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, 2019

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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	☐	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 the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	FLXN	NASDAQ

As of May 1, 2019, the registrant had 37,992,631 shares of Common Stock ($0.001 par value) outstanding.

FLEXION THERAPEUTICS, INC.
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 87,935	$ 87,229
Marketable securities	129,913	171,555
Accounts receivable, net	15,130	13,121
Inventories	10,324	7,637
Prepaid expenses and other current assets	4,656	5,500
Total current assets	$ 247,958	$ 285,042
Property and equipment, net	10,329	10,710
Right-of-use assets	6,332	—
Total assets	$ 264,619	$ 295,752
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 11,007	$ 12,340
Accrued expenses and other current liabilities	15,785	14,310
Operating lease liabilities	1,142	—
Current portion of long-term debt	11,280	9,967
Total current liabilities	$ 39,214	$ 36,617
Long-term operating lease liability, net	5,639	—
Long-term debt, net	—	3,640
2024 convertible notes, net	146,939	144,879
Other long-term liabilities	251	537
Total liabilities	$ 192,043	$ 185,673
Commitments and contingencies		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2019 and December 31, 2018 and 0 shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Stockholders' equity		
Common stock, $0.001 par value; 100,000,000 shares authorized; 37,992,631 and 37,946,341 shares issued and outstanding, at March 31, 2019 and December 31, 2018, respectively	38	38
Additional paid-in capital	632,797	628,944
Accumulated other comprehensive income (loss)	105	(77)
Accumulated deficit	(560,364)	(518,826)
Total stockholders' equity	72,576	110,079
Total liabilities and stockholders' equity	$ 264,619	$ 295,752

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,	
	2019	**2018**
Revenues		
Product revenue, net	$ 10,564	$ 2,194
Operating expenses		
Cost of sales	1,762	2,698
Research and development	15,424	11,551
Selling, general and administrative	32,222	26,899
Total operating expenses	49,408	41,148
Loss from operations	(38,844)	(38,954)
Other (expense) income		
Interest income	1,011	1,161
Interest expense	(3,936)	(3,919)
Other income	231	143
Total other (expense) income	(2,694)	(2,615)
Net loss	$ (41,538)	$ (41,569)
Net loss per common share, basic and diluted	$ (1.09)	$ (1.10)
Weighted average common shares outstanding, basic and diluted	37,992	37,620
Other comprehensive income (loss):		
Unrealized gains (losses) from available-for-sale securities, net of tax of $0	182	(169)
Total other comprehensive income (loss)	182	(169)
Comprehensive loss	$ (41,356)	$ (41,738)

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

Flexion Therapeutics, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited in thousands)

	Common Stock		Additional Paid-in-Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2018	37,946	$ 38	$ 628,944	$ (77)	$ (518,826)	$ 110,079
Issuance of common stock for equity awards	47		—			—
Stock-based compensation expense			3,853			3,853
Net loss					(41,538)	(41,538)
Other comprehensive income				182		182
Balance at March 31, 2019	37,993	$ 38	$ 632,797	$ 105	$ (560,364)	$ 72,576

	Common Stock		Additional Paid-in-Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2017	37,611	$ 38	$ 609,810	$ (407)	$ (349,167)	$ 260,274
Issuance of common stock for equity awards	22	—	414			414
Stock-based compensation expense			3,657			3,657
Net loss					(41,569)	(41,569)
Other comprehensive loss				(169)		(169)
Balance at March 31, 2018	37,633	$ 38	$ 613,881	$ (576)	$ (390,736)	$ 222,607

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,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (41,538)	$ (41,569)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation	219	563
Amortization of right-of-use assets	263	—
Stock-based compensation expense	3,853	3,657
Accretion of discount on marketable securities	(431)	(230)
Amortization of debt discount and debt issuance costs	2,069	1,884
Premium paid on securities purchased	—	(3)
Changes in operating assets and liabilities:		
Accounts receivable	(2,009)	(1,987)
Inventory	(2,326)	(726)
Prepaid expenses, other current and long-term assets	844	(620)
Accounts payable	(348)	(2,806)
Accrued expenses and other current liabilities	1,665	(3,144)
Lease liabilities and other long-term liabilities	(242)	—
Net cash used in operating activities	(37,981)	(44,981)
Cash flows from investing activities		
Purchases of property and equipment	(1,068)	(334)
Purchases of marketable securities	(76,308)	(32,546)
Sale and redemption of marketable securities	118,563	99,462
Net cash provided by investing activities	41,187	66,582
Cash flows from financing activities		
Payments on notes payable	(2,500)	(2,500)
Proceeds from the exercise of stock options	—	414
Net cash used in by financing activities	(2,500)	(2,086)
Net increase in cash, cash equivalents, and restricted cash	706	19,515
Cash, cash equivalents, and restricted cash at beginning of period	87,229	128,389
Cash, cash equivalents, and restricted cash at end of period	$ 87,935	$ 147,904
Non-cash investing and financing activities		
Right-of-use asset obtained in exchange for operating lease obligation	$ 6,595	—
Purchases of property and equipment in accounts payable and accrued expenses	—	13
Supplemental disclosures of cash flow information		
Cash paid for interest	170	326

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 biopharmaceutical company focused on the discovery, development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, or OA, a type of degenerative arthritis. The Company has an approved product, ZILRETTA®, which it markets in the United States. ZILRETTA is the first and only extended-release, intra-articular, or IA (meaning in the joint), injection indicated for the management of OA knee pain. ZILRETTA is a non-opioid therapy that employs Flexion's proprietary microsphere technology to provide pain relief. The pivotal Phase 3 trial, on which the approval of ZILRETTA was based, showed that ZILRETTA met the primary endpoint of pain reduction at Week 12, with statistically significant pain relief extending through Week 16. The Company also has an additional pipeline program, (FX201), which is a gene-therapy product candidate in development for OA knee 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. Successfully commercializing ZILRETTA requires significant sales and marketing efforts and the Company's pipeline programs may require significant additional research and development efforts, including extensive preclinical and clinical testing. These activities will in turn require significant amounts of capital, qualified personnel and adequate infrastructure. There can be no assurance when, if ever, the Company will realize significant revenue from the sales of ZILRETTA or if the development efforts supporting the Company's pipeline, including future clinical trials, will be successful.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of March 31, 2019, and for the three months ended March 31, 2019 and 2018, 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 February 28, 2019.

The information presented in the condensed consolidated financial statements and related notes as of March 31, 2019, and for the three months ended March 31, 2019 and 2018, is unaudited. The December 31, 2018 condensed 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, 2019 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2019, 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, 2019, the Company had cash, cash equivalents, and marketable securities of approximately $217.8 million. Management believes that current cash, cash equivalents and marketable securities on hand at March 31, 2019 should be sufficient to fund operations for at least the next twelve months from the issuance date of these financial statements. The future viability of the Company is dependent on its ability to fund its operations through sales of ZILRETTA, and/or raise additional capital, such as debt or equity offerings, as needed. This funding is necessary for the Company to support the commercialization of ZILRETTA and to perform the research and development activities required to develop the Company's other product candidates in order to generate future revenue streams. The Company may not be able to obtain financing on acceptable terms, or at all. If the Company is unable to obtain funding on a timely basis, the Company may need to curtail its operations, including the commercialization of ZILRETTA and research and development activities, which could adversely affect its prospects.

Recent Accounting Pronouncements

Accounting Standards Recently Adopted

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-02, *Leases* ("ASU 2016-02"), to increase transparency and comparability among organizations by recognizing lease assets and liabilities, including operating leases, on the balance sheet and disclosing key information about leasing arrangements. The Company adopted ASU 2016-02 on January 1, 2019 using the "Comparatives under 840" approach, which was approved by the FASB in July 2018 as part of ASU 2018-11. Under this method, the condensed consolidated financial statements as of and for the three months ended March 31, 2019 are presented applying the new requirements under ASC 842, while the condensed consolidated financial statements as of December 31, 2018 and for the three months ended March 31, 2018 are presented under ASC 840. The required disclosures are presented under ASC 842 for the current year and ASC 840 for the prior year.

As part of its adoption of ASU 2016-02, the Company elected the package of practical expedients which allows it to not reassess (1) whether existing contracts contain leases, (2) the lease classification for existing leases, and (3) whether existing initial direct costs meet the new definition. Consequently, on adoption, the Company recognized lease liabilities of $7.0 million and corresponding right-of-use, or ROU, assets of $6.6 million based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. These lease liabilities and ROU assets relate to operating leases only, as the Company concluded that it does not have any finance leases. The difference between the lease liability and the ROU assets upon adoption relates to the deferred rent balance that had been recorded prior to adoption. The Company determined that no cumulative adjustment to retained earnings was required.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). The new standard expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Equity-based payments to nonemployees were previously covered under ASC 505-50 and required companies to measure the awards based on the fair value of the consideration received or the fair value of the equity instruments issued and remeasure the fair value of such awards at each reporting date. The Company adopted ASU 2018-07 on January 1, 2019. The adoption of ASU 2018-07 did not have a material impact on the Company's financial position or results of operations.

Accounting Standards Recently Issued

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The new standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 is effective for fiscal years, and the interim periods within those years, beginning after December 15, 2019 and early adoption is permitted. The Company is currently evaluating the impact of ASU 2016-13 on the Company's consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). The new standard modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, as part of the FASB's disclosure framework project. ASU 2018-13 is effective for fiscal years, and the interim periods within those years, beginning after December 15, 2019 and early adoption is permitted. Additionally, the new standard permits an entity to early adopt any removed or modified disclosures upon issuance of the ASU and delay adoption of the additional disclosures until their effective date. ASU 2018-13 removes the requirement to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy. The Company early adopted this portion of the standard as of the quarter ended September 30, 2018. The Company does not expect the adoption of the remainder of ASU 2018-13 to have any impact on its consolidated financial statements, as the changes to the disclosures are primarily relevant for companies with Level 3 assets and liabilities, which the Company does not have.

Consolidation

The accompanying condensed consolidated financial statements include the Company and its wholly-owned subsidiary, Flexion Therapeutics Securities Corporation. The Company has eliminated all intercompany transactions for the three months ended March 31, 2019 and the year ended December 31, 2018.

Revenue Recognition

On October 6, 2017, the U.S. Food and Drug Administration, or FDA, approved ZILRETTA. The Company entered into a limited number of arrangements with specialty distributors and a specialty pharmacy in the U.S. to distribute ZILRETTA. The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") Topic 606 - Revenue from Contracts with Customers ("Topic 606"). Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract with a customer under Topic 606, including when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for product revenue, see Product Revenue, Net (below).

