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

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2014

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 Incorporation or Organization)	**(I.R.S. Employer 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 ☒ No ☐

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

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

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

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

As of November 7, 2014, the registrant had 15,627,288 shares of Common Stock ($0.001 par value) outstanding.

FLEXION THERAPEUTICS, INC.
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Flexion Therapeutics, Inc.

Balance Sheets
(Unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 14,365,010	$ 16,188,254
Marketable securities	52,223,545	250,047
Prepaid expenses and other current assets	710,312	181,962
Total current assets	67,298,867	16,620,263
Property and equipment, net	681,866	375,239
Deferred offering costs	—	1,623,540
Other assets	16,501	28,875
Restricted cash	128,000	128,000
Total assets	$ 68,125,234	$ 18,775,917
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,498,948	$ 1,279,874
Accrued expenses and other current liabilities	2,696,380	2,256,680
Current portion of long-term debt	2,000,000	1,500,000
Total current liabilities	6,195,328	5,036,554
Long-term debt	2,081,667	3,546,667
Other long-term liabilities	56,804	90,373
Total liabilities	8,333,799	8,673,594
Commitments and contingencies		
Preferred Stock, $0.001 par value; 10,000,000 and 0 shares authorized, at September 30, 2014 and December 31, 2013, respectively, and 0 shares issued and outstanding at September 30, 2014 and December 31, 2013		
Convertible preferred stock (Series A and B), $0.001 par value; 0 and 73,780,250 shares authorized, 0 shares and 72,780,250 shares issued and outstanding, and aggregate liquidation preference of $0 and $75,043,464, at September 30, 2014 and December 31, 2013, respectively	—	74,806,213
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 100,000,000 and 94,000,000 shares authorized; 15,627,288 and 794,090 shares issued and outstanding, at September 30, 2014 and December 31, 2013, respectively	15,627	794
Additional paid-in capital	145,446,666	1,458,503
Accumulated other comprehensive income	754	(28)
Accumulated deficit	(85,671,612)	(66,163,159)
Total stockholders' equity (deficit)	59,791,435	(64,703,890)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 68,125,234	$ 18,775,917

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

Flexion Therapeutics, Inc.

Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,658,293	2,569,931	12,423,733	8,824,622
General and administrative	2,304,026	2,420,267	6,822,171	5,363,291
Total operating expenses	6,962,319	4,990,198	19,245,904	14,187,913
Loss from operations	(6,962,319)	(4,990,198)	(19,245,904)	(14,187,913)
Other income (expense):				
Interest income	153,122	38,777	318,524	218,762
Interest expense	(96,926)	(113,889)	(314,630)	(335,000)
Other income (expense), net	(129,484)	(35,070)	(266,443)	(192,088)
Total other income (expense)	(73,288)	(110,182)	(262,549)	(308,326)
Net loss	$ (7,035,607)	$ (5,100,380)	$ (19,508,453)	$ (14,496,239)
Net loss attributable to common stockholders	$ (7,035,607)	$ (5,100,380)	$ (19,508,453)	$ (14,496,239)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.45)	$ (6.46)	$ (1.50)	$ (18.37)
Weighted average common shares outstanding, basic and diluted	15,624,963	789,222	13,007,892	789,222
Other comprehensive (loss) income:				
Unrealized (losses) gains from available-for-sale securities, net of tax of $0	(2,468)	315	782	(1,103)
Total other comprehensive (loss) income	(2,468)	315	782	(1,103)
Comprehensive loss	$ (7,038,075)	$ (5,100,065)	$ (19,507,671)	$ (14,497,342)

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

Flexion Therapeutics, Inc.

Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)

	Series A and B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Par Value				
Balance at December 31, 2013	72,780,250	$ 74,806,213	794,090	$ 794	$ 1,458,503	$ (28)	$(66,163,159)	$ (64,703,890)
Conversion of Series A and Series B Convertible Preferred Stock	(72,780,250)	(74,806,213)	8,952,057	8,952	74,797,261			74,806,213
Issuance of Common Stock net of issuance costs			5,750,000	5,750	67,156,254			67,162,004
Exercise of stock options			131,141	131	282,414			282,545
Stock-based compensation expense					1,752,234			1,752,234
Net loss							(19,508,453)	(19,508,453)
Other comprehensive loss	—	—	—	—	—	782	—	782
Balance at September 30, 2014	$ —	$ —	15,627,288	$ 15,627	$145,446,666	$ 754	$(85,671,612)	$ 59,791,435

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

Flexion Therapeutics, Inc.

Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30, 2014	2013
Cash flows from operating activities		
Net loss	$ (19,508,453)	$ (14,496,239)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	84,943	54,168
Stock-based compensation expense	1,752,234	773,023
Amortization of premium (discount) on marketable securities	226,834	144,832
Other non-cash charges	12,374	47,375
Changes in operating assets and liabilities:		
Prepaid expenses and other current and long-term assets	(350,534)	412,102
Accounts payable	296,331	341,131
Accrued expenses and other current and long-term liabilities	671,891	66,689
Net cash used in operating activities	(16,814,380)	(12,656,919)
Cash flows from investing activities		
Purchases of property and equipment	(326,571)	(385,823)
Change in restricted cash	—	(98,000)
Purchases of marketable securities	(72,359,552)	(15,013,186)
Redemption of marketable securities	20,160,000	23,885,000
Net cash (used in) provided by investing activities	(52,526,123)	8,387,991
Cash flows from financing activities		
Proceeds from borrowings under term loan	—	5,000,000
Payments of debt issuance costs	—	(40,715)
Payment of initial public offering costs	(1,282,785)	(54,347)
Proceeds from the issuance of common stock	69,517,500	—
Proceeds from the exercise of stock options	282,545	—
Payments on debt	(1,000,001)	—
Net cash provided by financing activities	67,517,259	4,904,938
Net increase (decrease) in cash and cash equivalents	(1,823,244)	636,010
Cash and cash equivalents at beginning of period	16,188,254	12,835,330
Cash and cash equivalents at end of period	$ 14,365,010	$ 13,471,340
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 287,370	$ 266,667
Supplemental disclosures of non-cash financing activities:		
Conversion of convertible preferred stock into common stock	$ 74,806,213	—

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

Flexion Therapeutics, Inc.

