Flexion Therapeutics Inc
Form 10-Q
November 07, 2016

**UNITED STATES** 

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

or

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

FOR THE TRANSITION PERIOD FROM TO

Commission file number: 001-36287

Flexion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware 26-1388364 (State or Other Jurisdiction of (I.R.S. Employer

Incorporation or Organization) Identification No.)

10 Mall Road, Suite 301

Burlington, Massachusetts 01803

(Address of Principal Executive Offices) (Zip Code)

(781) 305-7777

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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

As of October 31, 2016, the registrant had 27,527,419 shares of Common Stock (\$0.001 par value) outstanding.

# FLEXION THERAPEUTICS, INC.

# TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION	
<u>Item 1. Financial Statements</u>	3
Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015 (Unaudited)	3
Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended	
September 30, 2016 and 2015 (Unaudited)	4
Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015	
(Unaudited)	5
Notes to Condensed Consolidated Financial Statements (Unaudited)	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3. Quantitative and Qualitative Disclosures about Market Risk	22
<u>Item 4. Controls and Procedures</u>	22
PART II. OTHER INFORMATION	
<u>Item 1. Legal Proceedings</u>	24
Item 1A. Risk Factors	24
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	27
Item 3. Defaults Upon Senior Securities	27
<u>Item 4. Mine Safety Disclosures</u>	27
<u>Item 5. Other Information</u>	27
<u>Item 6. Exhibits</u>	28

## PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Flexion Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited in thousands, except share amounts)

	September 30,	December 31,
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$66,809	\$62,944
Marketable securities	92,693	48,303
Accounts receivable	_	95
Prepaid expenses and other current assets	1,584	761
Total current assets	161,086	112,103
Property and equipment, net	11,223	7,442
Long-term investments	2,003	7,357
Other assets	30	157
Restricted cash	80	80
Total assets	\$174,422	\$127,139
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$2,029	\$3,692
Accrued expenses and other current liabilities	3,724	4,367
Current portion of long-term debt	6,634	_
Total current liabilities	12,387	8,059
Long-term debt	23,664	15,002
Other long-term liabilities	339	91
Total liabilities	36,390	23,152
Commitments and contingencies		
Preferred Stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2016		
and December 31, 2015 and 0 shares issued and outstanding at September 30, 2016		
and December 31, 2015	_	_
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 27,527,419 and		
21,570,395 shares issued and outstanding, at September 30, 2016 and		
December 31, 2015, respectively	28	22

Additional paid-in capital	326,605	243,854
Accumulated other comprehensive income	(27)	(97)
Accumulated deficit	(188,574)	(139,792)
Total stockholders' equity	138,032	103,987
Total liabilities and stockholders' equity	\$174,422	\$127,139

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 Mo Ended	nths	Nine Mor	nths Ended
	September 2016	r 30, 2015	Septembe 2016	er 30, 2015
Revenue	\$—	\$—	\$—	\$—
Operating expenses:	Ψ	Ψ	Ψ	Ψ
Research and development	9,047	7,829	29,933	23,724
General and administrative	8,388	3,197	18,295	8,860
Total operating expenses	17,435	11,026	48,228	32,584
Loss from operations	(17,435)	(11,026)	(48,228)	(32,584)
Other income (expense):				
Interest income	421	274	1,052	882
Interest expense	(561)	(202	(1,039)	(406)
Other income (expense), net	(207	(182)	(567)	(639)
Total other income (expense)	(347)	(110	(554)	) (163 )
Net loss	\$(17,782)			\$(32,747)
Net loss per share basic and diluted	\$(0.65)	\$(0.52)	\$(2.04)	) \$(1.52 )
Weighted average common shares outstanding, basic and diluted	27,524	21,507	23,938	21,478
Other comprehensive (loss) income:				
Unrealized gains from available-for-sale securities, net of tax				
of \$0	38	9	(70	8
Total other comprehensive (loss) income	38	9	(70	) 8
Comprehensive loss	\$(17,744)	\$(11,127)	\$(48,852)	\$(32,739)

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)

