EDGAR pro
by EDGAR Online

FLEXION THERAPEUTICS INC

FORM 10-Q
(Quarterly Report)

Filed 05/05/17 for the Period Ending 03/31/17

Address	10 MALL ROAD SUITE 301 BURLINGTON, MA 01803
Telephone	(781) 305-7777
CIK	0001419600
Symbol	FLXN
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

Powered By EDGAR Online
http://www.edgar-online.com
© Copyright 2017, EDGAR Online, Inc. All Rights Reserved.
Distribution and use of this document restricted under EDGAR Online, Inc. Terms of Use.

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

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2017

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☒

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

As of May 1, 2017 the registrant had 31,757,692 shares of Common Stock ($0.001 par value) outstanding.

FLEXION THERAPEUTICS, INC.
TABLE OF CONTENTS

PART I. FINANCI AL INFORMATION

Item 1. Financial Statements

Flexion Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited in thousands, except share amounts)

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 42,921	$ 30,915
Marketable securities	142,896	174,688
Prepaid expenses and other current assets	4,307	3,790
Total current assets	$ 190,124	$ 209,393
Property and equipment, net	11,841	11,664
Long-term investments	1,728	4,725
Restricted cash	600	480
Total assets	$ 204,293	$ 226,262
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,210	$ 2,161
Accrued expenses and other current liabilities	5,815	6,245
Current portion of long-term debt	9,967	9,134
Total current liabilities	$ 17,992	$ 17,540
Long-term debt	19,908	21,399
Other long-term liabilities	294	291
Total liabilities	$ 38,194	$ 39,230
Commitments and contingencies		
Preferred Stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2017 and December 31, 2016 and 0 shares issued and outstanding at March 31, 2017 and December 31, 2016	—	-
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized; 31,752,692 and 31,667,469 shares issued and outstanding, at March 31, 2017 and December 31, 2016, respectively	32	32
Additional paid-in capital	401,694	398,757
Accumulated other comprehensive income	(62)	(71)
Accumulated deficit	(235,565)	(211,686)
Total stockholders' equity	166,099	187,032
Total liabilities and stockholders' equity	$ 204,293	$ 226,262

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

Flexion Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited in thousands, except per share amounts)

	Three Months Ended March 31,	
	2017	**2016**
Revenue	$ —	$ —
Operating expenses:		
Research and development	10,756	11,981
General and administrative	13,026	4,692
Total operating expenses	23,782	16,673
Loss from operations	(23,782)	(16,673)
Other income (expense):		
Interest income	557	336
Interest expense	(632)	(276)
Other income (expense), net	(22)	(202)
Total other income (expense)	(97)	(142)
Net loss	$ (23,879)	$ (16,815)
Net loss per share basic and diluted	$ (0.75)	$ (0.78)
Weighted average common shares outstanding, basic and diluted	31,704	21,570
Other comprehensive (loss) income:		
Unrealized gains from available-for-sale securities, net of tax of $0	9	(89)
Total other comprehensive (loss) income	9	(89)
Comprehensive loss	$ (23,870)	$ (16,904)

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

Flexion Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited in thousands)

	Three Months Ended March 31,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (23,879)	$ (16,815)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	453	186
Stock-based compensation expense	2,378	1,641
Amortization of premium (discount) on marketable securities	155	196
Other non-cash charges	11	9
Loss on disposal of fixed assets	—	2,278
Premium paid on securities purchased	(264)	—
Changes in operating assets and liabilities:		
Accounts receivable	—	39
Prepaid expenses, other current and long-term assets	(517)	(572)
Accounts payable	138	(1,009)
Accrued expenses and other current and long-term liabilities	131	51
Net cash used in operating activities	(21,394)	(13,996)
Cash flows from investing activities		
Purchases of property and equipment	(1,018)	(3,094)
Change in restricted cash	(120)	—
Purchases of marketable securities	(25,450)	(3,006)
Sale and redemption of marketable securities	60,328	16,097
Discount received on securities purchased	29	—
Net cash provided by investing activities	33,769	9,997
Cash flows from financing activities		
Payment of debt issuance costs	—	(42)
Payments on notes payable	(833)	—
Payments of public offering costs	(95)	—
Proceeds from the exercise of stock options	559	—
Net cash used in financing activities	(369)	(42)
Net increase (decrease) in cash and cash equivalents	12,006	(4,041)
Cash and cash equivalents at beginning of period	30,915	62,944
Cash and cash equivalents at end of period	$ 42,921	$ 58,903
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 469	$ 237
Supplemental disclosures of non-cash financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 234	$ 2,450

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

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, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis ("OA"), a type of degenerative arthritis. In May 2016, the U.S Food and Drug Administration, or FDA, informed us that the safety and efficacy data from the registration program for Zilretta ™ (FX006), our lead investigational product candidate, were acceptable to support the submission of a new drug application, or NDA. In December 2016, we submitted the NDA for Zilretta, and in February 2017, we announced that the FDA accepted the Zilretta NDA for filing and has established a user fee goal date under the Prescription Drug User Fee Act, or PDUFA, of October 6, 2017.

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 the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance reporting capabilities. The Company's product candidates are all in the development stage. There can be no assurance that development efforts, including clinical trials, will be successful. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of March 31, 2017, and for the three months ended March 31, 2017 and March 31, 2016, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") and Generally Accepted Accounting Principles ("GAAP") for consolidated financial information including the accounts of the Company and its wholly-owned subsidiary after elimination of all significant intercompany accounts and transactions. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these condensed consolidated financial statements reflect all adjustments which are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the SEC on March 10, 2017.

The information presented in the condensed consolidated financial statements and related notes as of March 31, 2017, and for the three months ended March 31, 2017 and March 31, 2016, is unaudited. The December 31, 2016 consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the three months ended March 31, 2017 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2017, or any future period.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. As of March 31, 2017 and December 31, 2016, the Company had cash, cash equivalents, marketable securities, and long-term investments of approximately $187,545,000 and $210,328,000, respectively. Management believes that current cash, cash equivalents and marketable securities on hand at March 31, 2017, together with the gross proceeds of our offering of approximately $201 million described in note twelve, should be sufficient to fund operations for at least the next twelve months from the date of these financial statements. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations, to fund increased research and development costs in order to seek approval for commercialization of its product candidates, and to successfully commercialize Zilretta, if approved. 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 and seek approval for commercialization of the Company's product candidates, to establish a commercial infrastructure in order to generate future revenue streams, and to successfully commercialize Zilretta, if approved.