Notes to Financial Statements (Unaudited)

1. Overview and Nature of the Business

Flexion Therapeutics, Inc. ("Flexion" or the "Company") was incorporated under the laws of the state of Delaware on November 5, 2007. Flexion is a specialty pharmaceutical company focused on the development and commercialization of novel, injectable pain therapies. The Company is targeting anti-inflammatory and analgesic therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis ("OA"), a type of degenerative arthritis 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 early-stage 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. The Company's product candidates are all in the development stage and 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. There can be no assurance that development efforts, including clinical trials, will be successful or that the Company will have the ability to continue into later stages of clinical trials. 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.

On February 18, 2014, the Company completed an initial public offering ("IPO") of its common stock, which resulted in the sale of 5,750,000 shares of common stock at a price to the public of $13.00 per share, including shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares. The Company received net proceeds from the IPO of $67.2 million after deducting underwriting discounts, commissions, and offering costs paid by the Company. In preparation for the IPO, the Company's Board of Directors and stockholders approved a 1-for-8.13 reverse stock split of the Company's common stock and a proportional adjustment to the existing conversion ratios for each series of Convertible Preferred Stock, effective January 27, 2014. All share and per share amounts in the condensed financial statements and notes thereto have been retroactively adjusted, where necessary, to give effect to this reverse stock split. In connection with the closing of the IPO, all of the Company's outstanding redeemable convertible preferred stock automatically converted to common stock as of February 18, 2014, resulting in an additional 8,952,057 shares of common stock of the Company becoming outstanding. Following these transactions, the Company's total issued common stock as of September 30, 2014 was 15,627,288 shares. The significant increase in shares outstanding in February 2014 is expected to impact the year-over-year comparability of the Company's (loss) earnings per share calculations in 2014.

2. Basis of Presentation

The accompanying condensed financial statements as of September 30, 2014, and for the three and nine months ended September 30, 2014 and 2013, 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 condensed financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these 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 financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2014.

The information presented in the financial statements and related notes as of September 30, 2014, and for the three and nine months ended September 30, 2014 and 2013, is unaudited. The December 31, 2013 condensed 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, 2014 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2014, or any future period.

The accompanying condensed 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, 2014 and December 31, 2013, the Company had cash, cash equivalents and marketable securities of $66,588,555 and $16,438,301, respectively. Management believes that current cash, cash equivalents and marketable securities on hand at September 30, 2014 should be sufficient to fund operations into late 2015. 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. 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.

Use of Estimates

GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues, 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 financial statements include useful lives with respect to long-lived assets, 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.

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standard Board, or FASB, issued amended accounting guidance for development stage entities. The amendment eliminates certain financial reporting requirements for development stage entities, specifically, the presentation of inception-to-date information, the development stage entity label on the financial statements, the description of the activities in which the entity is engaged, and disclosure in the first year that the entity is no longer a development stage entity that it had been in prior years. In addition, the amendment clarifies guidance regarding entities that have not commenced planned principal operations. The amendment is effective retrospectively for annual reporting periods beginning after December 15, 2014, and interim periods therein with early adoption permitted. The Company elected to early adopt this standard in the period ended June 30, 2014. Other than a change in presentation, the adoption of this guidance did not have an impact on the Company's financial statements.

In May 2014, the FASB issued guidance which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. This guidance will be effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is not permitted. The Company is currently evaluating the potential impact that the adoption of this guidance and the related transition guidance may have on the Company's financial statements.

In August 2014, the FASB issued accounting guidance for the disclosure of uncertainties related to an entity's ability to continue as a going concern. The new standard requires management to perform an assessment at interim and annual periods as to the entity's ability to continue as a going concern and provides specific disclosure guidance. This guidance will be effective for fiscal years, and interim periods within those years, beginning after December 15, 2016 and early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the Company's financial statements.

3. Fair Value of Financial Assets

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2014 and December 31, 2013 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of September 30, 2014 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ —	$ 13,443,515	$ —	$ 13,443,515
Marketable securities	—	52,223,545	—	52,223,545
	$ —	$ 65,667,060	$ —	$ 65,667,060

	Fair Value Measurements as of December 31, 2013 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ —	$ 14,957,788	$ —	$ 14,957,788
Marketable securities	—	250,047	—	250,047
	$ —	$ 15,207,835	$ —	$ 15,207,835

As of September 30, 2014 and December 31, 2013, the Company's cash equivalents and marketable securities that are invested primarily in U.S. treasury bills, corporate bonds, money market funds, commercial paper and U.S. government agency holdings are 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, 2014 and the year ended December 31, 2013, there were no transfers between Level 1, Level 2 and Level 3.

