October 31, 2019. On September 30, 2015, we exercised an option to lease an additional 5,400 square feet under this amended lease. The total cash obligation for the base rent from inception through the lease termination date for the office space committed to under the original lease, and the amendment, including the Option Space is approximately $2,900,000.

Also in July, 2015, we and Patheon U.K. Limited, or Patheon, entered into a Manufacturing and Supply Agreement (the Manufacturing Agreement) and Technical Transfer and Service Agreement, or the Technical Transfer Agreement, for the manufacture of FX006.

Under the terms of the Technical Transfer Agreement, Patheon has agreed to undertake certain technical transfer activities and construction services needed to prepare its Swindon, United Kingdom facility for the manufacture of FX006 in dedicated manufacturing suites. This agreement will remain in full effect unless and until it expires or is terminated. Upon termination of this agreement (other than termination by us in the event that Patheon does not meet the construction and manufacturing milestones or for a breach by Patheon), we will pay for the wind down costs related to the removal of our manufacturing equipment and for Patheon s termination costs up to a capped amount.

Under the terms of the Manufacturing and Supply Agreement, following the FDA approval date of the suites, we have agreed to purchase finished, packaged or unpackaged product from Patheon. In addition, The Company will pay a monthly base fee to Patheon for the operation of the manufacturing suites, and will reimburse Patheon for purchases of raw materials and equipment made on its behalf, certain nominal expenses and additional services. The Company estimates that the aggregate monthly base fees and reimbursement costs for equipment will be approximately 100 million GBP over the entire term of the Manufacturing Agreement. Unless earlier terminated, this agreement will expire on the 10th anniversary of the FDA approval date for the initial manufacturing suite.

Future expenditures associated with the purchase of finished product from Patheon are primarily driven by the potential commercial requirements and demand for our products which cannot be fully determined at this time.

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.

Our term loan carries a fixed interest rate and, thus, we are not subject to interest rate risk.

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 marketable securities 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.

Most of our transactions are conducted in the U.S. dollar. We do have certain material agreements with vendors located outside the United States, which have transactions conducted primarily in British Pounds and Euros. As of September 30, 2015 we had approximately $1.1 million in payables to vendors denominated in currencies other than the U.S. dollar. A hypothetical 10% change in foreign exchange rates would not have a material effect on the value of our liability.

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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 September 30, 2015, the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 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 $32.7 million for the nine months ended September 30, 2015 and $27.3 million, $18.2 million and $15.0 million for fiscal years 2014, 2013 and 2012, respectively. As of September 30, 2015, we had an accumulated deficit of $126.2 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.

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We expect to continue to incur substantial and increased expenses as we expand our development activities, advance our clinical programs and scale-up manufacturing, 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.

If we fail to obtain additional financing, we would be forced to delay, reduce or eliminate our product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs, including our on-going and planned clinical trials for FX006.

As of September 30, 2015, we had cash, cash equivalents and marketable securities of $132.2 million and working capital of $126.4 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital requirements at least into 2017, including through completion of our Phase 3 clinical trial for FX006 and assuming no additional pivotal studies are required, the submission of an NDA for FX006 in the second half of 2016. Regardless of our expectations as to how long our cash, cash equivalents and marketable securities will fund our operations, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expect, the FDA could impose additional or different clinical development requirements on us prior to our submission of an NDA for FX006 or we could decide to conduct additional clinical trials or accelerate the timing of planned clinical trials. In any event, we may require additional capital prior to commercializing FX006 or any of our other product candidates.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. For example, while we have the ability to borrow an additional $15.0 million under our credit facility, we may not be able to satisfy the conditions to borrow the additional amounts at the time we desire to do so, including if our on-going Phase 3 clinical trial for FX006 fails to meet its primary endpoint. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek corporate partners for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail, or cease, operations.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

Our credit and security agreement contains restrictions that limit our flexibility in operating our business. We may also be required to repay the outstanding indebtedness earlier than we expect, if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.