In May 2014, the FASB issued guidance which supersedes all e xisting 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 exp ects to receive for those goods or services. In August 2015, the FASB issued Accounting Standards Update 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date. This latest standard defers the effective date of revenue standard ASU 2014-09 by one year and permits early adoption on a limited basis. Since the Company has not generated revenue to date, this guidance will only impact future periods, if any, when revenue is earned. This update will replace existing revenue recognition gu idance under GAAP when it becomes effective for the Company beginning January 1, 2018, with early adoption permitted in the first quarter of 2017. The updated standard will permit the use of either the retrospective or cumulative effect transition method. The Company is adopting this guidance as of January 1, 2017 and is currently evaluating the potential impact that the adoption of this guidance may have on the Company's future financial statements.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes* (Topic 740), to simplify the presentation of deferred income taxes. Under the new standard, both deferred tax liabilities and assets are required to be classified as noncurrent in a classified balance sheet. ASU 2015-17 will become effective for fiscal years, and the interim periods within those years, beginning after December 15, 2016, with early adoption allowed. Given the Company has a full valuation against its deferred tax assets and liabilities, the impact of adopting this guidance was not material to the Company's financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases* ("ASU 2016-02"), to increase transparency and comparability among organizations by recognizing lease assets and liabilities, including for operating leases, on the balance sheet and disclosing key information about leasing arrangements. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is currently evaluating the impact that the adoption of this guidance may have on the Company's financial statements.

In March 2016, the FASB released ASU 2016-09, which amends ASC Topic 718, Compensation-Stock Compensation, to require changes to several areas of employee share-based payment accounting in an effort to simplify share-based reporting. The update revises requirements in the following areas: minimum statutory withholding, accounting for income taxes, forfeitures, and intrinsic value accounting for private entities. For public companies, the new rules will become effective for annual reporting periods beginning after December 15, 2016, and interim reporting periods within such annual period. The Company adopted this guidance beginning on January 1, 2017 and no longer records stock compensation expense net of forfeitures. The Company adopted this guidance using a modified retrospective approach to reflect forfeitures as they occurred in the total stock based compensation expense recorded in the Company's financial statements. The impact of this adoption was not material to the Company's financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of cash flows* (Topic 230), to increase the consistency of presentation in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 will become effective for fiscal years, and the interim periods within those years, beginning after December 15, 2017. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the Company's financial statements.

Consolidation

The accompanying condensed consolidated financial statements include the Company and its wholly-owned subsidiary, Flexion Securities Corporation, Inc. The Company has eliminated all intercompany transactions for the three months ended March 31, 2017 and the year ended December 31, 2016.

Use of Estimates

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

Property and Equipment

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

	Estimated Useful Life (Years)
Computers, office equipment, and minor computer software	3
Computer software	7
Manufacturing equipment	7-10
Furniture and fixtures	5

Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Costs of major additions and improvements are capitalized and depreciated on a straight-line basis over their useful lives. Repairs and maintenance costs are expensed as incurred. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to income. Property and equipment includes construction-in-progress that is not yet in service.

Foreign Currencies

The Company maintains a bank account denominated in British Pounds. All foreign currency payables and cash balances are measured at the applicable exchange rate at the end of the reporting period. All associated gains and losses from foreign currency transactions are reflected in the consolidated statements of operations.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets that are measured at fair value on a recurring basis as of March 31, 2017 and December 31, 2016 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of March 31, 2017 Using:			
(In thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ —	$ 33,035	$ —	$ 33,035
Marketable securities	—	144,624	—	144,624
	$ —	$ 177,659	$ —	$ 177,659

	Fair Value Measurements as of December 31, 2016 Using:			
(In thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ —	$ 9,830	$ —	$ 9,830
Marketable securities	—	179,414	—	179,414
	$ —	$ 189,244	$ —	$ 189,244

As of March 31, 2017 and December 31, 2016, the Company's cash equivalents that are invested in money market funds are valued based on Level 2 inputs. The Company measures the fair value of marketable securities, which consist of U.S. government obligations, commercial paper, and corporate bonds, using Level 2 inputs and primarily relies on quoted prices in active markets for similar marketable securities. During the three months ended March 31, 2017 and year ended December 31, 2016, there were no transfers between Level 1, Level 2, and Level 3.

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

The Company has a term loan outstanding under its 2015 credit facility with MidCap Financial Funding XIII Trust and Silicon Valley Bank (the "2015 term loan"). The amount outstanding on its 2015 term loan is reported at its carrying value in the accompanying balance sheet. The Company determined the fair value of the 2015 term loan using an income approach that utilizes a discounted cash flow analysis based on current market interest rates for debt issuances with similar remaining years to maturity, adjusted for credit risk. The 2015 term loan was valued using Level 2 inputs as of March 31, 2017 and December 31, 2016. The result of the calculation yielded a fair value that approximates its carrying value.

4. Marketable Securities

As of March 31, 2017 and December 31, 2016 the fair value of available-for-sale marketable securities by type of security was as follows:

	March 31, 2017			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Government obligations	$ 58,012	$ —	$ (26)	$ 57,986
Commercial Paper	11,521	—	—	11,521
Corporate bonds	75,153	5	(41)	75,117
	$ 144,686	$ 5	$ (67)	$ 144,624

	December 31, 2016			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial Paper	$ 7,769	$ —	$ —	$ 7,769
U.S. Government obligations	75,524	5	(12)	75,517
Corporate Bonds	96,193	1	(66)	96,128
	$ 179,486	$ 6	$ (78)	$ 179,414

As of March 31, 2017 and December 31, 2016, marketable securities consisted of approximately $142,896,000 and $174,688,000, respectively, of investments that mature within twelve months and approximately $1,728,000 and $4,725,000, respectively, of investments that mature within seventeen months.