As outlined in footnote ten, the Company has a term loan with MidCap Financial SBIC, LP ("MidCap"). The term loan outstanding under the Company's credit and security agreement with MidCap is 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 September 30, 2014. The result of the calculation yielded a fair value that approximates carrying value.

4. Marketable Securities

As of September 30, 2014 and December 31, 2013, the fair value of available-for-sale marketable securities by type of security was as follows:

	September 30, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 8,994,407	$ 5,223	$ —	$ 8,999,630
Corporate bonds and US Government Obligations	$ 43,228,384	$ 3,141	$ (7,610)	$43,223,915
	$ 52,222,791	$ 8,364	$ (7,610)	$52,223,545

	December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 250,075	$ —	$ (28)	$ 250,047
	$ 250,075	$ —	$ (28)	$ 250,047

At September 30, 2014 and December 31, 2013, marketable securities consisted of investments that mature within one year.

5. Property and Equipment, Net

Property and equipment, net, as of September 30, 2014 and December 31, 2013 consisted of the following:

	September 30, 2014	December 31, 2013
Computer and office equipment	$ 314,718	$ 257,346
Manufacturing equipment	153,140	99,684
Furniture and fixtures	181,578	149,183
Leasehold improvements	130,626	130,626
Construction in Progress	248,346	—
	1,028,408	636,839
Less: Accumulated depreciation	(346,542)	(261,600)
Total property and equipment, net	$ 681,866	$ 375,239

Depreciation expense for the nine months ended September 30, 2014 and the year ended December 31, 2013, was $84,943 and $79,808, respectively. During the nine months ended September 30, 2014 and the year ended December 31, 2013, $0 and $16,695 of property and equipment was disposed of, resulting in a loss of $0 and $14,111, respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2014	December 31, 2013
Clinical research	$ 822,215	$ 163,521
Contract manufacturing services	485,000	529,287
Payroll and other employee-related expenses	800,851	792,165
Professional services fees	441,599	642,052
Interest expense	26,667	34,445
Other	120,048	95,210
Total accrued expenses and other current liabilities	$ 2,696,380	$ 2,256,680

7. Stock-Based Compensation

Stock Incentive Plan

The Company grants stock-based awards pursuant to its 2013 Equity Incentive Plan (the "2013 Plan"). The maximum number of shares that may be issued under the 2013 Plan is 2,337,616, which is the sum of (i) 1,230,012 shares, plus (ii) the number of shares remaining available for grant under our previous stock incentive plan at the time the 2013 Plan became effective, plus (iii) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to our previous stock incentive plan (such as upon the expiration or termination of a stock award prior to vesting), as such shares become available from time to time. The maximum number of shares that may be issued upon the exercise of incentive stock options ("ISOs") under the 2013 Plan is 4,684,989. As of September 30, 2014, 967,502 shares were available for future issuance under the 2013 Plan.

Stock Options

During the nine months ended September 30, 2014 and 2013, the Company granted stock options for the purchase of 663,150 and 201,722 shares of common stock, respectively, to certain employees and directors. The vesting conditions for all of these awards are time-based, and the awards typically vest 25% after one year and monthly thereafter for the next 36 months, except for annual option grants to non-employee directors of the Company whose initial grants vest 25% after one year and monthly thereafter for the next 24 months and whose annual grants vest in equal monthly installments during the 12-month period following the grant date, pursuant to the Company's Non-Employee Director Compensation Policy. Awards typically expire after 10 years.

Stock Option Valuation

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to the IPO, the Company was a private company and therefore lacked company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of its publicly-traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The relevant data used to determine the value of the stock option grants for the nine months ended September 30, 2014 and 2013 are as follows:

	2014	2013
Risk-free interest rates	1.54-2.04%	1.00%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.0	6.0
Expected volatility	61.87-66.98%	71.19%

The following table summarizes stock option activity for the nine months ended September 30, 2014:

	Shares Issuable Under Options	Weighted Average Exercise Price
Outstanding as of December 31, 2013	834,983	$ 2.99
Granted	663,150	16.66
Exercised	(131,141)	2.15
Canceled	(128,019)	8.81
Outstanding as of September 30, 2014	1,238,973	$ 9.78
Options vested and expected to vest at September 30, 2014	1,057,498	
Options exercisable at September 30, 2014	420,974	

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 131,141 options were exercised during the nine months ended September 30, 2014. The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2014 was $1,364,080.

At September 30, 2014 and 2013 the Company had options for the purchase of 1,238,973 and 839,852 shares of common stock outstanding, respectively, with a weighted average remaining contractual term of 8.3 and 8.2 years, respectively, and with a weighted average exercise price of $9.78 and $2.99 per share, respectively.

The weighted average grant date fair value of options granted during the nine months ended September 30, 2014 and 2013 was $10.15 and $4.88, respectively.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options for the three and nine months ended September 30, 2014 and 2013 as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
	2014	2013	2014	2013
Research and development	$ 170,668	$ 232,681	$ 466,465	$ 274,131
General and administrative	504,141	444,107	1,285,769	498,892
	$ 674,809	$ 676,788	$1,752,234	$ 773,023

As of September 30, 2014, unrecognized stock-based compensation expense for stock options outstanding was $7,822,984 which is expected to be recognized over a weighted average period of 3.0 years. As of September 30, 2013, unrecognized stock-based compensation expense for stock options outstanding was $2,530,427, which is expected to be recognized over a weighted average period of 3.0 years.

On March 31, 2014 the vesting of certain options granted to a terminated employee was accelerated. This change in vesting conditions was accounted for as a modification of these stock options and resulted in an aggregate increase in the fair value of the options of $70,494 and was recorded as stock-based compensation expense on the modification date, which was March 31, 2014.

8. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three and nine months ended September 30, 2014 and 2013:

	For the three months ended September 30,		For the nine months ended September 30,	
	2014	2013	2014	2013
Numerator:				
Net loss	$ (7,035,607)	$(5,100,380)	$(19,508,453)	$(14,496,239)
Net income attributable to participating securities	—	—	—	—
Net loss attributable to common stockholders:	$ (7,035,607)	$(5,100,380)	$(19,508,453)	$(14,496,239)
Denominator:				
Weighted average common shares outstanding, basic and diluted	15,624,963	789,222	13,007,892	789,222
Net loss per share attributable to common stockholders, basic and diluted	$ (0.45)	$ (6.46)	$ (1.50)	$ (18.37)

Stock options for the purchase of 1,234,199 and 809,216 weighted average shares of common stock were excluded from the computation of diluted net loss per share attributable to common stockholders for the three months ended September 30, 2014 and 2013, respectively, and 1,130,000 and 584,970 weighted average shares of common stock were excluded from the computation of diluted net loss per share attributable to common stockholders for the nine months ended September 30, 2014 and 2013, respectively. These options were excluded from the computations because they had an anti-dilutive impact to diluted net loss attributable to common stockholders incurred for those periods.

In February 2014, the Company issued an additional 5,750,000 shares of common stock in connection with its IPO and 8,952,057 shares of common stock in connection with the automatic conversion of its redeemable convertible preferred stock upon the closing of the IPO. The issuance of these shares resulted in a significant increase in the Company's weighted average shares outstanding for the three and nine months ended September 30, 2014 when compared to the comparable prior year period and is expected to continue to impact the year-over-year comparability of the Company's (loss) earnings per share calculations in 2014.

9. Related Party Transactions

The Company has retained, as external legal counsel, a firm that owns 3,075 shares of common stock of the Company. Legal fees of the firm incurred by the Company for the nine months ended September 30, 2014 and 2013 were $792,490 and $1,315,364 respectively. Legal fees of the firm paid by the Company during the nine months ended September 30, 2014 and 2013 were $995,262 and $310,792, respectively. Amounts payable to this firm as of September 30, 2014 and 2013 were $224,297 and $1,190,842, respectively.

10. Long-term Debt

On January 3, 2013, the Company entered into a credit and security agreement with MidCap Financial SBIC, LP ("MidCap") under which it immediately borrowed $5,000,000 as a term loan. The term loan accrues interest monthly at an interest rate of 8.0% per annum and has a term of 45 months. As the term loan has a 15-month interest-only period, the term loan principal balance, along with any accrued interest, is 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 is required to make a payment of $175,000 to the lender on September 1, 2016, which amount is being accreted to the carrying value of the debt using the effective interest rate method. As of September 30, 2014, the carrying value of the term loan was $4,082,000 of which $2,000,000 was classified as the current portion of long-term debt on the balance sheet. In connection with the credit and security agreement, the Company granted MidCap a security interest in all of the Company's personal property now owned or hereafter acquired, excluding intellectual property but including the proceeds from the sale, if any, of intellectual property, and a negative pledge on intellectual property. The credit and security agreement also contains certain representations, warranties, and non-financial covenants of the Company. As of September 30, 2014, the Company was compliant with all covenants.

11. Income Taxes

Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), contains rules that limit the ability of a company that undergoes an ownership change to utilize its net operating losses ("NOLs") and tax credits existing as of the date of such ownership change. Under the rules, such an ownership change is generally any change in ownership of more than 50% of a company's stock within a rolling three-year period. The rules generally operate by focusing on changes in ownership among stockholders considered by the rules as owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from new issuances of stock by the company. During the quarter ended June 30, 2014, the Company completed a Section 382 study through February 11, 2014. The results of this study showed that as of February 11, 2014, one historical ownership change within the meaning of Section 382 had occurred in 2009. As a result of this Section 382 limitation, approximately $0.3 million of NOLs will expire unutilized. Subsequent ownership changes as defined by Section 382 may potentially limit the amount of net operating loss carryforwards that could be utilized annually to offset future taxable income.

The Company has generated losses since inception and therefore has recorded no income tax benefits for those losses due to its uncertainty of realizing a benefit from those losses.

12. Subsequent Events

There were no subsequent events that require disclosure in the financial statements for the period ended September 30, 2014.

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, 2013 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 28, 2014.

Forward-Looking Statements

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

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of novel, injectable pain therapies. We are targeting 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 unique opportunities to achieve our goal of commercializing novel, patient-focused pain therapies. Our pipeline consists of three proprietary product candidates: FX006, a sustained-release, intra-articular, or IA, steroid; FX007, a TrkA receptor antagonist for the post-operative pain setting; and FX005, a sustained-release intra-articular p38 MAP kinase inhibitor. We retain the exclusive worldwide rights to our product candidates.

We were incorporated in Delaware in November 2007, and to date we have devoted substantially all of our resources to our development efforts relating to our product candidates, including conducting clinical trials with our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. We have incurred net losses in each year since our inception in 2007 and we expect to continue to incur significant expenses and operating losses over the next several years. From our inception through December 31, 2013, we have funded our operations primarily through the sale of our convertible preferred stock and, to a lesser extent, debt financing. From our inception through December 31, 2013, we raised $80.0 million from such transactions. On February 18, 2014, we completed the initial public offering of our common stock, which resulted in net proceeds to us of approximately $67.2 million, after deducting underwriting discounts, commissions and offering costs. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or third-party funding, and licensing or collaboration arrangements.