Product Revenue, Net— The Company sells ZILRETTA to its customers who then subsequently resell ZILRETTA to physicians, clinics and certain medical centers or hospitals. In addition to distribution agreements with customers, the Company enters into arrangements with government payers that provide for government mandated rebates and chargebacks with respect to the purchase of ZILRETTA.

The Company recognizes revenue on product sales when the customer obtains control of the Company's product, which occurs at a point in time (upon delivery to the customer). The Company has determined that the delivery of ZILRETTA to its customers constitutes a single performance obligation. There are no other promises to deliver goods or services beyond what is specified in each accepted customer order. The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with customers do not exceed one year and therefore the Company has elected to apply the practical expedient and no amount of consideration has been allocated as a financing component. Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Transaction Price, including Variable Consideration— Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, government chargebacks, discounts and rebates, and other incentives, such as voluntary patient assistance, and other fee for service amounts that are detailed within contracts between the Company and its customers relating to the Company’s sale of its products. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company’s best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company’s estimates. If actual results in the future vary from the Company’s original estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances— The Company compensates (through trade discounts and allowances) its customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company’s sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through March 31, 2019, as well as a reduction to trade receivables, net on the condensed consolidated balance sheets.

Product Returns— Consistent with industry practice, the Company generally offers customers a limited right of return for product that has been purchased from the Company based on the product’s expiration date. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as within accrued expenses and other current liabilities, net, on the condensed consolidated balance sheets. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has received an immaterial amount of returns to date and believes that future returns of ZILRETTA will be minimal.

The Company’s limited right of return allows for eligible returns of ZILRETTA in the following circumstances:

- Shipment errors that were the result of an error by the Company;
- Quantity delivered that is greater or less than the quantity ordered;

- Product distributed by the Company that is damaged in transit prior to receipt by the customer;
- Expired product, previously purchased directly from the Company, that is returned during the period beginning three months prior to the product's expiration date and ending three months after the product's expiration date;
- Product subject to a recall; and
- Product that the Company, at its sole discretion, has specified to be returned.

Government Chargebacks, Discounts and Rebates— Chargebacks for fees and discounts to qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified VA hospitals and 340b entities at prices lower than the list prices charged to customers who directly purchase the product from the Company. The 340b Drug Discount Program is a US federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Customers charge the Company for the difference between what they pay for the product and the statutory selling price to the qualified government entity. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and trade receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified government healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that customers have claimed, but for which the Company has not yet issued a credit.

Government Rebates— The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company estimates its exposure to utilization from the Medicare Part D coverage gap discount program to be immaterial. For Medicaid programs, the Company estimates the portion of sales attributed to Medicaid patients and records a liability for the rebates to be paid to the respective state Medicaid programs. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Other Incentives— Other incentives which the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as a component of accrued expenses and other current liabilities on the condensed consolidated balance sheets.

To date, the Company's only source of product revenue has been from the U.S. sales of ZILRETTA, which it began shipping to customers in October 2017.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2019 and 2018:

(In thousands)	Trade Discounts, Allowances and Government Chargebacks	Government Rebates and Other Incentives	Returns	Total
Balance as of December 31, 2018	$ 601	$ 491	$ 125	$ 1,217
Provision related to sales in the current year	741	24	57	822
Credits and payments made	(332)	(36)	(33)	(401)
Balance as of March 31, 2019	$ 1,010	$ 479	$ 149	$ 1,638
Balance as of December 31, 2017	$ 60	$ 15	$ 2	$ 77
Provision related to sales in the current year	186	49	12	247
Credits and payments made	(94)	—	—	(94)
Balance as of March 31, 2018	$ 152	$ 64	$ 14	$ 230

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, revenue and 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 estimates related to revenue, 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.

Leases

The Company determines if an arrangement is a lease at contract inception. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding right-of-use assets are recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the expected lease term. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. The Company made an accounting policy election to expense leases with a term of one year or less on a straight-line basis over the lease term. To date, the Company has not identified any material short-term leases, either individually or in the aggregate.

As the Company's leases do not provide an implicit rate, the Company utilized the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. The Company estimated the incremental borrowing rate based on a yield curve analysis of companies with a similar credit rating to its own, which was calculated using a number of financial ratios and qualitative considerations of the Company's business. The yields on the Company's currently outstanding debt (the 2024 Convertible Notes and term loan) were also used as inputs to the analysis to calculate a spread, adjusted for factors that reflect the profile of secured borrowing over the expected term of the lease.

The components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, utilities, performance of manufacturing services, purchase of inventory, etc.), and non-components (e.g., property taxes, insurance, etc.). Then the fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components. Although separation of lease and non-lease

components is required, certain practical expedients are available to entities. Entities electing the practical expedient would not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company has elected to use this practical expedient for its real estate leases and account for each lease component and related non-lease component as one single component. In contrast, the Company has elected not to apply the practical expedient for its lease of manufacturing space at Patheon and has instead allocated consideration between the lease and non-lease components of the contract. The Company calculated the fair value of the lease component using publicly available information to identify comparable rentals in the same geographic area. The remainder of the consideration was allocated to the non-lease components.

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, 2019 and December 31, 2018 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of March 31, 2019 Using:			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ —	$ 66,083	$ —	$ 66,083
Marketable securities	—	129,913	—	129,913
	$ —	$ 195,996	$ —	$ 195,996

	Fair Value Measurements as of December 31, 2018 Using:			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ —	$ 57,739	$ —	$ 57,739
Marketable securities	—	171,555	—	171,555
	$ —	$ 229,294	$ —	$ 229,294

As of March 31, 2019 and December 31, 2018 the Company's cash equivalents that are invested in money market funds and overnight repurchase contracts are valued based on Level 2 inputs. The Company measures the fair value of marketable securities using Level 2 inputs and primarily relies on quoted prices in active markets for similar marketable securities. Amortization and accretion of discounts and premiums are recorded in other income.

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, 2019 and December 31, 2018. The result of the calculation yielded a fair value that approximates its carrying value.

On May 2, 2017 the Company issued 3.375% convertible senior notes due 2024 (the "2024 Convertible Notes") with embedded conversion features. The Company estimated the fair value of the 2024 Convertible Notes using a discounted cash flow approach to derive the value of a debt instrument using the expected cash flows and the estimated yield related to the convertible notes. The significant assumptions used in estimating the expected cash flows were: the estimated market yield based on an implied yield and credit quality analysis of a term loan with similar attributes, and the average implied volatility of the Company's traded and quoted options available as of May 2, 2017. The Company recorded approximately $136.7 million as the fair value of the liability on May 2, 2017, with a corresponding amount recorded as a discount on the initial issuance of the 2024 Convertible Notes of approximately $64.5 million. The debt discount was recorded to equity and is being amortized to the debt liability over the life of the 2024 Convertible Notes using the effective interest method.

The fair value of the 2024 Convertible Notes, which differs from their carrying value, is influenced by interest rates, stock price and stock price volatility and is determined by prices for the 2024 Convertible Notes observed in market trading. The market for trading of the 2024 Convertible Notes is not considered to be an active market and therefore the estimate of fair value is based on Level 2 inputs. The estimated fair value of the 2024 Convertible Notes, face value of $201.3 million, was $174.0 million at March 31, 2019.

4. Marketable Securities

As of March 31, 2019 and December 31, 2018 the fair value of available-for-sale marketable securities by type of security was as follows:

	March 31, 2019			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 1,981	$ —	$ —	$ 1,981
U.S. government obligations	54,570	17	—	54,587
Corporate bonds	73,257	94	(6)	73,345
	$ 129,808	$ 111	$ (6)	$ 129,913

	December 31, 2018			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 36,723	$ —	$ —	$ 36,723
U.S. government obligations	39,910	—	(12)	39,898
Corporate bonds	94,999	20	(85)	94,934
	$ 171,632	$ 20	$ (97)	$ 171,555

As of March 31, 2019 and December 31, 2018, marketable securities consisted of approximately $129.9 and $171.6 million, respectively, of investments that mature within twelve months. There were no investments with maturities greater than twelve months as of March 31, 2019 or December 31, 2018.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of March 31, 2019 and December 31, 2018:

(In thousands)	March 31, 2019	December 31, 2018
Prepaid expenses	$ 3,853	$ 4,717
Deposits	291	66
Interest receivable on marketable securities	512	717
Total prepaid expenses and other current assets	$ 4,656	$ 5,500

6. Inventory

Inventory consisted of the following as of March 31, 2019 and December 31, 2018:

(In thousands)	March 31, 2019	December 31, 2018
Raw materials	$ 3,046	$ 2,367
Work in process	5,143	3,553
Finished goods	2,135	1,717
Total inventories	$ 10,324	$ 7,637

Finished goods manufactured by the Company have a shelf life of approximately 24 months from the date of manufacture.

The Company reduces its inventory to net realizable value for potentially excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. As of March 31, 2019, the Company determined that no write-downs to inventory for potentially excess, dated or obsolete inventory were required.

7. Property and Equipment, Net

Property and equipment, net, as of March 31, 2019 and December 31, 2018 consisted of the following:

(In thousands)	March 31, 2019	December 31, 2018
Computer and office equipment	$ 1,133	$ 1,133
Manufacturing equipment	12,147	12,000
Furniture and fixtures	609	604
Software	447	434
Leasehold improvements	815	815
Construction in progress	1,450	1,416
	16,601	16,402
Less: Accumulated depreciation	(6,272)	(5,692)
Total property and equipment, net	$ 10,329	$ 10,710

Depreciation expense for the three months ended March 31, 2019 was approximately $0.2 million, compared to $0.6 million for the same period in the prior year. No property and equipment was disposed of during the three months ended March 31, 2019. Construction in progress consists of equipment purchases related to the expansion of the Company's manufacturing capabilities at its contract manufacturer, Patheon U.K. Limited, as well as equipment related to the Company's portfolio expansion efforts that have not yet been placed into service.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of March 31, 2019 and December 31, 2018:

(In thousands)	March 31, 2019	December 31, 2018
Research and development	$ 1,372	$ 1,216
Payroll and other employee-related expenses	5,683	8,207
Professional services fees	4,281	2,544
Interest expense	2,879	1,195
Product revenue reserves	628	616
Accrual for employee stock purchase plan	740	251
Other	202	281
Total accrued expenses and other current liabilities	$ 15,785	$ 14,310

9. Debt

Term Loan

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 $30.0 million in term loans. The Company concurrently borrowed an initial term loan of $15.0 million 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. In addition, pursuant to the credit and security agreement, the Company is prohibited from paying cash dividends without prior consent of the Lenders.