5. Property and Equipment, Net

Property and equipment, net, as of March 31, 2017 and December 31, 2016 consisted of the following:

(In thousands)	March 31, 2017	December 31, 2016
Manufacturing equipment	$ 10,373	$ 10,099
Computers, office equipment, and minor computer software	659	573
Software	434	434
Construction—in progress	1,495	1,254
Furniture and fixtures	426	402
Leasehold improvements	283	278
	13,670	13,040
Less: Accumulated depreciation	(1,829)	(1,376)
Total property and equipment, net	$ 11,841	$ 11,664

Depreciation expense for the three months ended March 31, 2017 and 2016 was approximately $453,000 and $186,000, respectively. No property and equipment was disposed of during the three months ended March 31, 2017. Construction in progress is primarily comprised of amounts related to equipment purchased for the Company's portfolio expansion efforts.

.

6. Prepaid Expenses, Other Current Assets, and Other Assets

Prepaid expenses and other current assets and other assets consisted of the following as of March 31, 2017 and December 31, 2016:

	March 31, 2017	December 31, 2016
Prepaid expenses	$ 1,578	$ 1,085
Security Deposits	2,099	2,099
Interest receivable on marketable securities	629	605
Employee advances	1	1
Total prepaid expenses and other current assets	$ 4,307	$ 3,790

On December 1, 2016, Flexion paid a refundable NDA fee in the amount of $2,038,100 to the FDA. The Company evaluated each of the published criteria to qualify for a waiver and concluded all criteria were met and thus, obtaining a refund of the fee was probable. As of March 31, 2017 and December 31, 2016 the NDA fee was classified as a deposit in other current assets. On April 20, 2017 we were informed by the FDA that our NDA fee waiver was approved and the NDA fee would be refunded.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	March 31, 2017	December 31, 2016
Research and Development	$ 1,140	$ 1,606
Payroll and other employee-related expenses	1,495	3,393
Professional services fees	2,146	926
Other	877	159
Interest expense	157	161
Total accrued expenses and other current liabilities	$ 5,815	$ 6,245

8. Stock-Based Compensation

Stock Option Valuation

The fair value of each of the Company's stock option grants is estimated on the date of grant using the Black-Scholes option-pricing model. The Company currently 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 publicly-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, 2017 and 2016 are as follows:

	Three months ended March 31,	
	2017	2016
Risk-free interest rates	2.23-2.29%	1.39-1.90%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.0	6.1
Expected volatility	71.0-71.6%	83.8-84.1%

The following table summarizes stock option activity for the three months ended March 31, 2017:

(In thousands, except per share amounts)	Shares Under Issuable Options	Weighted Average Exercise Price
Outstanding as of December 31, 2016	3,268	$ 14.84
Granted	280	19.74
Exercised	(59)	9.47
Cancelled	(23)	17.86
Outstanding as of March 31, 2017	3,466	$ 16.20
Options vested and expected to vest at March 31, 2017	3,466	$ 16.20
Options exercisable at March 31, 2017	1,337	$ 13.28

Approximately 189,300 outstanding restricted stock units ("RSUs") are included in outstanding at March 31, 2017. The RSUs are performance based awards which will only begin vesting if and when a specified corporate performance based milestone is achieved. No outstanding performance awards were vested as of March 31, 2017.

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 approximately 59,000 options, with an aggregate intrinsic value of approximately $666,000, were exercised during the three months ended March 31, 2017.

At March 31, 2017 and 2016, there were options for the purchase of approximately 3,466,000 and 2,176,000 shares of the Company's common stock outstanding, respectively, with a weighted average remaining contractual term of 8.2 years and with a weighted average exercise price of $16.20 and $15.16 per share, respectively.

The weighted average grant date fair value of options granted during the three months ended March 31, 2017 and 2016 was $12.70 and $12.82, respectively.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options for the three months ended March 31, 2017 and 2016 as follows:

(In thousands)	Three months ended March 31, 2017	2016
Research and development	$ 879	$ 537
General and administrative	1,499	1,104
	$ 2,378	$ 1,641

As of March 31, 2017 unrecognized stock-based compensation expense for stock options outstanding was approximately $22,088,000, which was expected to be recognized over a weighted average period of 3.0 years.

Restricted Stock Units

On January 4, 2016, the Company granted RSUs with performance and time-based vesting conditions to certain executives. These RSUs vest, and the underlying shares of common stock become deliverable, in the event the Company receives approval from the U.S. Food and Drug Administration ("FDA") of a new drug application ("NDA") for Zilretta (the **"** Milestone **"**). Depending on when and if the Milestone is achieved, the maximum aggregate number of shares of the Company's common stock available to be earned under these awards is 189,300 with an approximate value of $3,997,000 as of the grant date. The amount of earned shares decreases the longer it takes to achieve the Milestone. If the Milestone is not achieved prior to July 1, 2018, these awards will not vest, will be forfeited in their entirety and no shares of common stock will be delivered. Since it is not possible for the Company to determine the probability of the performance condition being achieved, no compensation costs will be recorded until the Milestone is achieved. If the Milestone is achieved prior to the termination date, compensation costs will be recognized over the remaining requisite service period of these awards, beginning on the Milestone achievement date.

9. Net Loss per Share

Basic and diluted net loss per share was calculated as follows for the three months ended March 31, 2017 and 2016:

	For the three months ended March 31,	
(In thousands)	**2017**	**2016**
Numerator:		
Net loss	$ (23,879)	$ (16,815)
Net loss:	$ (23,879)	$ (16,815)
Denominator:		
Weighted average common shares outstanding, basic and diluted	31,704	21,570
Net loss per share, basic and diluted	$ (0.75)	$ (0.78)

Stock options and RSUs representing 3,504,000 and 2,378,000 weighted average shares of common stock were excluded from the computation of diluted net loss per share for the three months ended March 31, 2017 and 2016, respectively. These equity awards were excluded from the computations because the awards had an anti-dilutive impact due to the net loss incurred for those periods.

