Flexion Therapeutics Inc
Form 10-Q
May 12, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 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 x No ¨

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

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

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

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

As of May 7, 2014, the registrant had 15,623,778 shares of Common Stock ($0.001 par value) outstanding.

Table of Contents

FLEXION THERAPEUTICS, INC.

TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Flexion Therapeutics, Inc.

(A Development Stage Enterprise)

Balance Sheets

(Unaudited)

	March 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 35,789,245	$ 16,188,254
Marketable securities	42,723,190	250,047
Prepaid expenses and other current assets	845,164	181,962
Total current assets	79,357,599	16,620,263
Property and equipment, net	392,770	375,239
Deferred offering costs		1,623,540
Other assets	24,750	28,875
Restricted cash	128,000	128,000
Total assets	$ 79,903,119	$ 18,775,917
Liabilities, Convertible Preferred Stock and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,783,489	$ 1,279,874
Accrued expenses and other current liabilities	1,599,892	2,256,680
Current portion of long-term debt	2,000,000	1,500,000
Total current liabilities	5,383,381	5,036,554
Long-term debt	3,058,333	3,546,667
Other long-term liabilities	80,476	90,373
Total liabilities	8,522,190	8,673,594
Commitments and contingencies		
Preferred Stock, $.001 par value; 10,000,000 and 0 shares authorized, at March 31, 2014 and December 31, 2013, respectively, and 0 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively		

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 March 31, 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; 15,609,039 and 794,090 shares issued and outstanding, at March 31, 2014 and December 31, 2013, respectively	15,609	794
Additional paid-in capital	144,069,881	1,458,503
Accumulated other comprehensive income	842	(28)
Deficit accumulated during the development stage	(72,705,403)	(66,163,159)
Total stockholders equity (deficit)	71,380,929	(64,703,890)
Total liabilities, convertible preferred stock, and stockholders equity (deficit)	$ 79,903,119	$ 18,775,917

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

Table of Contents

Flexion Therapeutics, Inc.

(A Development Stage Enterprise)

Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended March 31,		Cumulative Period From Inception (November 5, 2007) to March 31, 2014
	2014	2013	
Revenue	$	$	$
Operating expenses:			
Research and development	4,150,847	3,186,696	46,445,212
General and administrative	2,283,913	1,520,943	25,909,432
Total operating expenses	6,434,760	4,707,639	72,354,644
Loss from operations	(6,434,760)	(4,707,639)	(72,354,644)
Other income (expense):			
Interest income	30,758	118,772	806,879
Interest expense	(111,667)	(108,333)	(771,820)
Other income (expense), net	(26,575)	(100,887)	(385,818)
Total other income (expense)	(107,484)	(90,448)	(350,759)
Net loss	$ (6,542,244)	$ (4,798,087)	$ (72,705,403)
Net loss attributable to common stockholders	$ (6,542,244)	$ (4,798,087)	$ (72,705,403)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.86)	$ (6.08)	
Weighted average common shares outstanding, basic and diluted	7,632,786	789,222	
Other comprehensive (loss)income:			
	842	1,381	842

Unrealized (losses)gains from available-for-sale securities, net of tax of $0			
Total other comprehensive (loss)income	842	1,381	842
Comprehensive loss	$ (6,541,402)	$ (4,796,706)	$ (72,704,561)

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

Table of Contents

Flexion Therapeutics, Inc.