Product Candidates and Recent Developments

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

Product Candidate	Development Phase	Indication
FX006 Intra-articular injectable steroid	Phase 2b	OA of the knee
FX007 TrkA receptor antagonist	Preclinical	Post-operative pain
FX005 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 2012, the number of patients that received knee injections of IA steroids increased approximately 12% to approximately 3 million patients. We estimate that an additional 1.3 million patients received knee injections of IA hyaluronic acid, or HA, which the U.S. Food and Drug Administration, or FDA, has approved for use only in the knee. Sales of HA in the United States grew over 6% to approximately $700 million in 2013, approximately 95% of which were related to knee therapy. Worldwide, HA sales are approaching $2 billion per year. However, recent negative guidance from specialty societies (e.g. the American Academy of Orthopedic Surgeons ("AAOS"), and the Osteoarthritis Research Society International ("OARSI")) may begin to put downward pressure on HA sales. For example, Sanofi Biosurgery, which sells the market leading HA treatment, Synvisc, reported a 7% drop in the first nine months 2014 net U.S.sales when compared to the first nine months 2013 net U.S. sales. This could be in part due to the fact that select payer groups have limited reimbursement for the entire class of HA products. We believe that FX006 has the potential to be a superior front line injectable treatment for OA pain management compared to existing therapies by providing safe, more effective and sustained pain relief to patients. We believe the following attributes make FX006 an attractive development candidate.

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

- 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 505(b)(2) regulatory pathway seeking approval of the already approved immediate-release steroid used by orthopedists and rheumatologists; and
- potential for pharmacoeconomic benefits due to superior efficacy and durability and the potential to delay costly and invasive total joint replacement.

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

Our clinical data suggest that, due to sustained-release, peak steroid concentrations in the joint with FX006 are orders of magnitude lower than those produced by currently available steroid suspensions. A pharmacodynamic clinical trial has 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 synovial fluid pharmacokinetic clinical trials to measure the duration of exposure to TCA following a single IA administration of FX006. TCA concentrations in the joint were determined at 6, 12, 16 and 20 weeks after injection of FX006 and at 6 and 12 weeks after injection of immediate-release TCA. The data from these clinical trials show that at 12 weeks both the FX006 10 mg and 40 mg dose groups had therapeutic 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. We began enrolling patients in a pivotal Phase 2b confirmatory clinical trial of FX006 in May 2014, however, on September 16, 2014 we were notified by the FDA that they had placed a clinical hold on the FX006 investigational new drug application, or IND, due to a single occurrence of an infection in the injected knee joint of a patient in the clinical trial. We are working closely with the FDA to provide them with all appropriate information and data required to expedite their review and evaluation of this event.

On September 9, 2014, the United States Patent and Trademark Office ("USPTO") issued a composition of matter patent, entitled "Corticosteroids for the Treatment of Joint Pain," for FX006. The patent describes and claims an injectable formulation comprised of controlled or sustained-release microparticles that contain TCA in a PLGA matrix. The patent has a term that extends into 2031.

On September 3, 2014, we announced that in a recent meeting with the FDA, the agency communicated that it will consider our ongoing placebo-controlled pivotal Phase 2b confirmatory trial of FX006 as one of two key efficacy trials required for registration of a single-dose administration for FX006. In addition, the FDA provided guidance that a second placebo-controlled pivotal trial would be sufficient to support the filing of a New Drug Application. The FDA also communicated that the approval of FX006 for single-dose administration will not require data from a repeat-dose safety trial, which enabled the most significant change from our prior clinical development plan. As a result, we have decided to advance the initiation of the Phase 3 trial of FX006, to remove the repeat-dose safety trial from our pre-approval plans, and to develop and file the repeat-dose safety data in a supplemental new drug application after approval and launch of FX006 for single-dose administration.

FX007—For Post-Operative Pain

FX007 is a small molecule TrkA receptor antagonist that is in development for the persistent relief of post-operative pain. TrkA is the receptor for nerve growth factor, commonly known as NGF, a small peptide that is released following tissue injury. NGF binds to TrkA on the surface of pain sensing neurons and renders these cells more responsive to external stimuli. In recent clinical trials of Pfizer's monoclonal antibody, tanezumab, systemic blockade of NGF demonstrated marked analgesia in a variety of painful conditions. Additionally, human genetic studies demonstrated that patients with a mutation in the TrkA gene have congenital insensitivity to pain. These data indicate that interruption of the NGF-TrkA pathway produces a profound analgesic effect, and in preclinical pharmacology experiments, FX007 has demonstrated both high affinity for the TrkA receptor and analgesic effects in OA and post-operative pain. However, systemic and persistent blockade of NGF 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 duration for analgesia of 36 to 72 hours. As a result, unlike FX005 and FX006 for OA pain, where the goal is months of pain relief, we do not believe it will be necessary to formulate FX007 with PLGA, which should expedite development of this compound.

We have conducted preclinical proof-of-concept, or PoC, studies using models of OA and post-operative pain and demonstrated efficacy in both. In addition, we are conducting formulation experiments with various delivery mechanisms, so that exposure at therapeutic concentration levels can be achieved. Upon completion of these experiments and selection of the most appropriate delivery vehicle, we plan to conduct a good laboratory practice ("GLP") toxicology study prior to filing an IND.

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. 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 increased substantially in a sub-population of patients with higher baseline pain scores.