10. Long-term Debt

On August 4, 2015, the Company entered into a credit and security agreement with MidCap Financial Trust, as agent, and MidCap Financial Funding XIII Trust and Silicon Valley Bank, as lenders, (the "Lenders"), to borrow up to $30,000,000 in term loans. The Company concurrently borrowed an initial term loan of $15,000,000 under the facility. The Company granted the Lenders a security interest in substantially all of its personal property, rights and assets, other than intellectual property, to secure the payment of all amounts owed under the credit facility. The Company agreed not to encumber any of its intellectual property without the Lenders' prior written consent. The Company also agreed to maintain a balance in cash or cash equivalents at Silicon Valley Bank equal to the principal balance of the loan plus 5% for so long as the Company maintains any cash or cash equivalents in non-secured bank accounts.

On July 22, 2016, the Company borrowed the remaining $15,000,000 under the credit and security agreement, in the form of a second term loan after receiving positive Phase 3 Zilretta clinical trial data meeting the trial's primary endpoint and which is sufficient to file an NDA for Zilretta. The second term loan is subject to the same credit terms as the initial term loan under the facility.

The credit and security agreement also contains certain representations, warranties, and covenants of the Company as well as a material adverse event clause. As of March 31, 2017, the Company was compliant with all covenants.

Borrowings under the credit facility accrue interest monthly at a fixed interest rate of 6.25% per annum. Following an interest-only period of 19 months, principal will be due in 36 equal monthly installments commencing March 1, 2017 and ending February 1, 2020 (the "maturity date"). Upon the maturity date, the Company will be obligated to pay a final payment equal to 9% of the total principal amounts borrowed under the facility. The final payment amount is being accreted to the carrying value of the debt using the effective interest rate method. As of March 31, 2017, the carrying value of the term loan was approximately $29,875,000, of which $9,967,000 was due within 12 months and $19,908,000 was due in greater than 12 months.

In connection with the credit and security agreement, the Company incurred debt issuance costs totaling approximately $150,000. These costs are being amortized over the estimated term of the debt using the straight-line method which approximates the effective interest method. The Company deducted the debt issuance costs from the carrying amount of the debt as of March 31, 2017 and December 31, 2016.

As of March 31, 2017, annual principal and in terest payments due under the 2015 term loan are as follows:

Year	Aggregate Minimum Payments *(in thousands)*
2017	$ 8,734
2018	11,082
2019	10,448
2020	4,383
Total	$ 34,647
Less interest	(2,072)
Less final payment	(2,700)
Total	$ 29,875

11. Foreign Currency

The Company maintains a bank account denominated in British Pounds. All foreign currency payables and cash balances are measured at the applicable exchange rate at the end of the reporting period. All associated gains and losses from foreign currency transactions are reflected in the consolidated statements of operations. Foreign currency losses for the three months ended March 31, 2017 were $0.1 million, compared to zero for the three months ended March 31, 2016.

12. Subsequent Event

On May 2, 2017, the Company completed an offering of convertible senior notes with a principal amount of $175 million maturing in 2024. In addition, the initial buyers exercised their option to purchase approximately $26 million of additional principal of the notes. The notes are general unsecured obligation of the Company and will accrue interest at a rate of 3.375 %, payable semiannually in arrears. The notes will be convertible, at the option of the holders if the Company's stock maintains a price of 130% or greater of the conversion price for a specified period, into cash, shares of the Company's common stock, or a combination of cash and shares, as determined by the Company.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIO NS

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, 2016 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 10, 2017.

Forward-Looking Statements

This discussion and analysis contains "forward-looking statements" that is statements related to future, not past, events – as defined in Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act that reflect our current expectations regarding future development activities, results of operations, financial condition, cash flows, performance and business prospects, and opportunities, as well as assumptions made by and information currently available to our management. Forward looking statements, include any statement that does not directly related to a current historical fact. The Company has tried to identify forward-looking statements by using words such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. 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, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a type of degenerative arthritis, referred to as OA.

In May 2016, the U.S Food and Drug Administration, or FDA, informed us that the safety and efficacy data from the registration program for Zilretta ™ (FX006), our lead investigational product candidate, were acceptable to support the submission of a new drug application, or NDA. In December 2016, we submitted the NDA for Zilretta, and in February 2017, we announced that the FDA accepted the Zilretta NDA for filing and has established a user fee goal date under the Prescription Drug User Fee Act, or PDUFA, of October 6, 2017.

We were incorporated in Delaware in November 2007, and to date we have devoted substantially all of our resources to developing our product candidates, including conducting clinical trials with our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. From our inception through March 31, 2017, we have funded our operations primarily through the sale of our common stock and convertible preferred stock and, to a lesser extent, debt financing. From our inception through March 31, 2017, we have raised $422.3 million from such transactions, including from our initial and follow-on public offerings. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or third-party funding, and licensing or collaboration arrangements.

Zilretta —Late Stage Candidate for Intra-articular Therapy for Patients with Moderate to Severe OA Pain

Zilretta is an injectable, extended-release, intra-articular, or IA, meaning "in the joint," steroid that we are developing as a treatment for patients with moderate to severe OA pain. We specifically designed Zilretta to combine a commonly administered steroid, triamcinolone acetonide, or TA, with poly lactic-co-glycolic acid, referred to as PLGA, with the goal of providing extended therapeutic concentrations in the joint and persistent analgesic effect. Zilretta is intended to address the limitations of current IA therapies by providing extended, local analgesia while avoiding systemic side effects, which are effects that can occur throughout the body as a result of drug that is released from the site of injection into circulating blood. To date, we have completed seven clinical trials, and more than 800 patients with OA of the knee have been treated with Zilretta. The overall frequency of treatment-related adverse events in these trials has been similar to those observed with placebo and no drug-related serious adverse events have been reported. Both the magnitude and duration of pain relief provided by Zilretta in clinical trials have been shown to be clinically meaningful with the magnitude of pain relief amongst the largest seen to date in OA clinical trials.