## Nine Months Ended

	Septemb 2016	per 30,		2015		
Cash flows from						
operating activities						
Net loss	\$	(48,782	)	\$	(32,747	)
Adjustments to						
reconcile net loss to						
cash used in operating						
activities:						
Depreciation		700			130	
Stock-based						
compensation expense		4,963			3,099	
Amortization of						
premium (discount) on						
marketable securities		544			637	
Other non-cash						
charges		26			31	
Loss on disposal of						
fixed assets		2,278			_	
Premium paid on						
securities purchased		(273	)		_	
Changes in operating						
assets and liabilities:						
Accounts receivable		95			(46	)
Prepaid expenses,						
other current and						
long-term assets		(697	)		(243	)
Accounts payable		(1,029	)		389	
Accrued expenses and						
other current and						
long-term liabilities		690			786	
Net cash used in						
operating activities		(41,485	)		(27,964	)
Cash flows from						
investing activities						
Purchases of property						
and equipment		(8,165	)		(2,415	)
Change in restricted						
cash					24	

Purchases of				
marketable securities	(80,151	)	(106,465	)
Sale and redemption				
of marketable			001	
securities	40,897		95,704	
Discount received on				
securities purchased	17		_	
Net cash used in				
investing activities	(47,402	)	(13,152	)
Cash flows from				
financing activities				
Payment of debt				
issuance costs	(42	)	(108	)
Payments on debt	<del>_</del>		(3,500	)
Proceeds from the				
offering of common				
stock, net of				
underwriter's				
commission and fees	77,644		_	
Proceeds from the				
issuance of notes				
payable	15,000		15,004	
Payments of public				
offering costs	(256	)	(225	)
Proceeds from the				
exercise of stock				
options	166		216	
Proceeds from				
Employee Stock				
Purchase Plan	240		138	
Net cash provided by				
financing activities	92,752		11,525	
Net increase				
(decrease) in cash and				
cash equivalents	3,865		(29,591	)
Cash and cash				
equivalents at				
beginning of period	62,944		103,098	
Cash and cash				
equivalents at end of				
period	\$ 66,809		\$ 73,507	
Supplemental				
disclosures of cash				
flow information:				
Cash paid for interest	\$ 823		\$ 370	
Supplemental				
disclosures of				
non-cash financing				
activities:				
Purchases of property	\$ _		\$ 811	
and equipment in				

accounts payable and accrued expenses

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

Flexion Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

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

Flexion Therapeutics, Inc. ("Flexion," the "Company," "we," "our," or "us") 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. The Company's lead product candidate, Zilretta<sup>TM</sup> (also known as FX006), is a late-stage, injectable, extended-release, intra-articular, or IA, meaning "in the joint," investigational steroid that is being developed as a treatment for patients with moderate to severe knee OA pain.

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical industry, including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and 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. Financing Activities

On June 13, 2016, the Company completed a follow-on public offering of its common stock (the "2016 Offering"), which resulted in the sale of 5,500,000 shares of the Company's common stock at a price to the public of \$14.00 per share. On June 21, 2016, the Company completed the sale of an additional 400,000 shares of its common stock at the public offering price pursuant to the underwriters' exercise of their option to purchase additional shares. The Company received aggregate gross proceeds from the 2016 Offering of \$77.6 million after deducting underwriting commissions and fees paid by the Company.

The Company's total issued common stock as of September 30, 2016 was 27,527,419.

## 3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of September 30, 2016, and for the three and nine months ended September 30, 2016 and September 30, 2015, 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 11, 2016.

The information presented in the condensed consolidated financial statements and related notes as of September 30, 2016, and for the three and nine months ended September 30, 2016 and September 30, 2015, is unaudited. The December 31, 2015 consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2016, or any future period.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. As of September 30, 2016 and December 31, 2015, the Company had cash, cash equivalents, marketable securities, and long-term investments of \$161,505,000 and \$118,604,000, respectively. Management believes that current cash, cash equivalents and marketable securities on

hand at September 30, 2016 should be sufficient to fund operations for at least the next twelve months. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations, 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 August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements — Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures, if required. ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016, and applies to annual and interim periods thereafter. The Company does not believe that the adoption of ASU 2014-15 will have a significant impact on the Company's financial statement disclosures.

In April 2015, the FASB released Accounting Standards Update ("ASU") 2015-05, Customers Accounting for Fees Paid in a Cloud Computing Arrangement ("CCA"). Previously, there was no specific U.S. GAAP guidance on accounting for such fees from the customer's perspective. Under the new standard, customers apply the same criteria as vendors to determine whether a CCA contains a software license or is solely a service contract. For public companies, the new standard is effective for annual periods, including interim periods, beginning after December 15, 2015 with early adoption allowed. The Company adopted this guidance as of January 1, 2016 and applied it to new internally used software acquired during the quarterly period ended June 30, 2016.