On July 22, 2016, the Company borrowed the remaining $15.0 million under the credit and security agreement, in the form of a second term loan. 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, 2019, 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 is 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 straight-line method, which approximates the effective interest method. As of March 31, 2019, the carrying value of the term loan was approximately $11.3 million, all of which is due within 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, 2019 and December 31, 2018.

As of March 31, 2019, annual principal and interest payments due under the 2015 term loan were as follows:

Year	Aggregate Minimum Payments *(in thousands)*
2019	7,779
2020	4,383
Total	$ 12,162
Less interest	(323)
Less unamortized portion of final payment	(559)
Total	$ 11,280

2024 Convertible Notes

On May 2, 2017 the Company issued an aggregate of $201.3 million principal amount of the 2024 Convertible Notes. The 2024 Convertible Notes have a maturity date of May 1, 2024, are unsecured and accrue interest at a rate of 3.375% per annum, payable semi-annually on May 1 and November 1 of each year, beginning November 1, 2017. The Company received $194.8 million for the sale of the 2024 Convertible Notes, after deducting fees and expenses of $6.5 million.

Upon conversion of the 2024 Convertible Notes, at the election of each holder of a 2024 Convertible Note (the Holder), the note will be convertible into cash, shares of the Company's common stock, or a combination thereof, at the Company's election (subject to certain limitations in the 2015 term loan), at a conversion rate of approximately 37.3413 shares of common stock per $1,000 principal amount of the 2024 Convertible Notes, which corresponds to an initial conversion price of approximately $26.78 per share of the Company's common stock.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, fundamental change events and certain corporate events that occur prior to the maturity date of the notes. In addition, if the Company delivers a notice of redemption, the Company will increase, in certain circumstances, the conversion rate for a Holder who elects to convert its notes in connection with such a corporate event or notice of redemption, as the case may be. At any time prior to the close of business on the business day immediately preceding February 1, 2024, Holders may convert all, or any portion, of the 2024 Convertible Notes at their option only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2017 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

(2) during the five business day period after any ten consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;

(3) if the Company calls any or all of the notes for redemption, at any time prior to the close of business on the business day immediately preceding the redemption date; and

(4) upon the occurrence of specified corporate events.

On or after February 1, 2024, until the close of business on the business day immediately preceding the maturity date, Holders may convert their notes at any time, regardless of the foregoing circumstances. The Company may redeem, for cash, all or any portion of the 2024 Convertible Notes, at its option, on or after May 6, 2020 if the last reported sale price of the Company's common stock has been at least 130% of the conversion price for at least 20 trading days during any 30 consecutive day trading period, at a redemption price equal to 100% of the principal amount of the 2024 Convertible Notes to be redeemed, plus accrued and unpaid interest, subject to the Holders' right to convert as described above.

The 2024 Convertible Notes are considered convertible debt with a cash conversion feature. Per ASC 470-20, Debt with Conversion and Other Options, the Company has separated the convertible debt into liability and equity components based on the fair value of a similar debt instrument excluding the embedded conversion option. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the 2024 Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the 2024 Convertible Notes and the fair value of the liability of the 2024 Convertible Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense using the effective interest method over seven years. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. The liability component of $136.7 million was recorded as long-term debt at May 2, 2017 with the remaining equity component of $64.5 million recorded as additional paid-in capital.

In connection with the issuance of the 2024 Convertible Notes, the Company incurred approximately $6.5 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total debt issuance costs, $4.4 million were allocated to the liability component and are recorded as a reduction of the 2024 Convertible Notes in our consolidated balance sheets. The remaining $2.1 million was allocated to the equity component and is recorded as a reduction to additional paid-in capital.

Debt discount and issuance costs of $68.9 million are being amortized to interest expense over the life of the 2024 Convertible Notes using the effective interest rate method. As of March 31, 2019, the stated interest rate was 3.375%, and the effective interest rate was 9.71%. Interest expense related to the 2024 Convertible Notes for the three months ended March 31, 2019 was $3.6 million, including $1.9 million related to amortization of the debt discount.

The table below summarizes the carrying value of the 2024 Convertible Notes as of March 31, 2019:

		(in thousands)
Gross proceeds	$	201,250
Portion of proceeds allocated to equity component (additional paid-in capital)		(64,541)
Debt issuance costs		(6,470)
Portion of issuance costs allocated to equity component (additional paid-in capital)		2,075
Amortization of debt discount and debt issuance costs		14,625
Carrying value 2024 Convertible Notes	$	146,939

10. 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, 2019 and 2018 were as follows:

	Three months ended March 31,	
	2019	2018
Risk-free interest rates	2.56% - 2.67%	2.72 - 2.74%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.0	6.0
Expected volatility	69.3% - 69.5%	71.4 - 71.5%

The following table summarizes stock option activity for the three months ended March 31, 2019:

(In thousands, except per share amounts)	Shares Issuable Under Options	Weighted Average Exercise Price Per Share
Outstanding as of December 31, 2018	4,435	$ 19.21
Granted	638	14.47
Exercised	—	7.15
Cancelled	(92)	21.85
Outstanding as of March 31, 2019	4,981	$ 18.56
Options vested and expected to vest at March 31, 2019	4,981	$ 18.56
Options exercisable at March 31, 2019	2,689	$ 17.67

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. Options to purchase a total of approximately 118 shares of the Company's common stock, with an aggregate intrinsic value of approximately $622, were exercised during the three months ended March 31, 2019.

At March 31, 2019 and 2018, there were options for the purchase of approximately 4,980,879 and 4,404,000 shares of the Company's common stock outstanding, respectively, with a weighted average remaining contractual term of 7.6 years and 8.1 years, respectively, and with a weighted average exercise price of $18.56 and $18.42 per share, respectively.

The weighted average grant date fair value of options granted during the three months ended March 31, 2019 and 2018 was $9.17 and $14.48 per share, respectively.

Restricted Stock Units

On January 4, 2016, the Company granted 189,300 restricted stock units ("RSUs") with performance and time-based vesting conditions to certain executives. These RSUs began vesting, and the underlying shares of common stock became deliverable, beginning when ZILRETTA was approved (the "Milestone"). The number of shares eligible for vesting varied based on the timing of achieving the Milestone. As a result of the Milestone being achieved on October 6, 2017, the number of shares of the Company's common stock earned under these awards was 122,800, subject to ongoing employment with the Company for a period of 2 years. The 122,800 shares had an approximate value of $2.2 million as of the original grant date of which $1.6 million was recognized in the fourth quarter of 2017 upon achieving the Milestone and the remaining $0.6 million is being recognized over a period of two years.

During the three months ended March 31, 2019, the Company awarded 771,356 RSUs to employees at an average grant date fair value of $14.75 per share. The RSUs vest in four substantially equal installments on each of the first four anniversaries of the vesting commencement date, subject to the employee's continued employment with, or services to, the Company on each vesting date. Compensation expense is recognized on a straight-line basis.

The following table summarizes the RSU activity for the three months ended March 31, 2019:

(In thousands, except per share amounts)	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested balance as of December 31, 2018	252	$ 22.25
Granted	771	14.75
Vested/Released	(46)	22.31
Cancelled	(3)	20.89
Nonvested Balance as of March 31, 2019	974	$ 16.31

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and RSUs and shares purchased under the Employee Stock Purchase Plan for the three months ended March 31, 2019 and 2018 as follows:

	For the three months ended March 31,	
(In thousands)	2019	2018
Research and development	$ 1,156	$ 1,150
Selling, general and administrative	2,697	2,507
Total	$ 3,853	$ 3,657

As of March 31, 2019, unrecognized stock-based compensation expense for stock options outstanding was approximately $27.0 million which is expected to be recognized over a weighted average period of 2.6 years. As of March 31, 2019, unrecognized stock-based compensation expense for RSUs outstanding was $14.8 million which is expected to be recognized over a period of 3.5 years.

11. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three months ended March 31, 2019 and 2018:

	For the three months ended March 31,	
(In thousands, except per share amounts)	2019	2018
Numerator:		
Net loss	$ (41,538)	$ (41,569)
Net loss:	$ (41,538)	$ (41,569)
Denominator:		
Weighted average common shares outstanding, basic and diluted	37,992	37,620
Net loss per share, basic and diluted	$ (1.09)	$ (1.10)

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated as including them would have an anti-dilutive effect:

	For the three months ended March 31,	
	2019	2018
Shares issuable upon conversion of the 2024 Convertible Notes	7,515	7,515
Stock options	4,770	4,264
Restricted stock units	471	218
Total	12,756	11,997

12. Commitments and Contingencies

Operating Leases

Burlington Lease

In May 2013, the Company entered into a lease for office space in Burlington, Massachusetts (the "Lease"). The term of the Lease was for 42 months with minimum monthly lease payments beginning at $17,588 per month and escalating over the lease term. In July 2015, the Company amended the Lease to add approximately 4,700 square feet of additional office space, with the option to lease an additional 5,400 square feet in the same building in Burlington, Massachusetts. In addition, at the time, the Company leased approximately 6,700 square feet of temporary space for use prior to delivery of the additional space. This amendment also extended the term of the Lease through October 31, 2019. On September 30, 2015, the Company exercised its option for the additional 5,400 square feet of office space. On September 21, 2016, the Company entered into another amendment to extend the Lease for the 6,700 square feet of temporary space until October 31, 2017.

On April 7, 2017, the Company further amended the Lease to extend the term to October 31, 2023 on the then-existing office space, including the temporary space, consisting of approximately 28,600 square feet of office space in Burlington, Massachusetts. From November 2016 through October 2017, the Company's lease payment for this space was approximately $80,000 per month. Also, as part of this amendment to the Lease, the Company leased an additional 1,471 square feet of office space beginning in 2018. The lease payment for the 1,471 square feet of office space is approximately $4,100 per month.

On October 6, 2017, the Company exercised its option for an additional 6,450 square feet of space, and the term for the space commenced in April 2018. The Company has approximately 36,500 square feet of office space in Burlington, Massachusetts under a lease term expiring on October 31, 2023. Starting in December 2017, the Company's minimum monthly lease payment is approximately $87,000 and it increases over the life of the amended Lease. In addition to the base rent for the office space, which increases over the term of the amended Lease, the Company is responsible for its share of operating expenses and real estate taxes.

Upon adoption of ASU 2016-02, the Company recorded a right-of-use asset and corresponding lease liability for the Lease on January 1, 2019, by calculating the present value of lease payments, discounted at 8.9%, the Company's estimated incremental borrowing rate, over the 4.8-year remaining term.

The straight-line lease cost for the Lease amounted to $0.3 million for the three months ended March 31, 2019 and was included in operating expenses. As of March 31, 2019, the remaining lease term on the Lease was 4.6 years.

Woburn Lease

In February 2017, the Company entered into a five-year lease for laboratory space located in Woburn, Massachusetts with a monthly lease payment of approximately $15,000, which increases over the term of the lease, plus a share of operating expenses.