Based on results of various toxicology studies we have conducted, 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 product 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. 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 grant income or from licensing rights to our product candidates to third parties. If we fail to complete the development of FX006 or our other product candidates, our ability to generate future revenue, and our results of operations and financial position will be adversely affected.

Operating Expenses

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

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;
- personnel costs, including salaries, benefits, stock-based compensation and travel expenses for employees engaged in scientific research and development functions;
- costs related to compliance with regulatory requirements;
- expenses related to the in-license of certain technologies from pharmaceutical companies; and
- allocated expenses for rent and maintenance of facilities, insurance and other general overhead.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Direct research and development expenses by program:				
FX006	$3,264,497	$ 978,647	$ 8,217,735	$4,233,988
FX007	93,780	160,074	517,580	316,223
FX005	22,535	333,389	99,038	1,630,316
Total direct research and development expenses	3,380,812	1,472,110	8,834,353	6,180,527
Personnel and other costs	1,277,481	1,097,821	3,589,380	2,644,095
Total research and development expenses	$4,658,293	$2,569,931	$12,423,733	$8,824,622

Our research and development expenses are expected to increase in the foreseeable future. Specifically, our costs associated with FX006 will increase as we conduct our pivotal Phase 2b confirmatory clinical trial 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. We anticipate that we will decide upon 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, and business development, functions. Other general and administrative expenses include an allocation of facility-related costs, patent filing expenses, and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase in the future as we continue to build our corporate infrastructure to support the continued development of FX006 and FX007. Additionally, we anticipate increased expenses related to the audit, legal, regulatory, investor relations and tax-related services associated with maintaining compliance with the Securities and Exchange Commission and Nasdaq requirements, director and officer insurance premiums and other costs associated with operating as a publicly-traded company.

Other Income (Expense)

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

Interest expense. In January 2013, we borrowed $5.0 million under a credit facility with MidCap Financial SBIC, LP, or MidCap, and began to incur interest related to this borrowing at a fixed rate of 8.0% per annum. We expect to incur future interest expense related to this borrowing until September 1, 2016. See “Liquidity and Capital Resources” for a more detailed description of our credit facility.

Other expense. Other expense consists of the net amortization of premiums related to our marketable securities, 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, 2013 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, 2014 except for the adoption of amended accounting guidance for development stage entities issued by the FASB in June 2014. The amendment eliminates certain financial reporting requirements for development stage entities, specifically, the presentation of inception-to-date information, the development stage entity label on the financial statements, the description of the activities in which the entity is engaged, and disclosure in the first year that the entity is no longer a development stage entity that it had been in prior years. In addition, the amendment clarifies guidance regarding entities that have not commenced planned principal operations. The amendment is effective retrospectively for annual reporting periods beginning after December 15, 2014, and interim periods therein with early adoption permitted. The Company elected to early adopt this standard in the period ended June 30, 2014. Other than a change in presentation, the adoption of this guidance did not have an impact on the Company's financial statements.

RESULTS OF OPERATIONS

Comparison of the three and nine months ended September 30, 2014 and 2013

The following table summarizes our results of operations for the three and nine months ended September 30, 2014 and 2013 (certain items may not sum correctly due to rounding):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2014	2013	Change	2014	2013	Change
	(in thousands)			(in thousands)		
Revenue	$ —	$ —	$ —	$ —	$ —	$ —
Operating expenses:						
Research and development	4,658,293	2,569,931	2,088,362	12,423,733	8,824,622	3,599,111
General and administrative	2,304,026	2,420,267	(116,241)	6,822,171	5,363,291	1,458,880
Total operating expenses	6,962,319	4,990,198	1,972,121	19,245,904	14,187,913	5,057,991
Loss from operations	(6,962,319)	(4,990,198)	(1,972,121)	(19,245,904)	(14,187,913)	(5,057,991)
Other income (expense):						
Interest income	153,122	38,777	114,345	318,524	218,762	99,762
Interest expense	(96,926)	(113,889)	16,963	(314,630)	(335,000)	20,370
Other expense	(129,484)	(35,070)	(94,414)	(266,443)	(192,088)	(74,355)
Total other income (expense)	(73,288)	(110,182)	36,894	(262,549)	(308,326)	45,777
Net loss	$(7,035,607)	$(5,100,380)	$(1,935,227)	$(19,508,453)	$(14,496,239)	$(5,012,214)

Research and Development Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2014	2013	Change	2014	2013	Change
	(in thousands)			(in thousands)		
Direct research and development expenses by program:						
FX006	$3,264,497	$ 978,647	$2,285,850	$ 8,217,735	$4,233,988	$ 3,983,747
FX007	93,780	160,074	(66,294)	517,580	316,223	201,357
FX005	22,535	333,389	(310,854)	99,038	1,630,316	(1,531,278)
Total direct research and development expenses	3,380,812	1,472,110	1,908,702	8,834,353	6,180,527	2,653,826
Personnel and other costs	1,277,481	1,097,821	179,660	3,589,380	2,644,095	945,284
Total research and development expenses	$4,658,293	$2,569,931	$2,088,362	$12,423,733	$8,824,622	$ 3,599,110

Research and development expenses were $4.7 million and $2.6 million for the three months ended September 30, 2014 and 2013, respectively. The increase in research and development expenses year over year of $2.1 million, or 81%, was primarily due to $2.3 million in FX006 program expenses related to the pivotal Phase 2b dose confirmatory trial, these costs were partially offset by decreases in FX005 program expenses of $0.3 million due to the completion of toxicology studies and $0.1 million in pharmacology and other expenses related to FX007. Additionally, there was an increase of $0.2 million in personnel and other employee related costs as a result of higher headcount levels.