Based on the strength of our pivotal and other clinical trials, we believe that Zilretta has the potential to address a significant unmet medical need for OA pain management by providing safe, effective and extended pain relief. Zilretta is an injectable, IA, extended-release investigational treatment for patients with moderate to severe OA pain, and we believe it is uniquely distinguished by the following attributes:

- significant improvements in validated OA specific measures compared to the current injectable standard of care,

- significant pain relief against placebo as measured by the weekly mean of the Average Daily Pain, or ADP, score in the phase 3 trial :
    - demonstrating at week 12, the primary endpoint, at p value of <0.0001, 2 sided
    - at each week beginning at week1 and continuing through week 16
    - demonstrating, on average, an approximately 50 percent reduction in pain from baseline over weeks 1 through 12
- persistent therapeutic concentrations of drug in the joint and durable efficacy,
- statistically significant (p<0.05, 2-sided) reduction in the rise of blood glucose compared to that observed following immediate-release TA injection in Type 2 diabetic patients who also have knee OA,
- reduced rescue medicine consumption compared with placebo and immediate-release TA, and
- an acceptable safety profile with limited systemic exposures and the potential for fewer serious side effects compared to oral treatment options for OA pain.
- amongst the largest analgesic effects seen in OA clinical trials.

In December 2016, we submitted the NDA for Zilretta, and in February 2017, we announced that the FDA accepted the Zilretta NDA for filing and has established a user fee goal date under the Prescription Drug User Fee Act, or PDUFA, of October 6, 2017. Additionally, there has been strong enrollment in our clinical trial to evaluate the safety of repeat administration of Zilretta in patients with OA of the knee. The repeat dose study is expected to be fully enrolled in the second half of 2017, and the data readout is anticipated in 2018.

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, including Zilretta, or we may generate revenue from licensing rights to our product candidates to third parties. If we fail to complete the development of Zilretta or other product candidates, our ability to generate future revenue and our results of operations and financial position will be adversely affected.

Operating Expenses

The majority of our operating expenses to date have been related to the development activities of Zilretta.

Research and Development Expenses

Since our inception, we have focused our resources on our development activities, including: preclinical studies, 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 potential future commercial supplies, and are tracked on a program-by-program basis. We do not allocate personnel costs, facilities or other indirect expenses to specific research and development programs. These indirect expenses are included within the amounts designated as “Personnel and other costs” in the table below.

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

	Three Months Ended March 31,	
(In thousands)	**2017**	**2016**
Direct research and development expenses by program:		
Zilretta	$ 4,772	$ 8,108
FX007	—	205
Portfolio expansion	328	97
Other	234	138
Total direct research and development expenses	5,334	8,548
Personnel and other costs	5,422	3,433
Total research and development expenses	$ 10,756	$ 11,981

The Company previously performed research and development for the U.S. Department of Defense under a cost reimbursable grant for a Phase 2 clinical trial investigating Zilretta in active military and medically retired veterans with post-traumatic knee OA Reimbursements were recorded as an offset to research and development expenses when invoices for allowable costs were prepared and submitted to the U.S. Department of Defense. Due to the challenges of enrolling military personnel with post-traumatic knee OA, we discontinued this Phase 2 trial and terminated the grant. Payments under cost reimbursable grants with agencies of the U.S. government were provisional payments subject to adjustment upon audit by the U.S. government. We were reimbursed for approximately $757,000 under the grant.

Our research and development expenses are expected to increase in the foreseeable future. Specifically, our costs associated with Zilretta will increase as we conduct additional clinical trials, make initial investments for commercial product supply, and further the manufacturing process in anticipation of validation and commercialization, including the costs for the build-out of the portion of the dedicated manufacturing facility with our contract manufacturer, Patheon UK Limited, or Patheon. Evonik Corporation, or Evonik, our supplier of PLGA for Zilretta, had previously manufactured finished drug product for our Zilretta clinical trial materials; however, in early 2016 we decided to use Patheon as our sole supplier of Zilretta finished drug product for clinical trials and commercial supply. We impaired approximately $2,265,000 in manufacturing equipment located at the Evonik facility, resulting in a loss of $2,180,000 which was recorded in research and development expenses for the three months ended March 31, 2016.

We cannot determine with certainty the duration of and completion costs associated with future clinical trials of Zilretta or the regulatory approval process. The duration, costs and timing associated with the development and commercialization of Zilretta will depend on a variety of factors, including uncertainties associated with the results of our clinical trials and our ability to obtain regulatory approval. As a result of these uncertainties, we are currently unable to estimate with any precision our future research and development expenses for any product candidate, when or if we will achieve regulatory approval, generate revenue from sales of any product candidate or achieve a positive cash flow position.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future as we continue to build our corporate and commercial infrastructure to support the continued development and potential launch of Zilretta or any other product candidates. Additionally, we anticipate increased expenses related to the audit, legal and compliance, regulatory, investor relations and tax-related services associated with maintaining compliance with the Securities and Exchange Commission and Nasdaq requirements and healthcare laws and compliance 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. We have borrowed $30.0 million under our 2015 term loan facility, and we incur interest related to this borrowing at a fixed rate of 6.25% per annum. We expect to incur future interest expense related to this borrowing until February 1,

2020, as well as interest expense related to the convertible senior notes issued on May 2, 2017 as disclosed in footnote twelve in these financial statements.

Foreign currency gain (loss). We maintain a bank account denominated in British Pounds. All foreign currency payables and cash balances are measured at the applicable exchange rate at the end of the reporting period. All associated gains and losses from foreign currency transactions are reflected in the consolidated statements of operations, within other income and expense.

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

Critical Accounting Policies and Significant Judgments and Estimates

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

We believe that the estimates, assumptions and judgments involved in the accounting policies described in Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2016 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 three months ended March 31, 2017.