(A Development Stage Enterprise)

Consolidated 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)	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Par Value				
Balance at December 31, 2010	28,950,000	28,835,747	530,240	530	228,751	(1,055)	(21,547,907)	(21,319,681)
Issuance of Series A Convertible Preferred Stock	13,000,000	13,000,000						
Stock-based compensation expense					83,190			83,190
Net loss							(11,446,909)	(11,446,909)
Other comprehensive income						1,858		1,858
Balance at December 31, 2011	41,950,000	41,835,747	530,240	530	311,941	803	$ (32,994,816)	(32,681,542)
Issuance of Series A Convertible Preferred Stock, net of issuance costs of $11,476	13,093,464	13,081,988						
Issuance of Series B Convertible Preferred Stock, net of issuance costs of $111,522	17,736,786	19,888,478						
			258,982	259	41,851			42,110

Exercise of stock options								
Stock-based compensation expense					96,278			96,278
Net loss							(14,981,619)	(14,981,619)
Other comprehensive income						1,647		1,647
Balance at December 31, 2012	72,780,250	74,806,213	789,222	789	450,070	2,450	$ (47,976,435)	(47,523,126)
Exercise of stock options			4,868	5	12,266			12,271
Stock-based compensation expense					996,167			996,167
Net loss							(18,186,724)	(18,186,724)
Other comprehensive loss						(2,478)		(2,478)
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	67,184,423			67,190,173
Exercise of stock options			112,892	113	193,199			193,312
Stock-based compensation expense					436,495			436,495
Net loss							(6,542,244)	(6,542,244)
Other comprehensive loss						870		870
Balance at March 31, 2014	$	$	15,609,039	$ 15,609	$ 144,069,881	$ 842	$ (72,705,403)	$ 71,380,929

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

Table of Contents

Flexion Therapeutics, Inc.

(A Development Stage Enterprise)

Statements of Cash Flows

(Unaudited)

	Three Months Ended March 31,		Cumulative Period from Inception (November 5, 2007) to March 31,
	2014	2013	2014
Cash flows from operating activities			
Net loss	$ (6,542,244)	$ (4,798,087)	$ (72,705,403)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation	27,344	10,567	462,280
Stock-based compensation expense	436,495	32,439	1,789,761
Amortization of premium (discount) on marketable securities	9,271	85,994	571,146
Loss on disposal of property and equipment			168,107
Other non-cash charges	4,125	20,157	107,368
Changes in operating assets and liabilities:			
Prepaid expenses and other current and long-term assets	(663,202)	88,213	(792,346)
Accounts payable	671,763	(235,020)	1,631,568
Accrued expenses and other current and long-term liabilities	(430,366)	(234,554)	1,649,608
Net cash used in operating activities	(6,486,814)	(5,030,291)	(67,117,911)
Cash flows from investing activities			
Purchases of property and equipment	(44,875)	(5,360)	(1,023,155)
Change in restricted cash		(98,000)	(128,000)
Purchases of marketable securities	(42,731,544)	(7,730,192)	(124,216,215)
Redemption of marketable securities	250,000	4,250,000	80,912,644
Net cash used in investing activities	(42,526,419)	(3,583,552)	(44,454,726)
Cash flows from financing activities			
Proceeds from issuance of related-party notes			4,100,000
Payment of related-party notes			(4,100,000)
Proceeds from borrowings under term loan		5,000,000	5,000,000
Payments of debt issuance costs			(61,876)
Payment of initial public offering costs	(1,096,588)		(2,169,298)

Proceeds from issuance of Series A Convertible Preferred Stock, net of issuance costs			54,917,735
Proceeds from issuance of Series B Convertible Preferred Stock, net of issuance costs			19,888,478
Proceeds from the issuance of common stock	69,517,500		69,539,150
Proceeds from the exercise of stock options	193,312		247,693
Net cash provided by financing activities	68,614,224	5,000,000	147,361,882
Net increase (decrease) in cash and cash equivalents	19,600,991	(3,613,843)	35,789,245
Cash and cash equivalents at beginning of period	16,188,254	12,835,330	
Cash and cash equivalents at end of period	$ 35,789,245	$ 9,221,487	$ 35,789,245
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 100,000	$ 62,222	
Supplemental disclosures of non-cash financing activities:			
Initial public offering costs included in accounts payable or accrued expenses	$ 158,029		
Conversion of convertible preferred stock into common stock	$ 74,806,213		

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

Table of Contents

Flexion Therapeutics, Inc.