Research and development expenses were $12.4 million and $8.8 million for the nine months ended September 30, 2014 and 2013, respectively. The increase in research and development expenses year over year of $3.6 million, or 41%, was primarily due to $4.0 million in FX006 program expenses related to the initiation of the pivotal Phase 2b dose confirmatory trial and increased manufacturing expenses related to clinical trial materials. FX007 expenses increased $0.2 million due to incurred costs for toxicology studies. Additionally, there was an increase of $0.9 million in personnel and other employee related costs, which was offset by a decrease of $1.5 million in FX005 program expenses due to the completion of toxicology studies.

General and Administrative Expenses

General and administrative expenses were $2.3 million and $2.4 million for the three months ended September 30, 2014 and 2013, respectively. The decrease in general and administrative expenses year over year of $0.1 million, or 5%, was primarily due to a decrease in professional service fees of $0.2 million, partially offset by, higher insurance costs of $0.1 million.

General and administrative expenses were $6.8 million and $5.4 million for the nine months ended September 30, 2014 and 2013, respectively. The increase in general and administrative expenses year over year of $1.4 million, or 27%, was primarily due to costs associated with salary and related costs due to additional headcount and stock compensation expense of $1.0 million, and insurance costs of $0.4 million for additional insurance coverage required for a publicly-traded company.

Other Income (Expense)

Interest income was $0.2 million and $0.04 million for the three months ended September 30, 2014 and 2013, respectively, and $0.3 million and $0.2 million for the nine months ended September 30, 2014 and 2013, respectively. Interest expense was consistent year over year.

Liquidity and Capital Resources

To date, we have not generated any product revenue and have incurred losses since our inception in 2007. As of September 30, 2014, we had an accumulated deficit of $85.5 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, 2014, we have funded our operations principally through the receipt of funds from the private placement of $80.0 million of equity and debt securities. In addition, on February 18, 2014, we completed the initial public offering of our common stock, which resulted in net proceeds to us of approximately $67.2 million, after deducting underwriting discounts, commissions and offering costs. As of September 30, 2014, we had cash and cash equivalents of $14.4 million and marketable securities of $52.2 million. We anticipate that our existing cash, cash equivalents and marketable securities will fund our operations into late 2015. 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, 2014 and 2013:

	2014	2013
Cash flows (used in) operating activities	$(16,814,380)	$(12,656,919)
Cash flows (used in) provided by investing activities	(52,526,123)	8,387,991
Cash flows provided by financing activities	67,517,259	4,904,938
Net increase (decrease) in cash and cash equivalents	$ (1,823,244)	$ 636,010

Net Cash Used in Operating Activities

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 net 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.

Operating activities used $12.7 million of cash in the nine months ended September 30, 2013. The cash flow used in operating activities resulted primarily from our net loss of $14.5 million offset by net cash provided by changes in our operating assets and liabilities of $0.8 million, and net non-cash charges of $1.0 million. Net cash provided by changes in our operating assets and liabilities consisted primarily of a $0.1 million increase in our accrued expenses and other current liabilities, a $0.4 million decrease in prepaid expenses and other current assets, and a $0.3 million increase in our accounts payable.

Net Cash (Used in) Provided by Investing Activities

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 and purchases of property and equipment of $0.3 million, partially offset by cash received from the redemption of marketable securities of $20.2 million.

Net cash provided by investing activities was $8.4 million for the nine months ended September 30, 2013. Net cash provided by investing activities consisted primarily of cash received from the redemption of marketable securities of $23.9 million, offset by cash paid to purchase marketable securities of $15.0 million, a change in restricted cash of $0.1 million, and purchases of property and equipment of $0.4 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $67.5 million and $4.9 million for the nine months ended September 30, 2014 and 2013, respectively. 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 principle on our term loan of $1.0 million. Net cash provided by financing activities in the nine months ended September 30, 2013 primarily consisted of $5.0 million in proceeds from borrowings under our term loan.

Contractual Obligations

As of September 30, 2014, there are no material changes, outside of the ordinary course of business, in our outstanding contractual obligations from those disclosed within “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, as contained in our Annual Report on Form 10-K filed by us with the SEC on March 28, 2014.

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 our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on our investment portfolio.

We have borrowed $5.0 million under our credit facility. Amounts outstanding under the credit facility bear interest at a fixed rate equal to 8.0% per annum. During the nine months ended September 30, 2014, we made principle payments totaling $1.0 million on this loan.

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

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of September 30, 2014, 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, 2014 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 and subsequent Quarterly Reports on Form 10-Q, 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 and subsequent Quarterly Reports on Form 10-Q 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 $19.5 million for the nine months ended September 30, 2014 and $18.2 million, $15.0 million and $11.4 million for fiscal years 2013, 2012 and 2011, respectively. As of September 30, 2014, we had an accumulated deficit of $85.7 million.

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

We expect to continue to incur substantial and increased expenses as we expand our development activities and advance our clinical programs, particularly with respect to our planned clinical development for FX006. We also expect to continue incurring expenses associated with creating additional infrastructure to support 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.

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 trial or submitted a New Drug Application, or 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 positive results generated in the completed FX006 Phase 2b dose-ranging clinical trial do not ensure that our pivotal Phase 2b confirmatory clinical trial will demonstrate similar results.