Upon adoption of ASU 2016-02, the Company recorded a right-of-use asset and corresponding lease liability for the Lease on January 1, 2019, by calculating the present value of lease payments, discounted at 8.4%, the Company's estimated incremental borrowing rate, over the 3.2-year remaining term. The Woburn lease includes an option to extend the term of the lease for two years. Since the Company adopted ASU 2016-02 using the Comparatives under 840 approach, it did not reassess the determination of its operating leases as leases, and therefore no options to extend the lease were included in the calculation of the lease liability as of March 31, 2019. The straight-line lease cost for the Woburn lease amounted to $46 thousand for the three months ended March 31, 2019 and was included in operating expenses. As of March 31, 2019, the remaining lease term on the Woburn lease was 2.9 years.

Manufacturing and Supply Agreement with Patheon UK Limited

In July 2015, the Company and Patheon UK Limited ("Patheon") entered into a Manufacturing and Supply Agreement (the "Manufacturing Agreement") and Technical Transfer and Service Agreement (the "Technical Transfer Agreement") for the manufacture of ZILRETTA.

Patheon agreed in the Technical Transfer Agreement to undertake certain transfer activities and construction services needed to prepare Patheon's United Kingdom facility for the commercial manufacture of ZILRETTA in dedicated manufacturing suites. The Company provided Patheon with certain equipment and materials necessary to manufacture ZILRETTA and pays Patheon a monthly fee for such activities and reimburses Patheon for certain material, equipment and miscellaneous expenses and additional services.

The initial term of the Manufacturing Agreement is 10 years from approval by the FDA of the Patheon manufacturing suites for ZILRETTA, or until October 6, 2027. The Company pays a monthly base fee to Patheon for the operation of the manufacturing suites and a per product fee for each vial based upon a forecast of commercial demand. The Company also reimburses Patheon for purchases of materials and equipment made on its behalf, certain nominal expenses and additional services. The Manufacturing Agreement will remain in full effect unless and until it expires or is terminated. Upon termination of the Manufacturing Agreement (other than termination by Flexion in the event that Patheon does not meet the construction and manufacturing milestones or for a breach by Patheon), Flexion will be obligated to pay for the costs incurred by Patheon associated with the removal of Flexion's manufacturing equipment and for Patheon's termination costs up to a capped amount.

The Manufacturing Agreement with Patheon contains an operating lease for the use of dedicated manufacturing suites. With the adoption of ASU 2016-02, the Company recorded a right-of-use asset and corresponding lease liability for the operating lease. As of March 31, 2019, the remaining lease term on the Patheon leases was 8.6 years. As of March 31, 2019, the discount rate was 8.24%. The straight-line lease cost amounted to $45 thousand for the three months ended March 31, 2019 and is included in inventory as part of manufacturing overhead.

The components of lease expense and related cash flows were as follows:

(In thousands)	For the three months ended March 31,	
Operating lease cost	**2019**	**2018**
Operating lease cost included in operating expenses	$ 369	$ —
Operating lease cost included in inventory	45	—
Total operating lease cost	414	—
Operating cash flows from operating leases	505	—

Maturities of lease liability due under these lease agreements as of March 31, 2019 were as follows:

Year	Operating Lease Obligations (in thousands)
2019	$ 1,253
2020	1,710
2021	1,752
2022	1,623
2023	1,380
Thereafter	677
Present value of imputed interest	(1,760)
Total	$ 6,635

As of December 31, 2018, future minimum lease payments under the Company's lease obligations under ASC 840 were as follows:

Year	Aggregate Minimum Payments (in thousands)
2019	1,491
2020	1,533
2021	1,576
2022	1,447
2023	1,203
Total	$ 7,250

As of December 31, 2018, future minimum payments under the Company's agreed obligations under the Manufacturing Agreement with Patheon were as follows:

Year	Aggregate Minimum Payments (in thousands)
2019	8,027
2020	8,027
2021	8,027
2022	8,027
2023	8,027
2024 and thereafter	30,102
Total	$ 70,237

Other Commitments and Contingencies

Evonik Supply Agreement

In November 2016, the Company entered into a Supply Agreement with Evonik Corporation ("Evonik") for the purchase of PLGA which is used in the manufacturing of clinical and commercial supply of ZILRETTA. Pursuant to the Supply Agreement, Flexion is obligated to submit rolling monthly forecasts to Evonik for PLGA supply, a portion of which will constitute binding orders. In addition, Flexion agreed to certain minimum purchase requirements, which do not apply (i) during periods in which Evonik is in material breach of the Supply Agreement or is unable to perform its obligations due to a force majeure event, (ii) with respect to orders that Evonik is unable to supply in excess of binding orders, (iii) for orders Evonik is unable to timely deliver or does not deliver conforming product and provides a credit for such order, or (iv) during an uncured material quality failure by Evonik. Flexion agreed to purchase PLGA batches at a specified price per gram in U.S. dollars, subject to adjustment from time to time, including due to changes in price indices and in the event the initial term of the Supply Agreement is extended. The total term of the agreement is five years. Upon termination of the Supply Agreement (other than termination due to the bankruptcy of either Evonik or Flexion) Flexion is obligated to pay the costs associated with the binding supply forecast provided to Evonik. The Supply Agreement will renew for two successive two year terms upon mutual written consent by both parties.

FX201 Related Agreements

In December 2017, the Company entered into a definitive agreement with GeneQuine Biotherapeutics GmbH ("GeneQuine") to acquire the global rights to FX201. As part of the asset purchase transaction with GeneQuine, the Company made an upfront payment to GeneQuine of $2 million. The Company may also be required to make additional milestone payments during the development of FX201, including up to $8.7 million through Phase 2 proof of concept (PoC) clinical trial and, following successful PoC, up to an additional $54 million in development and global regulatory approval milestone payments. The transaction was accounted for as an asset acquisition, as it did not qualify as a business combination. The upfront fee was attributed to the intellectual property acquired, and recognized as research and development expense in December 2017 as the FX201 product candidate had not been commercially approved, and had no alternative future use. Future milestone payments earned prior to regulatory approval of FX201 would be recognized as research and development expense in the period when the milestone events become probable of being achieved. Future milestones earned upon regulatory approval would be recognized as an intangible asset and amortized to expense over the estimated

life of FX201. The first milestone of $750,000 was achieved on October 24, 2018 when the GLP toxicology study was initiated upon the dosing of the first animals. This milestone was recognized as research and development expense in the fourth quarter of 2018. As of March 31, 2019, no other milestones under the arrangement have been achieved. As part of the transaction, the Company became the direct licensee of certain underlying Baylor College of Medicine (Baylor) patents and other proprietary rights related to FX201 for human applications. The Baylor license agreement grants the Company an exclusive, royalty-bearing, world-wide right and license (with a right to sublicense) for human applications under its patent and other proprietary rights directly related to FX201, with a similar non-exclusive license to certain Baylor intellectual property rights that are not specific to FX201. The license agreement with Baylor includes a low single-digit royalty on net sales of FX201 and requires the Company to use reasonable efforts to develop FX201 according to timelines set out in the license agreement. In December 2017, the Company also entered into a Master Production Services Agreement with SAFC Carlsbad, Inc., a part of MilliporeSigma, for the manufacturing of preclinical and initial clinical supplies of FX201.

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

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2018 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 February 28, 2019.

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 flow, 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 relate to a current historical fact. We have 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 biopharmaceutical company focused on the discovery, 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.

On October 6, 2017, the U.S. Food and Drug Administration, or FDA, approved our product, ZILRETTA, for marketing in the United States. ZILRETTA is the first and only extended-release, intra-articular, or IA (meaning in the joint), injection indicated for the management of OA related knee pain. ZILRETTA is a non-opioid therapy that employs our proprietary microsphere technology to provide pain relief. The pivotal Phase 3 trial, on which the approval of ZILRETTA was based, showed that ZILRETTA met the primary endpoint of pain reduction at Week 12, with statistically significant pain relief extending through Week 16. We also have a pipeline program, (FX201), which is a gene-therapy product candidate in development for OA.

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, preparing for and undertaking the commercialization of ZILRETTA, providing general and administrative support for these operations and protecting our intellectual property. From our inception through March 31, 2019, we have raised approximately $756 million and funded our operations primarily through the sale of our common stock, convertible preferred stock, and convertible debt, as well as debt financing. 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® Updates

ZILRETTA combines a commonly administered steroid, triamcinolone acetonide, or TA, with poly lactic-co-glycolic acid, referred to as PLGA, delivering a 32 mg dose of TA to provide extended therapeutic concentrations in the joint and persistent analgesic effect. Both the magnitude and duration of pain relief provided by ZILRETTA in clinical trials were clinically meaningful with the magnitude of pain relief amongst the largest seen to date in OA clinical trials. The overall frequency of treatment-related adverse events in these trials was similar to those observed with placebo and no drug-related serious adverse events were reported.

Our promotional and marketing activities have increased each quarter since launch as our field sales representatives, known as Musculoskeletal Business Managers or MBMs, have expanded prescriber awareness and utilization of ZILRETTA. Furthermore, our Field Access Managers have been working with physician practices to help them navigate any reimbursement questions and to support their awareness of the product-specific Healthcare Common Procedure Coding System (HCPCS) reimbursement code for ZILRETTA (J3304), which became effective on January 1, 2019.

J codes are routine reimbursement codes assigned to physician-administered "buy and bill" products under Medicare Part B. They are granted by the Centers for Medicare and Medicaid Services, or CMS, and they are utilized by Medicare, commercial insurers and other government payers. Additionally, CMS publishes a defined payment rate for each J code, which is determined by the average sales price (ASP) of the product. We believe that our customers (physicians, clinics and certain medical centers and hospitals) have familiarity and comfort with obtaining reimbursement via J codes, and as a result, we believe that J3304 will further enhance their confidence regarding reimbursement for ZILRETTA.

To provide perspective on the progress of the ZILRETTA launch, we have closely tracked and reported quarterly updates on a number of quantitative uptake metrics across several dimensions, including prescriber awareness, clinical interest and market access and payer coverage. For 2019, we introduced new metrics to provide further color and transparency on our commercial activities and the clinical adoption of ZILRETTA. Since the launch in November 2017 through March 31, 2019:

- 2,247 of our 4,100 target accounts had purchased ZILRETTA. This reflects growth of 22% over the period from launch through December 31, 2018 when 1,837 accounts had purchased product.
- 71% of purchasing accounts (1,601) had placed at least one reorder.
- More than 310 accounts had made ZILRETTA purchases of more than 50 units; approximately 700 accounts had purchased 11 to 50 units; and in excess of 1,200 accounts had purchased between 1 and 10 units.
- Accounts purchasing more than 50 ZILRETTA units have been responsible for more than 60% of total ZILRETTA purchases (approximately 38,000 units).