(A Development Stage Enterprise)

Notes to Financial Statements (Unaudited)

1. Overview and Nature of the Business

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

The Company is subject to risks and uncertainties common to 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 March 31, 2014 was 15,609,039 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 for the next twelve months.

At March 31, 2014, the Company is considered a development stage enterprise. Until planned principal operations have commenced and significant revenue is generated, financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) are required to report cumulative statements of operations and comprehensive loss, stockholders equity (deficit) and cash flows.

2. Basis of Presentation

The accompanying condensed financial statements as of March 31, 2014, and for the three months ended March 31, 2014 and 2013, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the SEC) and 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 condensed financial statements reflect all adjustments which are necessary for a fair statement of the Company s financial position and results of its operations, as of and for the periods presented. These condensed financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company s Annual Report on Form 10-K filed with the SEC on March 28, 2014.

The information presented in the condensed financial statements and related notes as of March 31, 2014, and for the three months ended March 31, 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.

Table of Contents

Interim results for the three months ended March 31, 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 is in the development stage and has incurred recurring losses and negative cash flows from operations. As of March 31, 2014 and December 31, 2013, the Company had cash and cash equivalents and marketable securities of $78,512,435 and $16,438,301, respectively. Management believes that current cash, cash equivalents and marketable securities on hand at March 31, 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 as this capital is necessary for the Company to perform the research and development activities required to develop the Company s product candidates in order to generate future revenue streams.

3. Fair Value of Financial Assets

The following tables present information about the Company s assets and liabilities that are measured at fair value on a recurring basis as of March 31, 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 March 31, 2014 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$	$ 34,913,885	$	$ 34,913,885
Marketable securities		42,723,190		42,723,190
	$	$ 77,637,075	$	$ 77,637,075

	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 March 31, 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 three months ended March 31, 2014 and year ended December 31, 2013, there were

no transfers between Level 1, Level 2 and Level 3.

The term loan outstanding under the Company s credit and security agreement 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 March 31, 2014. The result of the calculation yielded a fair value that approximates carrying value.

Table of Contents

4. Marketable Securities

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

	March 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 13,785,700	$ 11,314	$	$ 13,797,014
Corporate bonds and US Government Obligations	$ 28,936,648	$	$ (10,472)	$ 28,926,176
	$ 42,722,348	$ 11,314	$ (10,472)	$ 42,723,190

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

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2014	December 31, 2013
Clinical research	$ 393,090	$ 163,521
Contract manufacturing services	408,850	529,287
Payroll and other employee-related expenses	458,490	792,165
Preclinical services		5,685
Consultant fees and expenses	11,726	21,718
Professional services fees	237,789	642,052
Interest expense	34,445	34,445
Other	55,502	67,807
Total accrued expenses and other current liabilities	$ 1,599,892	$ 2,256,680

6. Stock-Based Compensation

Stock Incentive Plan

The Company grants stock-based awards pursuant to its Stock Incentive Plan (the 2013 Plan). The maximum number of shares that may be issued under the 2013 Plan is 4,684,989 shares. As of March 31, 2014, 1,034,020 shares were available for future issuance under the 2013 Plan.

Table of Contents

Stock Options

During the three months ended March 31, 2014 and 2013, the Company granted stock options for the purchase of 530,675, and 0 shares of common stock, respectively, to certain employees and directors. The vesting conditions for most 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 which 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 three months ended March 31, 2014 is as follows:

	2014
Risk-free interest rates	1.54-1.87%
Expected dividend yield	0.00%
Expected term (in years)	6.0
Expected volatility	64.3-66.9%

Table of Contents

The following table summarizes stock option activity for the three months ended March 31, 2014:

	Shares Issuable Under Options	Weighted Average Exercise Price
Outstanding as of December 31, 2013	834,983	$ 2.99
Granted	530,675	17.37
Exercised	(112,892)	1.71
Canceled	(62,062)	2.62
Outstanding as of March 31, 2014	1,190,704	$ 9.54
Options vested and expected to vest at March 31, 2014	1,099,029	
Options exercisable at March 31, 2014	319,140	

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 112,892 options were exercised during the three months ended March 31, 2014. The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2014 was $1,143,483.