In our completed 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 doses we are studying in our pivotal Phase 2b confirmatory clinical 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, and we expect that our planned Phase 3 clinical trial will be, 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 (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 obtain regulatory approval or would limit the commercial potential of FX006, if approved.

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. 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 trial results 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. For example, if the results of our pivotal Phase 2b confirmatory or other clinical trials for FX006 demonstrate unexpected safety findings or do not achieve the primary efficacy endpoints, the prospects for approval of FX006 as well our stock price and our ability to create stockholder value would be materially and adversely affected.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial elements and the rate of dropout among clinical trial participants. We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, our ability to create long-term stockholder value will be limited.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates. We are conducting a pivotal Phase 2b confirmatory clinical trial of FX006, our planned Phase 3 clinical trial of FX006 and a proof of concept clinical trial for FX007 that we plan to initiate following the generation of additional preclinical data. Our clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, and clinical trial sites;
- delays in obtaining required institutional review-board approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

For example, our completed Phase 2b dose-ranging clinical trial for FX006 was subject to a clinical hold imposed by the FDA due to the observation of effects of PLGA microspheres on synovial tissue from FX006 injections. While we later resumed enrollment at non-U.S. sites and the clinical hold was eventually lifted without restriction by the FDA, the hold delayed our completion of the trial and resulted in additional expense. Also, on September 16, 2014 we were notified by the FDA that they had placed a clinical hold on the FX006 IND due to a single occurrence of an infection in the injected knee joint of a patient in the clinical trial. We are working closely with the FDA to provide them with all appropriate information and data required to expedite their review and evaluation of this event. We cannot predict if or when the FDA will lift the clinical hold or whether we will be required to re-manufacture FX006 clinical trial materials and/or change our manufacturing process for FX006 before resuming our pivotal Phase 2b confirmatory clinical trial or initiating our planned Phase 3 clinical trial for FX006.

If initiation or completion of our clinical trials are delayed for any of the above reasons or other reasons, including the on-going clinical hold on our FX006 IND, our development costs may increase, our approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be adversely impacted, which could have a material adverse effect on our business.

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.

This 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 add to the label, 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.

We have not previously submitted an NDA or any similar drug approval filing to the FDA or any comparable foreign regulatory 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.

Risks Related to Our Business Operations and Industry

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of September 30, 2014, we had 21 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize FX006 and our other product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Related to Ownership of Our Common Stock

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. As of December 31, 2013, we had $35.1 million and $32.8 million of federal and state net operating loss carryforwards, respectively, and $1.6 million and $1.1 million of federal and state research and development tax credit carryforwards, respectively, available to offset our future taxable income, if any. These federal net operating loss carryforwards and research and development tax credit carryforwards expire at various dates beginning in 2028 and 2029, respectively, if not utilized and are subject to review and possible adjustment by the Internal Revenue Service. The state net operating loss carryforwards and research and development tax credit carryforwards expire at various dates beginning in 2014 and 2024, respectively, if not utilized and are subject to review and possible adjustment by the state tax authorities. During the quarter ended June 30, 2014 we completed a Section 382 study through February 11, 2014. The results of this study showed that as of February 11, 2014, one historical ownership change within the meaning of Section 382 had occurred in 2009. As a result of this Section 382 limitation, approximately $0.3 million of net operating loss carryforwards will expire unutilized. Subsequent ownership changes as defined by Section 382 may potentially limit the amount of net operating loss carryforwards that could be utilized annually to offset future taxable income.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On February 11, 2014, we commenced our initial public offering pursuant to a registration statement on Form S-1 (File No. 333-193233) that was declared effective by the SEC on February 11, 2014 and that registered an aggregate of 5,000,000 shares of our common stock for sale to the public at a price of $13.00 per share. In addition, at the closing of the initial public offering on February 18, 2014, the underwriters exercised their over-allotment option to purchase 750,000 additional shares of our common stock in the initial public offering at the public offering price of $13.00 per share, for an aggregate offering price of $74.8 million. BMO Capital Markets Corp. and Wells Fargo Securities, LLC acted as joint book-running managers of our initial public offering, which has now terminated. After deducting underwriting discounts, commissions and offering costs paid by us of $7.6 million, the net proceeds from the offering were approximately $67.2 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

The net proceeds from the offering were invested primarily in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, and direct or guaranteed obligations of the U.S. government pending their use. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

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)	Form of 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+(3)	Flexion Therapeutics, Inc. Change in Control Bonus Plan
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

\+ Indicates management contract or compensatory plan.
(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.
(3) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on September 2, 2014.

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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 14, 2014

By: /s/ Michael D. Clayman, M.D
Michael D. Clayman, M.D.
President and Chief Executive Officer

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael D. Clayman, M.D., certify that:

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

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

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

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

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

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

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

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

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

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

Date: November 14, 2014

/s/ Michael D. Clayman, M.D.
Michael D. Clayman, M.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Frederick W. Driscoll, certify that:

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

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

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

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

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

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

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

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

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

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

Date: November 14, 2014

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

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael D. Clayman, M.D., President and Chief Executive Officer of Flexion Therapeutics, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based upon my knowledge:

(1) this Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

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

Date: November 14, 2014

/s/ Michael D. Clayman, M.D.
Michael D. Clayman, M.D.
President and Chief Executive Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Frederick W. Driscoll, Chief Financial Officer of Flexion Therapeutics, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based upon my knowledge:

(1) this Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

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

Date: November 14, 2014

/s/ Frederick W. Driscoll
Frederick W. Driscoll
Chief Financial Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.