In addition, sampling of ZILRETTA equaled approximately 10% of the total ZILRETTA units purchased in the first quarter of 2019.

Results from an "Awareness, Trial and Usage" (ATU) survey conducted in early April 2019 indicated 74% of the 120 orthopedic surgeons sampled had awareness of ZILRETTA and 32% had administered the product. By comparison, an ATU conducted in February 2018 indicated that 42% of 118 orthopedic surgeons sampled were aware of ZILRETTA and only 9% had administered the product.

Regulatory Developments, Clinical Updates and Recent Publications

At the end of 2018, we submitted a supplemental New Drug Application, or sNDA, to the FDA to revise the product label for ZILRETTA to allow for repeat administration. The sNDA includes the full data set from a Phase 3b single-arm, open-label clinical trial which evaluated the safety and tolerability of repeat administration of ZILRETTA. In February 2019, we received a "Day 74" letter from the FDA confirming that our sNDA was accepted for filing. Under the Prescription Drug User Fee Act (PDUFA), we anticipate a decision from the FDA on or before October 14, 2019.

In April 2019, an independent evaluation of clinical data for ZILRETTA conducted by *Adis Drug Review* was published in the journal, *Drugs*. Their assessment included data from six clinical trials conducted over the past seven years, which evaluated 1,347 patients, 613 of whom were treated with ZILRETTA. The evidence-based evaluation concluded that ZILRETTA provided effective pain relief, while being generally well-tolerated as demonstrated in clinical studies, and it expands the treatment options for OA knee pain.

Also in April, we announced that the results from a post-hoc analysis of data from the pivotal Phase 3 trial of ZILRETTA were published in *Advances in Therapy*. The findings indicated that patients with unilateral OA knee pain experienced significant and durable pain relief with a single intra-articular injection of ZILRETTA compared to immediate-release triamcinolone acetonide in crystalline suspension as measured by Average Daily Pain (ADP) intensity scores. The analysis also indicated that ZILRETTA patients in this subgroup experienced improvements on OA-specific measures of pain, stiffness, function and quality of life scores that lasted up to six months. Furthermore, the analysis showed that patients in this subgroup who were treated with ZILRETTA experienced a profound magnitude of analgesic effect, with ADP scores that were reduced by >60% at Weeks 3-17. These results suggest that bilateral knee pain may have been a confounding factor in the pivotal trial which assessed the impact of ZILRETTA treatment in only one knee.

At the 2019 Osteoarthritis Research Society International World Congress (OARSI) held in May, we presented positive results from the Phase 2 pharmacokinetic (PK) study evaluating ZILRETTA in patients with hip OA. The data show showed PK profiles consistent with previous studies in the knee. We also presented a poster on the previously published Phase 3b data indicating repeat administration of ZILRETTA for OA knee pain resulted in substantial improvements in OA symptoms and had no deleterious impact on cartilage or joint structure per X-ray. Additionally, we gave an encore poster presentation of data from an *in vitro* study which suggests that TA can have dose-dependent chondroprotective effects on inflamed and injured cartilage.

With respect to ZILRETTA clinical trials, we have recently been made aware of a non-safety issue in the Phase 3 trial of ZILRETTA in hip OA pain which resulted in the inability to deliver a full dose in a small number of trial participants. As a result, we have temporarily paused enrollment and dosing as we work with investigators to identify and address the root cause of the issue.

Pipeline Updates

FX201 – Intra-articular Gene Therapy for the Treatment of OA

FX201 is our preclinical stage, IA gene therapy candidate which is designed to produce human interleukin-1 receptor antagonist (IL-1Ra) whenever inflammation is present within the joint. Based on the promising preclinical data generated to date, a single injection of FX201 could potentially enable expression of IL-1Ra in an osteoarthritic joint for at least a year. By controlling chronic inflammation for extended periods of time, we believe FX201 holds the potential to both reduce OA pain and potentially modify disease. We acquired the rights to FX201 via a definitive agreement with GeneQuine Biotherapeutics GmbH, or GeneQuine, and have an exclusive license to the underlying intellectual property rights for human use of FX201 from Baylor College of Medicine in Houston, Texas.

In 2018, we held a pre-Investigational New Drug (IND) meeting with the FDA and initiated Good Laboratory Practice (GLP) toxicology studies. Those studies advanced during the first quarter of 2019 and pending successful results, we anticipate filing an IND and initiating first-in-human clinical trials in the second half of this year.

Financial Overview

Revenue

Net product sales consist of sales of ZILRETTA, which was approved by the FDA on October 6, 2017 and launched in the United States in October 2017. We had not generated any revenue prior to the launch of ZILRETTA.

Cost of Sales

Cost of sales consists of third-party manufacturing costs, freight and indirect overhead costs associated with sales of ZILRETTA. Cost of sales also includes period costs related to certain inventory manufacturing services, inventory adjustment charges, and unabsorbed manufacturing and overhead costs, as well as any write-offs of inventory that fails to meet specifications or is otherwise no longer suitable for commercial manufacture.

Research and Development Expenses

Our research and development activities include: preclinical studies, clinical trials, and chemistry, manufacturing, and controls, or CMC activities. Our research and 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 certain regulatory requirements;
- expenses related to the in-license of certain technologies; 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 Results of Operations section below. Inventory acquired prior to receipt of the marketing approval of ZILRETTA was recorded as research and development expense as incurred. We began capitalizing the costs associated with the production of ZILRETTA after the FDA approval on October 6, 2017.

Our research and development expenses are expected to increase in the foreseeable future. Specifically, our costs will increase as we conduct additional clinical trials for ZILRETTA and conduct further developmental activities for our portfolio.

We cannot determine with certainty the duration of and completion costs associated with ongoing and future clinical trials or the associated regulatory approval process, post-marketing development of ZILRETTA or development of any product candidates in our pipeline. The duration, costs and timing associated with the further development of ZILRETTA or the development of other product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials. As a result of these uncertainties, we are currently unable to estimate with any precision our future research and development expenses for expanded

indications for ZILRETTA or any product candidates in our pipeline, or when we may generate sufficient revenue to achieve a positive cash flow position.

Selling, General and Administrative Expenses

Selling, 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 selling, 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 selling, 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 commercialization of ZILRETTA or any other product candidates. In particular, we expect to incur ongoing increases in selling, general and administrative expenses related to the commercialization of ZILRETTA, including external marketing spend and the operation of our field sales force. 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 SEC 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. Interest expense consists of contractual interest on our 2024 Convertible Notes, which accrue interest at a rate of 3.375% per annum, payable semi-annually, and our term loan facility, which accrues interest at a fixed rate of 6.25% per annum. Also included in interest expense is the amortization of the final payment on the term loan and the debt discount related to the convertible notes, which is being amortized to interest expense using the effective interest method over the expected life of the debt.

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 income (expense). Other income (expense) consists of the net accretion of premiums and discounts related to our marketable securities and our realized gains (losses) on redemptions of our marketable securities. We will continue to record either income or expense related to accretion of discounts or amortization of premiums on marketable securities for as long as we hold these investments. Also included in other income (expense) is the amortization of debt issuance costs on our term loan facility and the 2024 Convertible Notes, which are being amortized over the respective terms of the loans.

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, 2018 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, 2019.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended March 31, 2019 and 2018

The following tables summarize our results of operations for the three months ended March 31, 2019:

	Three Months Ended March 31,			
(In thousands)	2019	2018	Change	% Increase/ (Decrease)
Revenues:				
Product revenue, net	$ 10,564	2,194	$ 8,370	381.5%
Operating expenses:				
Cost of sales	1,762	2,698	(936)	(34.7)%
Research and development	15,424	11,551	3,873	33.5%
Selling, general and administrative	32,222	26,899	5,323	19.8%
Total operating expenses	49,408	41,148	8,260	20.1%
Loss from operations	(38,844)	(38,954)	110	(0.3)%
Other (expense) income:				
Interest income	1,011	1,161	(150)	(12.9)%
Interest expense	(3,936)	(3,919)	(17)	0.4%
Other income	231	143	88	61.5%
Total other (expense) income	(2,694)	(2,615)	(79)	3.0%
Net loss	$ (41,538)	$ (41,569)	$ 31	(0.1)%

Product Revenue

We began commercially selling ZILRETTA within the United States in October 2017, following FDA approval on October 6, 2017. For the three months ended March 31, 2019 and 2018, we recorded $10.6 million and $2.2 million, respectively, of net product revenue. For further discussion regarding our revenue recognition policy, see Note 2, "Summary of Significant Accounting Policies", in the Notes to Condensed Consolidated Financial Statements included in Part I, Item I of this Quarterly Report on Form 10-Q.

Cost of Sales

Cost of sales was $1.8 million and $2.7 million for the three months ended March 31, 2019 and 2018, respectively. For the three months ended March 31, 2018, the majority of cost of sales related to unabsorbed manufacturing and overhead costs related to the operation of the facility at Patheon, as the majority of product sold during that period was previously charged to research and development expense prior to FDA approval of ZILRETTA and therefore is not included in cost of sales during the period. For the three months ended March 31, 2019, cost of sales consisted of $1.3 million related to the actual cost of units sold, as well as $0.4 million of period costs and adjustments.

Research and Development Expenses

	Three Months Ended March 31,			
(In thousands)	2019	2018	Change	% Increase/ (Decrease)
Direct research and development expenses by program:				
ZILRETTA	$ 5,290	$ 4,069	$ 1,221	30.0%
Portfolio expansion	1,648	761	887	116.6%
Other	589	327	262	80.1%
Total direct research and development expenses	7,527	5,157	2,370	46.0%
Personnel and other costs	7,897	6,394	1,503	23.5%
Total research and development expenses	$ 15,424	$ 11,551	$ 3,873	33.5%

Research and development expenses were $15.4 million and $11.6 million for the three months ended March 31, 2019 and 2018, respectively. The increase in research and development expenses of $3.9 million was primarily due to an increase of $1.5 million in salary and other employee-related costs for additional headcount and stock-based compensation expense, as well as a $1.1 million increase in preclinical expenses related to our portfolio expansion and other program costs, and an increase of $1.2 million in development expenses for ZILRETTA, including CMC and clinical trial costs largely related to the hip OA Phase 3 registration trial initiated in December 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $32.2 million and $26.9 million for the three months ended March 31, 2019 and 2018, respectively. Selling expenses were $23.8 million and $18.1 million for the three months ended March 31, 2019 and 2018, respectively. The year-over-year increase in selling expenses of $5.7 million was primarily due to salary and other employee-related costs and external costs related to physician and patient marketing and reimbursement support activities. General and administrative expenses were $8.4 million and $8.8 million for the three months ended March 31, 2019 and 2018, respectively, which represents a decrease of $0.4 million.