At March 31, 2014 and 2013 the Company had options for the purchase of 1,190,704 and 662,730 shares of common stock outstanding, respectively, with a weighted average remaining contractual term of 8.73, and 7.73 years, respectively, and with a weighted average exercise price of $9.54 and $1.32 per share, respectively.

The weighted average grant date fair value of options granted during the three months ended March 31, 2014 and 2013 was $10.49 and $0, respectively.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options for the three months ended March 31, 2014 and 2013 as follows:

	2014	2013
Research and development	$ 113,518	$ 11,568
General and administrative	322,977	20,781
	$ 436,495	$ 32,439

As of March 31, 2014, unrecognized stock-based compensation expense for stock options outstanding was $7,717,771, which is expected to be recognized over a weighted average period of 3.3 years. As of March 31, 2013, unrecognized stock-based compensation expense for stock options outstanding was $261,142, which is expected to be recognized over a weighted average period of 1.4 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.

Table of Contents

7. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three months ended March 31, 2014 and 2013:

	2014	2013
Numerator:		
Net loss	$ (6,542,244)	$ (4,798,087)
Net income attributable to participating securities		
Net loss attributable to common stockholders:	$ (6,542,244)	$ (4,798,087)
Denominator:		
Weighted average common shares outstanding, basic and diluted	7,632,786	789,222
Net loss per share attributable to common stockholders, basic and diluted	$ (0.86)	$ (6.08)

Stock options for the purchase of 942,165 and 416,425 weighted average shares of common stock were excluded from the computation of diluted net loss per share attributable to common stockholders for the three months ended March 31, 2014 and 2013, respectively, because those options had an anti-dilutive impact due to the 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 months ended March 31, 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 for the next twelve months.

8. 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 three months ended March 31, 2014 and 2013 were $421,711 and $95,832, respectively, and from the date of inception (November 5, 2007) through March 31, 2014 were $3,348,332. Legal fees of the firm paid by the Company during the three months ended March 31, 2014 and 2013 were $561,475 and $180,653, respectively. Amounts payable to this firm as of March 31, 2014 and 2013 were $239,502 and $32,808, respectively.

9. Long-term Debt

On January 3, 2013, the Company entered into a credit and security agreement with 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 March 31, 2014, the carrying value of the term loan was $5,058,333, 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 March 31, 2014, the Company was compliant with all covenants.

Table of Contents

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 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 of 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, 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 are a development stage company and 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 have 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 or debt financings.

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

Table of Contents

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

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

OA is a type of degenerative arthritis that is caused by the progressive breakdown and eventual loss of cartilage in one or more joints. Arthritis is the most common cause of disability in the United States and OA is the most common joint disease, affecting 27 million Americans, with numbers expected to grow as a result of aging, obesity and sports injuries. Recent data suggest that OA accounts for over $185 billion of annual healthcare expenditures in the United States, which does not include loss of productivity costs. We estimate that by 2030, 45 million people will have OA, and that approximately 24 million of those people will have knee OA. OA commonly affects large weight-bearing joints like the knees and hips, but also occurs in the shoulders, hands, feet and spine. Patients with OA suffer from joint pain, tenderness, stiffness and limited movement. As the disease progresses, it becomes increasingly painful and debilitating, culminating, in many cases, in the need for total joint arthroplasty, or TJA. According to IMS Health, each year approximately ten million patients in the United States receive IA steroid injection treatments in the knee, hip, shoulder, hand and foot. Our clinical trials to date have treated patients with knee OA, which represents the most common joint treated with IA therapies for OA. In 2012, the number of patients that received knee injections of IA steroids increased approximately 12% to three 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 $690 million in 2012, 93% 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. 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;

Potential for pharmacoeconomic benefits due to superior efficacy and durability and the potential to delay costly and invasive total joint replacement.