On August 4, 2015, we entered into a credit and security agreement with MidCap Financial Trust, as agent, MidCap Financial Funding XIII Trust and Silicon Valley Bank, as agent, to borrow up to an amount of $30.0 million and contemporaneously drew down $15.0 million under the facility. The agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

incur or assume certain debt;

merge or consolidate or acquire all or substantially all of the capital stock or property of another entity;

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enter into any transaction or series of related transactions that would be deemed to result in a change in control of us under the terms of the agreement;

change the nature of our business;

change our organizational structure or type;

amend, modify or waive any of our organizational documents;

license, transfer or dispose of certain assets;

grant certain types of liens on our assets;

make certain investments;

pay cash dividends;

enter into material transactions with affiliates; and

amend or waive provisions of material agreements in certain manners.

The restrictive covenants of the agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial.

A breach of any of these covenants could result in an event of default under the agreement. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, which could potentially include negative results in our on-going or planned clinical trials, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the agreement occurs. In the case of a continuing event of default under the agreement, the lenders could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted the lenders a security interest under the agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the agreement are secured by all of our existing and future assets, excluding intellectual property, which is subject to a negative pledge arrangement.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required. In such an event, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result.

Risks Related to Our Reliance on Third Parties

Our agreements with Patheon may involve unanticipated expenses and delays, including the need for the Patheon facilities to receive regulatory approvals required for manufacturing to commence at the Patheon suites.

We and Patheon have entered into a Manufacturing Agreement and Technical Transfer Agreement for the manufacture of FX006. Under the terms of the Technical Transfer Agreement, Patheon has agreed to undertake certain technical transfer activities and construction services needed to prepare its Swindon, United Kingdom facility for the manufacture of FX006 in dedicated manufacturing suites. We have agreed with Patheon, among other things, to provide them with the equipment necessary to manufacture FX006 in these suites, to pay for construction of the suites, and to make payments related to their establishment and validation of manufacturing processes in the suites.

The Patheon facilities must be approved by the FDA prior to the commercial production and manufacturing of FX006. If the construction of the Patheon suites is delayed, if Patheon experiences unanticipated cost overruns, or if the Patheon suites do not receive regulatory approvals in the timeframe anticipated, if at all, this could have a material adverse effect on our business, financial position and results of operation. In particular, if we are unable to obtain commercial supply of FX006 from Patheon using the new manufacturing suites or if Patheon experiences a delay in obtaining FDA approval for the commercial manufacturing of FX006, we may not realize an appropriate return, or any return, on our significant investment in establishing and validating the Patheon manufacturing suites.

Further, if and when the Patheon facilities are constructed and have received the required FDA approvals, the production under these agreements involves additional risks, many of which would be outside of our control, such as disruptions or delays in production, manufactured products that do not meet our required specifications, the failure of Patheon to comply with cGMP regulations or other regulatory requirements, protection of our intellectual property and manufacturing process, loss of control of our complex manufacturing process and inabilities to fulfill our commercial needs.

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Risks Related to Clinical Development and Regulatory Approval

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development. We have never completed a pivotal clinical program or submitted an NDA.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials. In particular, the results generated in the completed FX006 Phase 2b clinical trials do not ensure that our on-going Phase 3 clinical trial will be successful.

In our earlier Phase 2b dose-ranging clinical trial, the 60 mg dose of FX006 unexpectedly showed inferior efficacy compared to the 40 mg dose. While we have investigated potential causes of this clinical outcome and believe we understand the basis for the performance of the 60 mg dose, we may not be correct. Therefore, we cannot guarantee that the underlying cause is unique to the 60 mg dose and will not impact the 40 mg dose we are studying in our on-going Phase 3 pivotal trial, or will not otherwise result in regulatory delays or the need for additional studies prior to seeking or obtaining regulatory approval.