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. The Company is currently evaluating the potential impact that the adoption of this guidance may have on 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 is currently evaluating the impact that the adoption of this guidance may have on 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 and nine months ended September 30, 2016 and the year ended December 31, 2015, the year Flexion Securities Corporation, Inc. was established.

#### U.S. Government Grant

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. Due to the challenges of enrolling military personnel with post-traumatic knee OA, the Company discontinued the trial and terminated the grant. The related costs incurred under the grant prior to the termination have been included in research and development expense in the statement of operations. The Company was reimbursed and has offset research and development expenses in the statement of

operations when invoices for allowable costs were prepared and submitted to the U.S. Department of Defense. Payments under cost reimbursable grants with agencies of the U.S. government are provisional payments subject to adjustment upon audit by the U.S. government.

#### Accounts Receivable

Accounts receivable represents allowable costs under the Company's now terminated U.S. Government agency grant for which the Company has not yet received reimbursement. The Company invoiced the government on a quarterly basis for reimbursable costs under the grant. Reimbursable costs that have not been invoiced on the last day of the quarter are recorded as unbilled accounts receivable. As of September 30, 2016 there were no unbilled accounts receivable, and as of December 31, 2015, there were unbilled accounts receivable of \$95,000.

#### 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.

#### 4. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets that are measured at fair value on a recurring basis as of September 30, 2016 and December 31, 2015 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of						
	September 30, 2016 Using:						
	Le	vel	Le	vel			
(In thousands)	1	Level 2	3		Total		
Assets:							
Cash equivalents	\$-	-\$44,540	\$		\$44,540		
Marketable securities	_	- 94,696			94,696		
	\$-	-\$139,236	\$		\$139,236		
	Fa	ir Value Me	asu	reme	ents as of		
	De	ecember 31,	201	5 U	sing:		
	Le	vel	Le	vel			
(In thousands)	Le 1				Total		
(In thousands) Assets:		. • 1			Total		
,	1	. • 1			Total \$61,534		
Assets:	1 \$-	Level 2	3				

As of September 30, 2016 and December 31, 2015, 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 nine months ended September 30, 2016 and year ended December 31, 2015, 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 September 30, 2016 and December 31, 2015. The result of the calculation yielded a fair value that approximates its carrying value.

### 5. Marketable Securities

As of September 30, 2016 and December 31, 2015 the fair value of available-for-sale marketable securities by type of security was as follows:

September 30, 2016 Gross Unrealized Gross Unrealized

(In thousands)	Amortized	aoss	Los	sses	Fair Value
U.S. Government obligations	\$17,017 \$	7	\$	(1	) \$ 17,023
Commercial Paper	2,996	_			2,996
Corporate bonds	74,710	2		(35	) 74,677
-	\$94,723 \$	9	\$	(36	) \$ 94,696

December 31, 2015
Gross Unrealized Gross Unrealized

(In thousands)	Amortized	dains s		Los	sses		Fair Value
Corporate Bonds	\$55,757	\$	4	\$	(101	)	\$ 55,660
_	\$55.757	\$	4	\$	(101	)	\$ 55,660

As of September 30, 2016 and December 31, 2015, marketable securities consisted of \$92,693,000 and \$48,303,000, respectively, of investments that mature within twelve months and \$2,003,000 and \$7,357,000, respectively, of investments that mature within fifteen months.

### 6. Property and Equipment, Net

Property and equipment as of September 30, 2016 and December 31, 2015 consisted of the following:

	September 30,	December 31,
(In thousands)	2016	2015
Manufacturing equipment	\$ 10,099	\$ 2,534
Computers, office equipment, and minor computer software	539	393
Software	436	342
Construction—in progress	429	4,134
Furniture and fixtures	402	290
Leasehold improvements	278	239
	12,183	7,932
Less: Accumulated depreciation	(960)	(490)
Total property and equipment, net	\$ 11,223	\$ 7,442

Depreciation expense for the nine months ended September 30, 2016 and 2015 was \$700,000 and \$130,000, respectively. During the nine months ended September 30, 2016, \$2,630,000 of property and equipment was disposed of, resulting in a loss of \$2,278,000. Of the \$2,630,000 disposed of during the nine months ended September 30, 2016, \$2,265,000 was related to manufacturing equipment that will no longer be used due to the Company's decision to not utilize Evonik Corporation ("Evonik") for supplies of clinical or commercial Zilretta finished drug product, resulting in a loss of \$2,180,000. Construction-in progress is primarily comprised of amounts related to the purchase of a dedicated manufacturing suite for use by the Company's contract manufacturer of Zilretta finished drug product, Patheon UK Limited ("Patheon").