To date, two clinical trials have been conducted to test FX006 against immediate-release TCA injection. A total of 252 patients were enrolled in these two clinical trials, of which 196 patients received FX006 and 56 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

Table of Contents

make its own naturally occurring steroids) seen with commercially available steroid suspensions. Preclinical data demonstrate not only that FX006 is well-tolerated with a single dose administration, but also in an inflammatory arthritis rat model, it demonstrated the potential to prevent joint damage and do so more effectively than immediate-release steroids. We are currently conducting a synovial fluid pharmacokinetic clinical trial to measure the duration of exposure to TCA from FX006 in the joint. This clinical trial has completed patient enrollment and topline data are expected to be announced in the second quarter of 2014. A confirmatory Phase 2b clinical trial of FX006 has begun patient enrollment and topline data are expected in the first half of 2015. A repeat dose safety clinical trial of FX006 is expected to begin in the second half of 2014.

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 and its low solubility characteristics should allow it to remain in the tissues for a sufficient period of time to effectively treat patients experiencing post-operative pain. As a result, unlike FX005 and FX006, 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. We plan to file an investigational new drug, or IND, application and to initiate a PoC clinical trial in the second half of 2014.

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.

Table of Contents

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 any revenue since our inception. We do not have any products approved for sale, and we do not expect to generate any revenue from the sale of products in the near future. In the future, if our research and development efforts result in clinical success and regulatory approval, we may generate revenue from the sales of our product candidates, or we may generate revenue from 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 and FX005.

Research and Development Expenses

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

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical studies and clinical trials;
- costs of acquiring, developing and manufacturing clinical trial materials;
- 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 March 31,	
	2014	**2013**
Direct research and development expenses by program:		
FX006	$ 2,811,027	$ 1,885,201
FX007	228,974	75,729
FX005	71,161	479,573
Total direct research and development expenses	3,111,162	2,440,503
Personnel and other costs	1,039,685	746,193
Total research and development expenses	$ 4,150,847	$ 3,186,696

Table of Contents

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 confirmatory Phase 2b and repeat dose safety clinical trials 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 make determinations as to 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. Prior to 2013, we had only incurred interest expense on our related-party debt which had been outstanding during 2008 and 2009. 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 quarter ended March 31, 2014.

Table of Contents

RESULTS OF OPERATIONS

Comparison of the three months ended March 31, 2014 and 2013

The following table summarizes our results of operations for the three months ended March 31, 2014 and 2013 (certain items may not sum correctly due to rounding):

	Three Months Ended March 31,		
	2014	2013	Change
	(in thousands)		
Revenue	$	$	$
Operating expenses:			
Research and development	4,150,847	3,186,696	964,151
General and administrative	2,283,913	1,520,943	762,970
Total operating expenses	6,434,760	4,707,639	1,727,121
Loss from operations	(6,434,760)	(4,707,639)	(1,727,121)
Other income (expense):			
Interest income	30,758	118,772	88,014
Interest expense	(111,667)	(108,333)	3,334
Other expense	(26,575)	(100,887)	(74,312)
Total other income (expense)	(107,484)	(90,448)	(17,036)
Net loss	$ (6,542,244)	$ (4,798,087)	$ (1,744,157)

Research and Development Expenses

	Three Months Ended March 31,		
	2014	2013	Change
	(in thousands)		
Direct research and development expenses by program:			
FX006	$ 2,811,027	$ 1,885,201	$ 925,826
FX007	228,974	75,729	153,245
FX005	71,161	479,573	(408,412)
Total direct research and development expenses	3,111,162	2,440,503	670,659
Personnel and other costs	1,039,685	746,193	293,492