We have conducted preclinical toxicology studies in healthy dogs with single and repeat doses of FX006, blank microspheres and immediate-release TCA. The findings from the studies related to the administration of TCA were similar between the immediate-release TCA and FX006 groups and known effects of immediate-release TCA. In the single-dose study, local cartilage findings of reduced extracellular matrix had completely reversed by the end of the nine-month recovery period in both the FX006 and TCA study arms. In the repeat-dose toxicity study, three doses were administered either one month or three months apart. A larger reduction in extracellular matrix in cartilage was noted which partially recovered by six months following the last dose, however, structural changes in cartilage were observed with repeat administrations of both FX006 and immediate-release TCA. All of our clinical trials to date have been or are being conducted with single doses of FX006. However, we intend to study FX006 in a separate repeat dose safety clinical trial and to submit repeat dose data in a supplemental NDA after an approval and launch of FX006 for single-dose administration. Immediate-release TCA has a long history of safe clinical use in patients and in a randomized, double-blind clinical trial conducted in 2003 by Raynauld et al administering immediate-release TCA or saline every three months for up to two years in 68 OA patients, it was well-tolerated and demonstrated no deleterious effects in the knee joint when assessed by clinical exam and X-ray evaluation. Nonetheless, it is possible that we could observe similar outcomes to those observed in our preclinical studies with repeated doses of FX006 that would harm our ability to maintain regulatory approval or would limit the commercial potential of FX006.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In addition to the safety and efficacy traits of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. For example, although our completed FX006 pivotal Phase 2b clinical trial showed statistical significant pain relief with the 40 mg dose compared to placebo at weeks 1-11 and week 13, the result was not statistically significant at week 12 and therefore the primary efficacy endpoint of the trial was not achieved. We believe after consultations with external regulatory advisors that, assuming positive Phase 3 efficacy data, our recently completed Phase 2b clinical trial could be considered a pivotal trial by the FDA. However, we cannot guarantee that the FDA will accept the Phase 2b trial as

pivotal or that we won t be required to conduct an additional pivotal trial which would delay our NDA submission timeline and result in additional development costs. In addition, data obtained from trials and studies 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. Our future clinical trials may not be successful.

If FX006 or any other product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be materially harmed. If the results of our on-going Phase 3 or other clinical trials for FX006 demonstrate unexpected safety findings or do not achieve the primary efficacy endpoint, the prospects for approval of FX006 as well our stock price and our ability to create stockholder value would be materially and adversely affected.

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The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate s clinical development and may vary among jurisdictions. For example, we cannot guarantee that the FDA will not require additional or different clinical trials in support of our submission of an NDA for FX006 despite the most recent guidance we have received from the FDA. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;

we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

we may be unable to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;

the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and

the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

In addition, despite our receipt of Fast Track designation for FX006, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program or otherwise. The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market FX006 or our other product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products,

may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates. For example, we believe that, to the extent our clinical development of FX006 continues to focus on knee OA, any initial indication of FX006 would be limited to the treatment of knee OA, as opposed to the treatment of OA generally. If an initial indication is limited to knee OA, we would likely need to conduct additional clinical trials in order to market FX006 for other indications and expand its market potential. In addition, we are choosing to pursue an initial approval of FX006 for single-dose administration. While we intend to develop and submit clinical data for repeated dosing of FX006 in a supplemental NDA, if we were unable to expand the label for FX006 to include repeat dosing, our ability to fully market FX006 would be limited.

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We have not previously submitted an NDA or any similar drug approval filing to the FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approval for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

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

Recent Sales of Unregistered Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit number	Description of document
3.1[(1)]	Amended and Restated Certificate of Incorporation of the Registrant.
3.2[(1)]	Amended and Restated Bylaws of the Registrant.
4.1[(2)]	Form of Common Stock Certificate of the Registrant.
4.2[(2)]	Amended and Restated Investor Rights Agreement, dated December 3, 2012, by and among the Registrant and certain of its stockholders.
4.3[(2)]	Conversion, Amendment and Waiver Agreement, dated January 27, 2014, by and among the Registrant and certain of its stockholders.
10.1	Manufacturing and Supply Agreement, dated July 31, 2015, by and between the Registrant and Patheon UK Limited.
10.2	Technical Transfer and Service Agreement, dated July 31, 2015, by and between the Registrant and

	Patheon UK Limited.
10.3	First Amendment of Lease, dated July 13, 2015, by and between the Registrant and CIP II/RJK 10-20 BMR Owner, LLC.
10.4	Credit and Security Agreement, dated August 4, 2015, by and between the Registrant and MidCap Financial Trust.
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.

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Exhibit number	Description of document
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

(1) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed with the SEC on February 19, 2014.

(2) Incorporated by reference to the Registrant s Registration Statement on Form S-1 (File No. 333-193233), as amended.

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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: November 9, 2015

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