RESULTS OF OPERATIONS

Comparison of the three months ended March 31, 2017 and 2016

The following tables summarize our results of operations for the three months ended March 31, 2017:

	Three Months Ended March 31,			
(In thousands)	**2017**	**2016**	**Change**	**% Increase/ (Decrease)**
Revenue	$ —	$ —	$ —	—
Operating expenses:				
Research and development	10,756	11,981	(1,225)	(10.2)%
General and administrative	13,026	4,692	8,334	177.6%
Total operating expenses	23,782	16,673	7,109	42.6%
Loss from operations	(23,782)	(16,673)	(7,109)	42.6%
Other income (expense):				
Interest income	557	336	221	65.8%
Interest expense	(632)	(276)	(356)	129.0%
Other expense	(22)	(202)	180	(89.1)%
Total other income (expense)	(97)	(142)	45	(31.7)%
Net loss	$ (23,879)	$ (16,815)	$ (7,064)	42.0%

Research and Development Expenses

(In thousands)	Three Months Ended March 31, 2017	2016
Direct research and development expenses by program:		
Zilretta	$ 4,772	$ 8,108
FX007	—	205
Portfolio expansion	328	97
Other	234	138
Total direct research and development expenses	5,334	8,548
Personnel and other costs	5,422	3,433
Total research and development expenses	$ 10,756	$ 11,981

Research and development expenses were $10.8 million and $12.0 million for the three months ended March 31, 2017 and 2016, respectively. The decrease in research and development expenses year over year of $1.2 million was primarily due to the $2.3 million loss recorded on the disposal of manufacturing equipment for the three months ended March 31, 2016, a $1.0 million decrease in development expenses for Zilretta, including CMC and clinical trial costs, and a $0.2 million decrease related to the termination of the FX007 program. This decrease was offset by an increase of $2.0 million in personnel and other employee-related costs for additional headcount and stock compensation expense, and an increase of $0.3 million in preclinical expenses related to our portfolio expansion and other program costs.

General and Administrative Expenses

General and administrative expenses were $13.0 million and $4.7 million for the three months ended March 31, 2017 and 2016, respectively. The increase in general and administrative expenses of $8.3 million was primarily due to additional costs associated with building a commercial infrastructure to effectively support the potential commercialization of Zilretta, including increases in public relations and promotional expenses, market research expenses, and salary and related costs associated with additional headcount cost related to the creation of commercial marketing and sales capabilities, and stock compensation expense.

Other Income (Expense)

Interest income was $0.6 million and $0.3 million for the three months ended March 31, 2017 and 2016, respectively. The increase in interest income was primarily due to an increase in average investment balance yield during 2017.

Interest expense was $0.6 million and $0.3 million for the three months ended March 31, 2017 and 2016, respectively. The increase in interest expense for the three months ended March 31, 2017 was primarily due to interest incurred on the $30 million borrowed under our 2015 term loan.

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, 2017, we had an accumulated deficit of $235.6 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 and convertible debt financings, government or other third-party funding, and licensing or collaboration arrangements.

Since our inception through March 31, 2017, we have funded our operations primarily through the sale of our common stock and convertible preferred stock and, to a lesser extent, debt financing. From our inception through March 31, 2017, we have raised $422.3 million from such transactions, including amounts from our initial and follow-on public offerings during 2014 and 2016. As of March 31, 2017, we had cash and cash equivalents of $42.9 million and marketable securities of $144.6 million. Based on our current operating plan we anticipate that our existing cash, cash equivalents and marketable securities, together with the gross proceeds of approximately $201 million from our recent convertible debt offering, will fund our operations for at least the next twelve months from the date of issuance of these financial statements. 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, 2017 and 2016:

	Three Months Ended March 31,	
(In thousands)	**2017**	**2016**
Cash flows used in operating activities	$ (21,394)	$ (13,996)
Cash flows provided by investing activities	33,769	9,997
Cash flows used in financing activities	(369)	(42)
Net increase (decrease) in cash and cash equivalents	$ 12,006	$ (4,041)

Net Cash Used in Operating Activities

Operating activities used $21.4 million of cash in the three months ended March 31, 2017. The cash flow used in operating activities resulted primarily from our net loss of $23.9 million for the period and cash used for changes in our operating assets and liabilities of $0.2 million, partially offset by non-cash charges of $2.7 million. Our non-cash charges consisted primarily of $2.4 million of stock-based compensation expense and $0.6 million of depreciation and amortization. Net cash used for changes in our operating assets and liabilities consisted primarily of a $0.5 million increase in our prepaid expenses and other current assets due primarily to insurance costs, partially offset by an increase of $0.3 million in accounts payable and accrued expenses.

Operating activities used $14.0 million of cash in the three months ended March 31, 2016. The cash flow used in operating activities resulted primarily from our net loss of $16.8 million for the period and cash used for changes in our operating assets and liabilities of $1.5 million, partially offset by non-cash charges of $4.3 million. Our non-cash charges consisted primarily of $1.6 million of stock-based compensation expense and $2.3 million of loss related to the disposal of our fixed assets ($2.2 million at Evonik), and $0.4 million of depreciation and amortization. Net cash used for changes in our operating assets and liabilities consisted primarily of a $0.6 million increase in prepaid expenses and other current assets due primarily to insurance costs and a decrease of $1.0 million in accounts payable.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $33.8 million in the three months ended March 31, 2017. Net cash used in investing activities consisted primarily of cash received for the redemption and sale of marketable securities of $60.3 million, partially offset by cash used to purchase marketable securities of $25.5 million. In addition, $1.0 million of cash was used to purchase manufacturing equipment.

Net cash used in investing activities was $10.0 million in the three months ended March 31, 2016. Net cash used in investing activities consisted primarily of cash received for the redemption and sale of marketable securities of $16.1 million, partially offset by cash used to purchase marketable securities of $3.0 million. In addition, $3.1 million of cash was used to purchase property and equipment.

Net Cash Used in Financing Activities

Financing activities used $0.4 million for the three months ended March 31, 2017. Net cash used in financing activities in the three months ended March 31, 2017 consisted of $0.8 million related to the payment of principal on our 2015 term loan and $0.1 million in public offering expenses incurred as part of our November 2016 equity offering, partially offset by $0.6 million received from the exercise of stock options.

Net cash used in financing activities in the three months ended March 31, 2016 was less than $0.1 million and consisted of payment of debt issuance costs.

Contractual Obligations

In February 2017, we and Alexandria Real Estate Equities, Inc. entered into a five year lease for laboratory space located in Woburn, Massachusetts with a total cash obligation of approximately $0.9 million. There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments” in our Annual Report on Form 10-K for the year ended December 31, 2016.