Total research and development expenses	$ 4,150,847	$ 3,186,696	$ 964,151

Research and development expenses were $4.2 million and $3.2 million for the three months ended March 31, 2014 and 2013, respectively. The increase in research and development expenses year over year of $1.0 million, or 31%, was primarily due to an increase of $0.9 million in FX006 program expenses related to preparation for the initiation of the Phase 2b dose confirmatory trial and increased manufacturing expenses related to clinical trial supplies. FX007 expenses increased $0.2 million due to incurred costs for toxicology studies. Additionally, an increase of $0.3 million in personnel and other costs primarily related to employee related cost increases for headcount, stock compensation expense and consulting costs was offset by a decrease of $0.4 million in FX005 program expenses due to the completion of the Phase 2a clinical trial.

Table of Contents

General and Administrative Expenses

General and administrative expenses were $2.3 million and $1.5 million for the three months ended March 31, 2014 and 2013, respectively. The increase in general and administrative expenses year over year of $0.8 million, or 53%, was primarily due to increases associated with salary and related costs due to additional headcount and stock compensation expense of $0.4 million, $0.2 million in legal fees related to corporate legal activity and patents for our intellectual property, $0.1 million in professional and consulting fees during the first quarter of 2014, and an increase in facilities related costs due to our relocation to new offices in the second quarter of 2013.

Other Income (Expense)

Interest income was $0.03 and $0.1 million for the three months ended March 31, 2014 and 2013, respectively. Interest expense was consistent year over year.

Liquidity and Capital Resources

To date, we have not generated any revenue and have incurred losses since our inception in 2007. As of March 31, 2014, we had an accumulated deficit of $72.7 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 March 31, 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 March 31, 2014, we had cash and cash equivalents of $35.8 million and marketable securities of $42.7 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 three months ended March 31, 2014 and 2013:

	Three Months Ended March 31,	
	2014	**2013**
Cash flows used in operating activities	$ (6,486,814)	$ (5,030,291)
Cash flows used in investing activities	(42,526,419)	(3,583,552)
Cash flows provided by financing activities	68,614,224	5,000,000
Net increase (decrease) in cash and cash equivalents	$ 19,600,991	$ (3,613,843)

Net Cash Used in Operating Activities

Operating activities used $6.5 million of cash in the three months ended March 31, 2014. The cash flow used in operating activities resulted primarily from our net loss of $6.5 million for the period and cash used for changes in our operating assets and liabilities of $0.4 million, offset by non-cash charges of $0.5 million. Net cash used for changes in our operating assets and liabilities consisted primarily of a $0.7 million increase in our prepaid expenses and other current assets due primarily to increased insurance costs. Accrued expenses and other current liabilities decreased $0.4 million, this decrease was primarily attributable to an increase in vendor invoices received and processed to accounts payable prior to March 31, 2014, as compared to the previous year. These changes were partially offset by a $0.7 million increase in our accounts payable due to the timing of our payments to manufacturers, CROs and legal counsel, as well as an increase in the timely receipt of invoices from our vendors. Our non-cash charges consisted of primarily of $0.4 million of stock-based compensation expense.

Operating activities used $5.0 million of cash in three months ended March 31, 2013. The cash flow used in operating activities resulted primarily from our net loss of $4.8 million for the year, and net cash used for changes in our operating assets and liabilities of $0.4 million, offset by net non-cash charges of $0.1 million. Net cash used for changes in our operating assets and liabilities consisted primarily of a $0.2 million decrease in our accrued expenses and other current liabilities, and a $0.2 million decrease in our accounts payable, partially offset by a $0.1 million decrease in prepaid expenses and other current assets. The decrease in accrued expenses and other current liabilities was primarily attributable to the decrease in expenses related to clinical research and contract manufacturing services. The increase in our prepaid expenses and other current assets was primarily due to prepayments we made for legal services related to our patent filings. The decrease in our accounts payable was primarily due to the timing of our payments to manufacturers and CROs. Our non-cash charges consisted of $0.1 million related to depreciation expense and amortization of premiums on marketable securities, as well as stock based compensation expense.