No property and equipment was disposed of during the nine months ended September 30, 2015.

### 7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September		
	30,	December 31,	
(In thousands)	2016	2015	
Payroll and other employee-related expenses	\$ 2,018	\$ 1,648	

Edgar Filing: Flexion Therapeutics Inc - Form 10-Q

Professional services fees	819	434
Other	258	74
Clinical research	204	552
Interest expense	156	81
Contract manufacturing services	149	1,444
Regulatory services	88	64
Consultant fees and expenses	32	70
Total accrued expenses and other current liabilities	\$ 3,724	\$ 4,367

#### 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 nine months ended September 30, 2016 and 2015 are as follows:

	Nine me	onths	
	ended		
	September 30,		
	2016	2015	
Risk-free interest rates	1.05-1/6	0.49-1.	92%
Expected dividend yield	0.00%	0.00	%
Expected term (in years)	6.0	6.0	
Expected volatility	79.8- <b>%</b>	.176.4-81	1.4%

The following table summarizes stock option activity for the nine months ended September 30, 2016:

	Shares Issuable	Weighted Average	
(In thousands, except per share amounts)	<b>Under Options</b>	Exercise Price	
Outstanding as of December 31, 2015	1,657	\$ 14.28	
Granted	948	16.67	
Exercised	(30	) 5.52	
Cancelled	(97	) 19.16	
Outstanding as of September 30, 2016	2,478	\$ 15.11	
Options vested and expected to vest at September 30,			
2016	2,141	\$ 14.72	
Options exercisable at September 30, 2016	1,078	\$ 11.95	

In addition to the approximately 948,000 common stock options granted, approximately 205,000 restricted common stock units ("RSUs") were also granted, of which approximately 10,000 RSUs were cancelled, during the nine months

ended September 30, 2016. The RSUs are performance based awards which will begin vesting upon the achievement of a corporate performance based milestone. No outstanding performance awards were vested as of September 30, 2016.

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 30,000 options, with an aggregate intrinsic value of \$236,000, were exercised during the nine months ended September 30, 2016.

At September 30, 2016 and 2015, there were options for the purchase of approximately 2,478,000 and 1,578,000 shares of the Company's common stock outstanding, respectively, with a weighted average remaining contractual term of 8.0 and 8.1 years, respectively, and with a weighted average exercise price of \$15.11 and \$10.32 per share, respectively.

The weighted average grant date fair value of options granted during the nine months ended September 30, 2016 and 2015 was \$11.90 and \$15.67, respectively.

#### **Stock-based Compensation**

The Company recorded stock-based compensation expense related to stock options for the three and nine months ended September 30, 2016 and 2015 as follows:

	Three months ended		Nine months ended	
	September 30,		September 30,	
(In thousands)	2016	2015	2016	2015
Research and development	\$543	\$332	\$1,656	\$941
General and administrative	1,160	789	3,307	2,158
	\$1,703	\$1,121	\$4,963	\$3,099

As of September 30, 2016 unrecognized stock-based compensation expense for stock options outstanding was \$11,227,000, which was expected to be recognized over a weighted average period of 2.7 years. As of September 30, 2015, unrecognized stock-based compensation expense for stock options outstanding was \$11,500,000, which was expected to be recognized over a weighted average period of 2.7 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 194,400 with an approximate value of \$3,538,000 as of the grant date. The amount of earned shares decreases the closer that the Milestone date is to the termination date of the award. If the Milestone is not achieved prior to July 1, 2018, the termination date of these awards, 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 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 and nine months ended September 30, 2016 and 2015:

Edgar Filing: Flexion Therapeutics Inc - Form 10-Q

For the three September 30, months ended

September 30,

(In thousands) 2016 2015 2016 2015

Numerator:

Net loss \$(17,782) \$(11,136) \$(48,782) \$(32,747)

Net loss: \$(17,782)