Other Income (Expense)

Interest income was $1.0 million and $1.2 million for the three months ended March 31, 2019 and 2018, respectively. The decrease in interest income was primarily due to a decrease in the average investment balance.

Interest expense was $3.9 million both for the three months ended March 31, 2019 and 2018, respectively.

Liquidity and Capital Resources

For the three months ended March 31, 2019, we generated $10.6 million in net product revenue. We have incurred significant net losses in each year since our inception, including net losses of $169.7 million, $137.5 million, and $71.9 million, for fiscal years 2018, 2017, and 2016, respectively, and $41.5 million for the three months ended March 31, 2019. As of March 31, 2019, we had an accumulated deficit of $560.4 million. We anticipate that we will continue to incur losses over the next few years. We expect that our research and development and selling, general and administrative expenses will continue to increase and, as a result, we may 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, 2019, we have funded our operations primarily through the sale of our common stock and convertible preferred stock and convertible debt, and through venture debt financing. From our inception through March 31, 2019, we had raised approximately $756 million from such transactions, including amounts from our initial and follow-on public offerings during 2014, 2016 and 2017, as well as our term loan facility entered into in 2015 and our 2024 Convertible Notes issuance in 2017. As of March 31, 2019, we had cash, cash equivalents, and marketable securities of $217.8 million. Based on our current operating plan we anticipate that our existing cash, cash equivalents, and marketable securities will fund our operations for at least the next twelve months from the date of issuance of the financial statements included in this report. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with an objective of capital preservation.

The following table shows a summary of our cash flows for each of the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
(In thousands)	**2019**	**2018**
Cash flows used in operating activities	$ (37,981)	$ (44,981)
Cash flows provided by investing activities	41,187	66,582
Cash flows used in financing activities	(2,500)	(2,086)
Net increase in cash and cash equivalents	$ 706	$ 19,515

Net Cash Used in Operating Activities

Operating activities used $38.0 million of cash in the three months ended March 31, 2019. The cash flow used in operating activities resulted primarily from our net loss for the period of $41.5 million and changes in our operating assets and liabilities of $2.4 million, offset by non-cash charges of $6.0 million. Changes in our operating assets and liabilities consisted primarily of a $2.0 million increase in accounts receivable, a $2.3 million increase in inventory and a $0.2 million decrease in lease liabilities and other long-term liabilities primarily due to principal lease payments, partially offset by a $0.8 million decrease in prepaid expenses and other current assets and an increase of $1.3 million in accounts payable and accrued expenses. Our non-cash charges consisted primarily of $3.9

million of stock-based compensation expense, $2.1 million related to the amortization of the debt discount and debt issuance costs related to the 2024 Convertible Notes, $0.3 million related to the amortization of right-of-use assets, and $0.2 million of depreciation, partially offset by $0.4 million of net accretion of discounts related to our investments.

Operating activities used $45.0 million of cash in the three months ended March 31, 2018. The cash flow used in operating activities resulted primarily from our net loss for the period of $41.6 million and changes in our operating assets and liabilities of $9.3 million, partially offset by non-cash charges of $5.9 million. Changes in our operating assets and liabilities consisted primarily of a $2.0 million increase in accounts receivable, a $0.7 million increase in inventory, and a $0.6 million increase in prepaid expenses and other current assets, as well as a decrease of $6.0 million in accounts payable and accrued expenses. Our non-cash charges consisted primarily of $3.7 million of stock-based compensation expense, $1.9 million related to the amortization of the debt discount and debt issuance costs related to the 2024 Convertible Notes, and $0.6 of depreciation and amortization, partially offset by $0.2 million of amortization and accretion related to our investments.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $41.2 million in the three months ended March 31, 2019. Net cash provided by investing activities consisted primarily of cash received for the redemption and sale of marketable securities of $118.6 million, partially offset by cash used to purchase marketable securities of $76.3 million. In addition, $1.1 million of cash was used for capital expenditures, including $0.2 million for lab equipment and $0.9 million for manufacturing equipment associated with the expansion of our manufacturing facilities at Patheon.

Net cash provided by investing activities was $66.6 million in the three months ended March 31, 2018. Net cash provided by investing activities consisted primarily of cash received from the redemption and sale of marketable securities of $99.5 million, partially offset by cash used to purchase marketable securities of $32.5 million. In addition, $0.3 million of cash was used to purchase manufacturing equipment.

Net Cash Used in Financing Activities

Net cash used in financing activities was $2.5 million for the three months ended March 31, 2019. Net cash used in financing activities in the three months ended March 31, 2019 related to the payment of principal on our 2015 term loan.

Net cash used in financing activities was $2.1 million for the three months ended March 31, 2018. Net cash used in financing activities in the three months ended March 31, 2018 consisted primarily of $2.5 million related to the payment of principal on our 2015 term loan, partially offset by $0.4 million received from the exercise of stock options.

Contractual Obligations

For a discussion of our contractual obligations, see “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2018 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2018. For further information regarding our contractual obligations and commitments, see Note 12, Commitments and Contingencies to our unaudited consolidated financial statements included elsewhere in this report.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposures to market risk are interest income sensitivity and equity price risk. Interest income 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.

Investments

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 investments 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.

Convertible Notes

On May 2, 2017, we issued $201.3 million aggregate principal amount of 2024 Convertible Notes. The 2024 Convertible Notes are senior unsecured obligations and bear interest at a rate of 3.375% per year, payable semi-annually in arrears on May and November 1st of each year. The 2024 Convertible Notes will mature on May 1, 2024, unless repurchased or converted earlier. The 2024 Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election (subject to certain limitations in the 2015 term loan), at a conversion rate of approximately 37.3413 shares of common stock per $1,000 principal amount of the 2024 Convertible Notes, which corresponds to a conversion price of approximately $26.78 per share of our common stock and represents a conversion premium of approximately 35% based on the last reported sale price of our common stock of $19.72 on May 2, 2017, the date the 2024 Convertible Notes offering was priced. As of May 2, 2017, the fair value of the 2024 Convertible Notes was $136.7 million. Our 2024 Convertible Notes include conversion and settlement provisions that are based on the price of our common stock at conversion or at maturity of the 2024 Convertible Notes. The amount of cash we may be required to pay is determined by the price of our common stock. The fair value of our 2024 Convertible Notes are dependent on the price and volatility of our common stock and will generally increase or decrease as the market price of our common stock changes. The estimated fair value of the 2024 Convertible Notes, face value of $201.3 million, was $174.0 million at March 31, 2019.

Foreign Currency Exchange

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, 2019 we had $1.3 million in liabilities denominated in British Pounds. No other payables to vendors were denominated in currencies other than in U.S. dollars; therefore, a hypothetical 10% change in foreign exchange rates would have an immaterial effect on the value of our liabilities. As of March 31, 2019, we had less than $0.1 million in cash denominated in British Pounds. A hypothetical 10% change in foreign exchange rates would result in an immaterial change in the amount 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 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 principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of March 31, 2019, 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, 2019 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 consider carefully the risks described below, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below with an asterisk (*) next to the title contain changes to the description of the risk factors associated with our business previously disclosed in our Annual Report on Form 10-K filed on February 28, 2019. The risks and uncertainties below are those identified by us as material, but there are also additional risks and uncertainties that we are unaware of that may become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected, and the market price of our common stock would likely decline.

Risks Related to Our Financial Condition and Need for Additional Capital

(*) We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses over the next few years.

We have a limited operating history. To date, we have focused primarily on developing our commercialized product, ZILRETTA. Any additional product candidates we develop will require substantial development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred significant net losses in each year since our inception, including net losses of $169.7 million, $137.5 million, and $71.9 million, for fiscal years 2018, 2017, and 2016, respectively, and $41.5 million for the three months ended March 31, 2019. As of March 31, 2019, we had an accumulated deficit of $560.4 million. We expect to incur net losses over the next few years as we continue to invest in the commercialization of ZILRETTA and advance our development programs.

We have devoted most of our financial resources to product development, including our nonclinical development activities and clinical trials, and more recently to commercial efforts. To date, we have financed our operations exclusively through the sale of equity securities and debt. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. The U.S. Food and Drug Administration, or FDA, granted marketing approval and we launched commercial sales of ZILRETTA in the fourth quarter of 2017. We have not generated significant revenues from sales of ZILRETTA and cannot guarantee that our commercialization efforts will result in substantial product revenues.

We also expect to continue to incur substantial and increased expenses as we invest in the commercialization of ZILRETTA, scale up commercial manufacturing of ZILRETTA, conduct additional clinical trials for this product and continue our development activities with respect to ZILRETTA, FX201 and other future product candidates. As a result of the foregoing, we expect to continue to incur significant losses and negative cash flows over the next few years.

(*)We have not generated significant revenue and may never be profitable.

Our ability to generate significant revenue and achieve profitability depends primarily on our ability to successfully commercialize ZILRETTA, as well as our ability to obtain regulatory approval for and then successfully commercialize other product candidates. We may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with new pharmaceutical products and development efforts, we are unable to predict the timing or amount of increased expenses, when, or if, we will begin to generate meaningful revenue from product sales, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we determine that additional sales and marketing personnel or other resources are necessary to successfully commercialize ZILRETTA or if we face any legal or regulatory action related to the commercialization of ZILRETTA.

If we are unable to generate significant revenues from product sales, particularly from sales of ZILRETTA, or to maintain an acceptable cost structure related to our operations, we may not become profitable and may need to obtain additional funding to continue operations.

(*) If we fail to obtain additional financing, we may be forced to delay, reduce or eliminate our product development programs and/or 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 increase in connection with our ongoing activities, particularly as we expand our sales and marketing activities, continue to commercialize ZILRETTA, and advance our clinical programs.

As of March 31, 2019, we had cash, cash equivalents, and marketable securities of approximately $217.8 million and working capital of $208.7 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 12 months from the issuance date of the financial statements included in this report. Regardless of our expectations as to how long our cash, cash equivalents, and marketable securities will fund our operations, changing circumstances may cause us to consume capital more rapidly than we currently anticipate.

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 scale back or discontinue commercialization of ZILRETTA or the further development of ZILRETTA or 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;
- seek corporate partners to assist in the commercialization of ZILRETTA on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to ZILRETTA or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail, or cease, operations.