Table of Contents

Net Cash Used in Investing Activities

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

Net cash used in investing activities was $3.6 million for the three months ended March 31, 2013. Net cash used in investing activities consisted primarily of cash paid to purchase marketable securities of $7.7 million, and a change in restricted cash of $0.1 million, partially offset by cash received from the redemption of marketable securities of $4.3 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $68.6 million and $5.0 million for the three months ended March 31, 2014 and 2013, respectively. Net cash provided by financing activities in the three months ended March 31, 2014 consisted of $69.5 million in proceeds from our initial public offering, and $0.2 million in proceeds received from the exercise of stock options, offset by the payment of fees incurred in connection with our initial public offering of $1.1 million. Net cash provided by financing activities in the three months ended March 31, 2013 primarily consisted of $5.0 million in proceeds from borrowings under our term loan.

Contractual Obligations

There have been 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.

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

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

Based on our management s evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of March 31, 2014, the end of the period covered by this report.

Table of Contents

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 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, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock would likely decline. You should consider all of the factors described below and in Item 1A of our Annual Report on Form 10-K when evaluating our business. The risk factors set forth below represent new risk factors or those containing changes, including material changes, to the similarly titled risk factors included in Item 1A of our Annual Report on Form 10-K.

Risks Related to Our Financial Condition and Need for Additional Capital

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

We are a development stage company with 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 $6.5 million for the three months ended March 31, 2014 and $18.2 million, $15.0 million and $11.4 million for fiscal years 2013, 2012 and 2011, respectively. As of March 31, 2014, we had an accumulated deficit of $72.7 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 an increase in our 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 conducted 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 planned confirmatory Phase 2b clinical trial will demonstrate similar results.

Table of Contents

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 intend to study in our planned confirmatory Phase 2b 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 animals with 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. Most observations were expected results; however, local cartilage findings of reduced extracellular matrix were observed but had partially reversed by the end of the recovery period in both the FX006 and TCA study arms. All of our clinical trials to date have been conducted with single doses of FX006. However, we intend to study FX006 in a separate repeat dose safety clinical trial, and it is possible that we could observe similar outcomes to those observed in preclinical studies with the repeat doses of FX006 that would harm our ability to seek or 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 planned confirmatory Phase 2b 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 protocols 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.

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 March 31, 2014, we had 16 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.

Table of Contents

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

Recent Sales of Unregistered Securities

During the period from January 1, 2014 through February 12, 2014 (the date that our Registration Statement on Form S-8 covering shares issuable pursuant to our equity incentive plans was filed with the SEC), we issued 111,867 shares of our common stock to employees pursuant to the exercise of stock options previously granted under our 2009 Equity Incentive Plan, for aggregate consideration of approximately $186,561.

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under the 2009 plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

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 have been 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.

23

Table of Contents

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+(2)	Flexion Therapeutics, Inc. 2013 Equity Incentive Plan and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder.
10.2+(2)	Flexion Therapeutics, Inc. 2013 Employee Stock Purchase Plan.
10.3+(3)	Flexion Therapeutics, Inc. Non-Employee Director Compensation Policy, as revised.
10.4+(3)	Amendment to Amended and Restated Offer Letter by and between the Registrant and Michael D. Clayman, M.D.
10.5+(3)	Amendment to Amended and Restated Offer Letter by and between the Registrant and Neil Bodick, M.D., Ph.D.
10.6+(3)	Amendment to Amended and Restated Offer Letter by and between the Registrant and Fred Driscoll.
10.7*	Letter Agreement, dated March 17, 2014, by and between the Registrant and AstraZeneca AB.
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.
* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.
(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 Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 28, 2014.

Table of Contents

SIGNATURES

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

Flexion Therapeutics, Inc.

Date: May 12, 2014

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