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 QUALITATI VE DISCLOSURES ABOUT MARKET RISK

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

Our 2015 term loan carries a fixed interest rate and, thus, we are subject to limited interest rate risk.

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

Most of our transactions are conducted in the U.S. dollar. We do have certain agreements with vendors located outside the United States, which have transactions conducted primarily in British Pounds and Euros. As of March 31, 2017 we had approximately $0.4 million in payables to vendors denominated in currencies other than the U.S. dollar. A hypothetical 10% change in foreign exchange rates would not have a material effect on the value of our liability. As of March 31, 2017, we also had approximately $7.2 million in cash denominated in British Pounds. A hypothetical 10% change in foreign exchange rates would result in either a $0.5 million increase, in the event the U.S. dollar strengthens relative to the British Pound, or a $0.6 million decrease, in the event the U.S. dollar weakens relative to the British Pound, of cash denominated in British Pounds.

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, 2017, 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 March 31, 2017 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 risk factors included in Item 1A of our Annual Report on Form 10-K. 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.

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

Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials, and building and maintaining sales and marketing capabilities, is expensive. We expect our expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs, including our on-going and planned clinical trials for Zilretta, continue our manufacturing scale-up activities and build a sales and marketing organization to commercialize Zilretta.

As of March 31, 2017 we had cash, cash equivalents and marketable securities of $187.5 million and working capital of $172.1 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital requirements for at least the next twelve months from the issuance date of these financial statements, including through the Prescription Drug User Fee Act, or PDUFA, action goal date of our NDA for Zilretta. Regardless of our expectations as to how long our cash, cash equivalents and marketable securities will fund our operations, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expect or the FDA could impose additional or different clinical development requirements on us prior to approving an NDA for Zilretta. In any event, we may require additional capital prior to commercializing Zilretta or any of our other product candidates.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

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

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

ITEM 2. UNREGISTERED SALES OF EQUI TY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit number	Description of document
3.1 (1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2 (1)	Amended and Restated Bylaws of the Registrant.
4.1 (2)	Form of Common Stock Certificate of the Registrant.
4.2 (2)	Amended and Restated Investor Rights Agreement, dated December 3, 2012, by and among the Registrant and certain of its stockholders.
4.3 (2)	Conversion, Amendment and Waiver Agreement, dated January 27, 2014, by and among the Registrant and certain of its stockholders.
10.1	Sixth Amendment of Lease, dated September 21, 2016, between the Registrant and CIP II/RJK 10-20 BMR Owner, LLC.
10.2	Amended Non-Employee Director Compensation Policy, dated March 15, 2017.
31.1	Certification of the Principal Executive Officer and 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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on February 19, 2014.
(2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-193233), as amended.

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 5, 2017

By: /s/ Michael D. Clayman
Michael D. Clayman
Chief Executive Officer
(Principal Financial Officer)

Exhibit 10.1

SIXTH AMENDMENT OF LEASE

AGREEMENT ("Sixth Amendment") made this 21 st day of September, 2016 by and between CIP II/RJK 10-20 BMR Owner, LLC, 55 Cambridge Street, Burlington, Massachusetts 01803 (hereinafter referred to as "Landlord") and Flexion Therapeutics, Inc. (hereinafter referred to as "Tenant").

RECITALS

1. Pursuant to that certain Lease dated February 22, 2013 by and between Landlord and Tenant, as amended by the First Amendment of Lease dated July 13, 2015 (the "First Amendment), the Second Amendment of Lease dated December 15, 2015 (the "Second Amendment"), the Third Amendment of Lease dated May 8, 2016 (the "Third Amendment"), the Fourth Amendment of Lease dated June 29, 2016 (the "Fourth Amendment"), and the Fifth Amendment of Lease dated July 21, 2016 (the "Fifth Amendment") (the First Amendment, Second Amendment , Third Amendment, Fourth Amendment, and Fifth Amendment together with the Lease, collectively the "Existing Lease"), Landlord is leasing to Tenant those certain premises known as 10 Burlington Mall Road, situated in Burlington, Massachusetts 01803, together with all improvements located thereon, consisting of 21,874 rentable square feet of area comprised of 11,754 rentable square feet of area (known as the "Original Premises"), the Phase I Expansion Space consisting of approximately 4,715 rentable square feet of area, and the Phase II Expansion Space consisting of approximately 5,405 rentable square feet of area, all as more particularly described in said Existing Lease (hereinafter referred to collectively as the "2016 Combined Space"). In addition to the 2016 Combined Space, Landlord is also leasing to Tenant 6,748 rentable square feet of area (herein referred to as the "Suite 210 Temporary Space").

2. Capitalized terms used herein and not defined herein shall have the meanings ascribed to such terms in the Existing Lease and the Existing Lease as amended by this Sixth Amendment is hereby known as the "Lease".

IN CONSIDERATION of the mutual covenants contained herein, the parties hereby agree as follows:

A. Suite 210 Temporary Space

Paragraph B(iii) of the First Amendment is hereby deleted in its entirety and replaced with the following:

"For the period from October 1 through October 31, 2016 Tenant shall pay for Suite 210 Temporary Space the amount of Eighteen Thousand Two Hundred Seventy-Five and 83/100 Dollars ($18,275.83). Commencing November 1, 2016, Tenant shall pay Fixed Annual Rent for the Suite 210 Temporary Space in the amount of Two Hundred Twenty Six Thousand Fifty-Eight Dollars ($226,058.00) per annum, payable in equal monthly installments of Eighteen Thousand Eight Hundred Thirty-Eight and 17/100 Dollars ($18,838.17), prorated for any partial month."

Paragraph B(v) of the First Amendment is hereby deleted in its entirety and replaced with the following:

"Tenant shall vacate and surrender the Suite 210 Temporary Space on or before October 31, 2017. In connection therewith, Tenant shall remove all of Tenant's fixtures, furniture and equipment from the Suite 210 Temporary Space and otherwise yield up the Suite 210 Temporary

Space to Landlord in accordance with the provisions of the Lease (it being understood, however, that Tenant shall have no obligation to remove any wiring or improvements made to the Suite 210 Temporary Space). In the event that Tenant fails to vacate and surrender the Suite 2 10 Temporary Space as set forth above on or before October 31, 2017, Landlord hereby reserves all of its rights and remedies under the Lease for such holdover."