We may sell additional equity or debt securities to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which could adversely impact our existing stockholders as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

(*) Our existing indebtedness contains restrictions that limit our flexibility in operating our business. In addition, we may be required to make a prepayment or repay our outstanding indebtedness earlier than we expect, which could have a materially adverse effect on our business, or may otherwise be unable to repay our indebtedness as it becomes due.

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

- incur or assume certain debt;
- merge or consolidate or acquire all or substantially all of the capital stock or property of another entity;
- enter into any transaction or series of related transactions that would be deemed to result in a change in control of us under the terms of the agreement;
- change the nature of our business;
- change our organizational structure or type;
- amend, modify or waive any of our organizational documents;

- license, transfer or dispose of certain assets;
- grant certain types of liens on our assets;
- make certain investments;
- pay cash dividends;
- enter into material transactions with affiliates; and
- amend or waive provisions of material agreements in certain manners.

The restrictive covenants in the credit agreement could prevent us from pursuing business opportunities that we or our stockholders may consider beneficial.

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

In April 2017, we also issued $201.3 million principal amount of our 3.375% Convertible Senior Notes due 2024, or the 2024 Convertible Notes. The 2024 Convertible Notes will mature on May 1, 2024, unless earlier redeemed, repurchased or converted in accordance with the terms of the indenture governing the notes. If specified bankruptcy, insolvency or reorganization-related events of default occur, or if certain other events of default occur and the trustee or certain holders of the 2024 Convertible Notes elect, the principal of, and accrued and unpaid interest on, all of the then-outstanding 2024 Convertible Notes will automatically become due and payable. In addition, if we undergo certain fundamental change transactions specified in the indenture governing the 2024 Convertible Notes, the holders of the notes may require us to repurchase their notes at a price equal to 100% of the principal amount of the notes, plus any accrued and unpaid interest.

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

Risks Related to Commercialization Activities

(*)Our prospects are highly dependent on the successful commercialization of ZILRETTA. To the extent ZILRETTA is not commercially successful, our business, financial condition and results of operations may be materially adversely affected.

ZILRETTA is our only drug that has been approved for sale and it has only been approved for the management of osteoarthritis, or OA, pain of the knee for patients in the United States. We are focusing a significant portion of our activities and resources on ZILRETTA, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize ZILRETTA in the United States.

Successful commercialization of ZILRETTA is subject to many risks. We have never, as an organization, commercialized a product prior to ZILRETTA, and there is no guarantee that we will be able to do so successfully with ZILRETTA for its approved indication. There are numerous examples of failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us.

Market acceptance of ZILRETTA and any other product for which we receive approval, will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of the product as well as competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, the medical community and patients of the product as a safe and effective treatment;
- the ability to distinguish safety and efficacy from existing, less expensive generic alternative therapies;

- the convenience of prescribing, administrating and initiating patients on the product;
- the potential and perceived advantages of the product over alternative treatments;
- the potential and perceived value of the product over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement by third-party payers and government authorities to support ZILRETTA's pricing;
- the prevalence and severity of adverse side effects; and
- the effectiveness of sales and marketing efforts.

With respect to ZILRETTA, while we have established our commercial team and sales force, there are many factors that could cause the commercialization of ZILRETTA to be unsuccessful, including a number of factors that are outside our control. The commercial success of ZILRETTA depends on the extent to which patients and physicians accept and adopt ZILRETTA as a treatment for OA pain of the knee, and we do not know whether our or others' revenue estimates in this regard will be accurate. For example, if the patient population suffering from OA pain of the knee is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to use ZILRETTA, the commercial potential of ZILRETTA will be limited. In addition, if ZILRETTA is not convenient for physicians to use, then it may not achieve widespread adoption, regardless of its efficacy and safety. For example, ZILRETTA is a buy-and-bill product and must be administered only by a health care professional in an office, clinic or hospital setting. In addition, ZILRETTA requires a multi-step preparation process, which may discourage some physicians from using ZILRETTA. Moreover, ZILRETTA's product label indicates that it is not intended for repeat administration, and we believe this has negatively impacted our commercialization efforts. While we successfully completed a Phase 3b repeat dose study of ZILRETTA and have submitted an sNDA to the FDA, we cannot predict whether or when the FDA may agree to modify the ZILRETTA product label with respect to repeat administration. We also do not know how physicians, patients and payers will respond to the pricing of ZILRETTA in the long-term. In particular, we provide product samples and do not know whether physicians that initially use ZILRETTA will continue to do so after using the product samples. If we experience any disruption in the commercial supply of ZILRETTA due to manufacturing or distribution issues, the disruption would impact ZILRETTA sales and may adversely affect physicians', patients' and payers' assessment of ZILRETTA, negatively impacting uptake and long-term commercialization efforts.

Physicians may not prescribe ZILRETTA and patients may be unwilling to use ZILRETTA if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for ZILRETTA in clinical development in additional indications, may adversely impact the commercial results and potential of ZILRETTA. Thus, significant uncertainty remains regarding the commercial potential of ZILRETTA.

If the commercialization of ZILRETTA is unsuccessful or perceived as disappointing, our stock price could decline significantly, and the long-term success of the product and our company could be harmed.

If we are unable to differentiate ZILRETTA from existing generic therapies for the treatment of OA, or if the FDA or other applicable regulatory authorities approve generic products that compete with ZILRETTA, our ability to successfully commercialize ZILRETTA would be adversely affected.

Immediate-release TA and other injectable immediate-release steroids, which are the current intra-articular, or IA, standard of care for OA pain, are available in generic form and are therefore relatively inexpensive compared to the pricing for ZILRETTA. These generic steroids also have well-established market positions and familiarity with physicians, healthcare payers and patients. Although we believe the proven and extended pain relief evidenced in our clinical trials demonstrate that ZILRETTA represents a clinically meaningful and highly efficacious option for patients and physicians, it is possible that we will receive data from additional clinical trials or in a post-marketing setting from physician and patient experiences with the commercial product that does not continue to support such interpretations. It is also possible that the FDA, physicians and healthcare payers will not agree with our interpretation of our existing and future clinical trial data. If we are unable to demonstrate the value of ZILRETTA based on our data, our opportunity for ZILRETTA to maintain premium pricing and be commercialized successfully would be adversely affected. For example, although ZILRETTA showed numeric improvements through week 12 in validated, OA specific pain, stiffness, function and quality of life exploratory measures and showed numeric improvements in average daily pain, it did not achieve statistical significance at the week 12 ADP timepoint compared to immediate-release TA. As a result, it is possible that healthcare payers will not agree with our assessment that ZILRETTA's proven pain relief supports premium pricing.

In addition to existing generic steroids, such as immediate-release TA, the FDA or other applicable regulatory authorities may approve other generic products that could compete with ZILRETTA, if we cannot adequately protect it with our patent portfolio. Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in

turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, conditions of use, or labeling as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as ZILRETTA. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our products would materially adversely impact our ability to successfully commercialize ZILRETTA.

(*)We face significant competition from other biopharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the pain and OA market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical and biotechnology companies. For example, the injectable OA treatment market today includes many injectable immediate-release steroids, including TA, the active ingredient in ZILRETTA, as well as hyaluronic acid, or HA, injections. In addition, we expect that injectable therapies, such as ZILRETTA, will continue to be used primarily after oral medications no longer provide adequate pain relief. To the extent that new or improved oral or other systemically administered pain medications are introduced that demonstrate better long-term efficacy and safety, patients and physicians may further delay the introduction of injectable therapies, such as ZILRETTA in the OA treatment continuum. ZILRETTA could also face competition from other formulations or devices that deliver pain medication on an extended basis, such as transdermal delivery systems or implantable devices.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staffs and experienced commercial and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than ZILRETTA or any other product candidate that we are currently developing or that we may develop.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of ZILRETTA and our other product candidates, including relative to marketed products and product candidates in development by third parties;
- the ability to distinguish safety and efficacy from existing, less expensive generic alternative therapies;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- the ability to commercialize and market ZILRETTA and any of our other product candidates that receive regulatory approval;
- the price of ZILRETTA and any of our future products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to protect our intellectual property rights;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of ZILRETTA and any of our other product candidates that receive regulatory approval; and
- acceptance of ZILRETTA and any of our other product candidates that receive regulatory approval by patients, physicians and other healthcare providers.

If our competitors market products that are more effective, safer, less expensive or offer discounts that allow physicians to receive more net reimbursement than ZILRETTA, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our products or product candidates obsolete, less competitive or not economical.

(*) If we are unable to maintain sales and marketing capabilities or enter into agreements with third parties to market, distribute and sell our product candidates, we may be unable to generate adequate revenue.

Our strategy is to commercialize ZILRETTA in the United States with a targeted sales and marketing organization. While we have established our commercial team and our sales force, we do not have prior experience commercializing pharmaceutical products as an organization. In order to successfully market ZILRETTA, we must continue to build and maintain our sales, marketing, managerial, compliance and related capabilities or make arrangements with third parties to perform these services. These efforts will continue to be expensive and time-consuming, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not generate significant revenue from ZILRETTA.

Additionally, our strategy in the United States includes distributing ZILRETTA solely through a limited network of third-party specialty distributors and one specialty pharmacy. While we have entered into agreements with a specialty pharmacy and specialty distributors to distribute ZILRETTA in the United States, they may not perform as agreed or they may terminate their agreements with us. For example, ZILRETTA sales are concentrated with two specialty distributors, which together represented approximately 81% and 94% of our sales for the years ended December 31, 2018 and 2017, respectively. Loss of either specialty distributor through contract termination or its failure to distribute effectively would adversely affect ZILRETTA's distribution. Also, we may need to enter into agreements with additional specialty distributors, specialty pharmacies, or directly with other third parties, and there is no guarantee that we will be able to do so on commercially reasonable terms or at all. In the event that our specialty distributors or specialty pharmacy do not fulfill their contractual obligations to us, the agreements are terminated without adequate notice, or we are unable to expand our network, shipments of ZILRETTA through, and associated revenues from, these sales channels would be adversely affected. In addition, we expect that it would take a significant amount of time to negotiate new contracts if we were required to change our specialty distributors or specialty pharmacy.

To date, we have not entered into any strategic collaborations for ZILRETTA or any of our other product candidates. We face significant competition in seeking appropriate strategic partners, and these strategic collaborations can be intricate and time consuming to negotiate and finalize. We may not be able to negotiate strategic collaborations for territories outside of the United States on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic collaboration outside of the United States because of the numerous risks and uncertainties associated with establishing strategic collaborations. To the extent that we enter into strategic collaborations, our future collaborators may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of ZILRETTA or our other product candidates in territories outside of the United States, or if our potential future collaborators do not successfully commercialize our product candidates in these territories, our ability to generate revenue from product sales will be adversely affected.