B. Further Agreement.

For the avoidance of doubt, Tenant acknowledges and agrees that Exhibit E of the First Amendment is of no further force and effect. Tenant also acknowledges and agrees that clause (i) in the definition of "Triggering Event" (regarding the Tenant's phase 2(b) clinical trial comparing FX006 against placebo) in Section K of the First Amendment is of no further force and effect.

C. Exterior Building Signage

Tenant may erect one sign (the "Sign") on the exterior of the Building, at a location, and of such dimensions and design as approved by the Landlord (which approval shall not be unreasonably withheld), identifying the Tenant; provided, however, that Tenant shall, at Tenant's expense, obtain and comply with all insurance, and all governmental permits, variances, approvals, authorizations, and the like, allowing or requiring the installation and maintenance of the Sign. Landlord will execute such instruments as Tenant may reasonably request with reference to any application by Tenant therefor, whether in the name of Tenant or Landlord or both, Landlord hereby consenting to all such applications, including, without limitation, such action as is necessary or appropriate to accomplish any or all of the foregoing. Upon the termination or expiration of this Lease, Tenant shall remove the Sign from the Building and restore any damage to the Building caused by the installation and/or removal of the Sign. All services performed in connection with the foregoing, and all costs incurred in the exercise of any of the rights or obligations of Tenant pursuant to this Paragraph, shall be at Tenant's expense. Tenant will not make any alterations, additions or improvements to the Sign without on each occasion the prior written consent of the Landlord (which consent shall not be unreasonably withheld). As a condition of such consent, Landlord may require Tenant to provide to Landlord at Tenant's expense a completion bond in form and substance satisfactory to Landlord. Landlord reserves the right at any time to make alterations, modifications, reductions, expansions or additions to and to build an additional story or stories on the Building in which the Premises is located, provided that such alterations, modifications, reductions, expansions or additions do not materially adversely affect Tenant's use of or access to the Premises. In the event Landlord exercises the aforesaid right, Tenant shall relocate the Sign, at Tenant's expense, to a location approved by Landlord.

D. Ratification of Lease

Except as amended and modified by this Sixth Amendment, all the terms, provisions, agreements, covenants and conditions of the Existing Lease are hereby affirmed and ratified. From and after the date hereof, all references to the Lease or Existing Lease shall mean the Lease or Existing Lease as amended hereby and to the extent that there any inconsistencies between this Sixth Amendment and the Existing Lease, this Sixth Amendment shall control. Landlord and Tenant each hereby ratifies and confirms its obligations under the Lease, and represents and warrants to the other that, to its knowledge, it has no defenses thereto. Additionally, Landlord and Tenant further confirm and ratify that, as of the date hereof, (a) the Landlord and Tenant are and remain in good standing and the Lease is in full force and effect, and (b) neither Landlord nor Tenant has any claims, counterclaims, set-offs or defenses against the other arising out of the Lease or in any way relating thereto or arising out of any other transaction between Landlord and Tenant.

E. Execution/Entire Agreement

This Sixth Amendment, together with the Lease as affected hereby, constitutes the entire agreement of the parties, and may not be amended except by written instrument signed by all parties. This Sixth Amendment shall have the effect of an agreement under seal and shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns. This Sixth Amendment may be executed in counterparts all of which taken together shall constitute an original executed document.

[Signatures on Following Page]

The parties hereto have hereunto set their hands and seals the day and year first above written.

LANDLORD: CIP II/RJK 10-20 BMR OWNER, LLC

/s/ Brandon Kelly

Name: Brandon Kelly
Title: President and CEO

TENANT: FLEXION THERAPEUTICS, INC.

/s/ Frederick W. Driscoll

Name: Frederick W. Driscoll
Title: Chief Financial Officer

FLEXION THERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

AS REVISED MARCH 15, 2017

Each member of the Board of Directors (the ***"Board"***) who is not also serving as an employee of Flexion Therapeutics, Inc. (***"Flexion Therapeutics"***) or any of its subsidiaries (each such member, an ***"Eligible Director"***) will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service following the Effective Date (as defined below), unless such compensation is disclaimed by such Eligible Director.

This policy will be effective upon the date hereof (the " ***Effective Date*** ") and may be amended at any time in the sole discretion of the Board upon recommendation of the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer :

    a. All Eligible Directors (other than Chairman of the Board): $40,0 00

    b. Chairman of the Board: $62,500

2. Annual Committee Chair Service Retainer :

    a. Chairman of the Audit Committee: $20,000

    b. Chairman of the Compensation Committee: $15,000

    c. Chairman of the Nominating & Corporate Governance Committee: $10,000

3. Annual Committee Member (other than Committee Chair) Service Retainer :

    a. Member of the Audit Committee: $10,000

b. Member of the Compensation Committee: $7,500

c. Member of the Nominating & Corporate Governance Committee: $5,000

Equity Compensation

The equity compensation set forth below will be granted under the Flexion Therapeutics, Inc. 2013 Equity Incentive Plan (the " ***Plan*** "). All stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying shares of the Company's Common Stock (the " ***Common Stock*** ") on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grant : On the date of the Eligible Director's initial election to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 25,000 shares. One-third of the shares subject to each stock option will vest on the one year anniversary of the date of grant and the balance of the shares will vest in a series of 24 equal monthly installments thereafter, such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. Annual Grant : On the date of each Flexion Therapeutics annual stockholder meeting held after January 1, 2015, each Eligible Director who continues to serve as a non-employee member of the Board will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for (a) 12,500 shares (with respect to all Eligible Directors other than the Chairman of the Board) or (b) 18,000 shares (with respect to the Chairman of the Board). The shares subject to the stock option will vest monthly over the one year following the date of grant such that all of the shares subject to the option will be fully vested on the one year anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my 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

d. 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. I have disclosed, based on my 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: May 5, 2017

/s/ Michael D. Clayman, M.D.
Michael D. Clayman, M.D.
President, Chief Executive Officer and 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: May 5, 2017

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