We and any future collaborators that we may engage will be competing with many companies that currently have extensive and well-funded marketing and sales operations. If we, alone or with commercialization partners, are unable to compete successfully against these established companies, the commercial success of ZILRETTA or any other approved products will be limited. In addition, if we are unable to effectively develop and maintain our commercial team, including our U.S. sales force, or maintain and, if needed, expand, our network of specialty distributors and specialty pharmacies, our ability to effectively commercialize ZILRETTA and generate product revenues would be limited.

(*) If we are unable to effectively train and equip our sales force, our ability to successfully commercialize ZILRETTA will be harmed.

ZILRETTA is a newly-marketed drug and, therefore, the members of our sales force have limited experience promoting ZILRETTA. As a result, we are required to expend significant time and resources to train our sales force to be credible, persuasive and compliant with applicable laws in marketing ZILRETTA for the treatment of patients with OA of the knee. In addition, we must train our sales force to ensure that an appropriate and compliant message about ZILRETTA is being delivered. If we are unable to maintain an effectively trained sales force and equip them with compliant and effective materials, including medical and sales literature to help them appropriately inform and educate regarding the potential benefits and safety of ZILRETTA and its proper administration, our

efforts to successfully commercialize ZILRETTA could be put in jeopardy, which would negatively impact our ability to generate product revenues.

If we are unable to achieve and maintain adequate levels of third-party payer coverage and reimbursement for ZILRETTA, or, if approved, any other product candidates, on reasonable pricing terms, their commercial success may be severely hindered.

Successful sales of ZILRETTA and any other approved product candidates depend on the availability of coverage and adequate reimbursement from third-party payers, including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payers, among others. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payers to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from third-party payers are critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. The resulting reimbursement payment rates for ZILRETTA and, if approved, our other product candidates, might not be adequate or may require co-payments that patients find unacceptably high.

As of January 1, 2019, we received a product-specific J-Code for ZILRETTA (J-3304), which may reduce reluctance by physicians to prescribe ZILRETTA based on reimbursement concerns. However, third-party payers nevertheless may require documented proof that patients meet certain eligibility criteria in order to be reimbursed for ZILRETTA, for example requiring that a patient first try and fail treatment with an injection of generic corticosteroid. Also, third-party payers may require that pre-approval, or prior-authorization, be obtained from the payer for reimbursement of ZILRETTA, or limit coverage to one injection or a limited number of injections over a set time period. Patients are unlikely to use ZILRETTA and, if approved, any other products, unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. For example, ZILRETTA is sold to physicians on a "buy and bill" basis. Buy and bill products must be purchased by healthcare providers before they can be administered to patients. Healthcare providers subsequently must seek reimbursement for the product from the applicable third-party payer, such as Medicare or a health insurance company. Healthcare providers may be reluctant to administer ZILRETTA because they would have to fund the purchase of the product and then seek reimbursement, which may be different from their purchase price, or because they do not want the additional administrative burden required to obtain reimbursement for the product.

In addition, the market for ZILRETTA and any of our other product candidates may depend significantly on access to third-party payers' medical policies, drug formularies, or lists of medications for which third-party payers provide coverage and reimbursement, as well as inclusion of ZILRETTA on the reimbursement policies and formularies used by large physician practices and hospitals. The industry competition to be included in such policies or formularies often leads to downward pricing pressures on pharmaceutical companies, and we may be required to offer discounted rates to certain government and other payers to ensure coverage of our drugs. Also, third-party payers, physician practices and hospitals may refuse to include a particular branded drug in their policies or formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available, or when the reimbursement landscape is unclear.

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer and one payer's determination to provide coverage for ZILRETTA does not ensure that other payers also will provide coverage. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for ZILRETTA or, if approved, any of our other product candidates, may not be available or adequate in either the United States or international markets, or may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales and distribution costs. If coverage and reimbursement are not available or only available at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval, including ZILRETTA, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Guidelines and recommendations published by various organizations can reduce the use of ZILRETTA and any other products we may commercialize.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products and product candidates. In addition, professional societies, such as the American Academy of Orthopedic Surgeons, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities with respect to specific products. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines that do not recognize ZILRETTA or our other product candidates, suggest limitations or inadequacies of ZILRETTA or our other product candidates, or suggest the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers, could result in decreased use or adoption of ZILRETTA or any future products.

(*) ZILRETTA is available to a much larger number of patients and in broader populations through our commercialization efforts as compared to the patients in the clinical studies. We do not know whether the results of ZILRETTA's use in such larger number of patients and broader populations will be consistent with the results from our clinical studies.

While the FDA granted approval of ZILRETTA based on the data included in the NDA, including data from our completed pivotal Phase 3 clinical trial, we do not know whether the results that served as the basis for the FDA's approval of ZILRETTA will be consistent with commercial results as a large number of patients and broader populations are exposed to ZILRETTA and are exposed over longer periods of time, including results related to safety and efficacy. New data relating to ZILRETTA, including from adverse event reports or our on-going studies of ZILRETTA related to hip OA or synovitis in knee OA, may result in changes to the product label and may adversely affect sales, or result in withdrawal of ZILRETTA from the market. The FDA and regulatory authorities in other jurisdictions may also consider any new data in connection with further marketing approval applications. If ZILRETTA or any additional approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a Risk Evaluation and Mitigation Strategy;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is promoted or administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from maintaining market acceptance of the affected product and could substantially increase the costs of commercializing ZILRETTA or any additional products.

(*) Recently enacted and future legislation, including health care reform measures, may increase the difficulty and cost for us to commercialize ZILRETTA and any future products and may affect the prices we may obtain.

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell ZILRETTA, and if approved for sale, our other potential products, profitably. Among policy makers and third-party payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been, and may continue to be, significantly affected by major legislative, congressional and enforcement initiatives. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA, was enacted, which was intended to, among other items, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the PPACA provisions of importance to the pharmaceutical industry are the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements under the federal Open Payments program, created under Section 6002 of PPACA, and its implementing regulations that require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made or distributed to physicians and teaching hospitals, and that applicable manufacturers and applicable group purchasing organizations report annually to CMS ownership and investment interests held by physicians and their immediate family members;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for non-compliance;
- an FDA-approval framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Some of the provisions of PPACA have yet to be implemented, and there have been legal and political challenges to certain aspects of PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, signed into law on December 22, 2017, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by PPACA on certain individuals that fail to maintain qualifying health coverage for all of part of a year commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriation for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. The Bipartisan Budget Act of 2018, among other things, amended PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, CMS announced published a final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace PPACA will impact PPACA and our business.

In addition, since the PPACA was enacted, other legislative changes have been proposed and adopted that may impact the extent to which we are able to successfully commercialize any of our product candidates that receive regulatory approval. For example, in August 2011, then-President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on

Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, two percent per fiscal year through 2027 unless Congress takes additional action. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices, including at the federal level several recent U.S. Congressional inquiries and legislation designed to, among other things, increase drug pricing transparency, reduce the cost of drugs under Medicare, review relationships between pricing and manufacturer patient assistance programs, and reform government program drug reimbursement methodologies. Any reduction in reimbursement from Medicare, Medicaid or other government-funded programs may result in a similar reduction in payments from private payers. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed a rule modifying the federal Anti-Kickback Statute discount safe harbor which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize ZILRETTA and any future products for which we receive regulatory approval.

We expect that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, as well as additional downward pressure on the price that we receive for any approved product, including ZILRETTA.

Risks Related to Product Development and Regulatory Compliance

We may never obtain regulatory approval of ZILRETTA for repeat administration or additional indications, approval of our other product candidates in the United States, or we may never obtain approval for or commercialize ZILRETTA or our other product candidates outside of the United States, which would limit our ability to realize their full market potential.

While ZILRETTA has been approved for the management of OA pain of the knee, the approved product label contains a limitation of use, or LOU, stating that ZILRETTA is not intended for repeat administration. On December 17, 2018, we submitted a supplemental new drug application, or sNDA, to the FDA to revise the product label for ZILRETTA. The sNDA is based on data from an open-label Phase 3b clinical trial, which indicated that repeat administration of ZILRETTA for treatment of OA knee pain was safe and well tolerated with no deleterious impact on cartilage or joint structure observed through X-ray analysis. We may not be successful in our efforts to modify or remove the LOU. It is possible that the FDA will disagree with our analysis or will find the data submitted in the sNDA insufficient to approve a label revision. If we are unable to revise or expand the label for ZILRETTA to allow for repeat dosing, our ability to fully market ZILRETTA may be limited.

While ZILRETTA has been approved by the FDA for the treatment of patients with OA of the knee in the United States, it has not been approved in any other jurisdiction for this indication or for any other indication. In order to market ZILRETTA for other indications or in other jurisdictions, or in order to market any of our other product candidates, we must obtain regulatory approval for each indication and in each applicable jurisdiction, and we may never be able to get such approval for ZILRETTA or our other product candidates. In particular, FX201 is at an early stage of development and may never reach IND submission or human clinical trials, in which case we may never recover our investment.

Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our potential future products in those countries. Other than ZILRETTA in the United States, we do not have any products approved for sale in any jurisdiction, and we do not have experience in obtaining regulatory approval in international markets. If we do not receive marketing approval for ZILRETTA for any other indication or from any regulatory agency other than the FDA, we will never be able to commercialize ZILRETTA for any other indication in the United States or for any indication in any other jurisdiction. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals for our other product candidates, or if regulatory approval in international markets is delayed, our potential market will be reduced and our ability to realize the full market potential of ZILRETTA or our other product candidates will be harmed. Even if we do receive additional regulatory approvals, we may not be successful in commercializing those opportunities.

(*) Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials. In particular, the results generated in our completed ZILRETTA pivotal Phase 3 clinical trial do not ensure that any ongoing or future ZILRETTA clinical trial, including our ongoing clinical trials of ZILRETTA in hip OA and synovitis in knee OA, will be successful or consistent with the results generated in the Phase 3 trial.

Product candidates may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In addition to the safety and efficacy trials of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. In any event, our future clinical trials may not be successful.

If ZILRETTA or any other product candidate is found to be unsafe or lack efficacy or feasibility in particular indications, we will not be able to obtain regulatory approval for the indication and our business could be materially harmed.

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

We may experience delays in clinical trials of our products and product candidates. Our clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

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

For example, our ZILRETTA IND was placed on clinical hold at two points during product development, which delayed completion of our trials and resulted in additional expense. We cannot guarantee that any existing or future IND we submit will not be subject to similar holds.

If initiation or completion of our clinical trials are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed, which could have a material adverse effect on our business.

The regulatory approval process of the FDA is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates or for ZILRETTA in additional indications, our business will be harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Although we received regulatory approval of ZILRETTA for the treatment of OA knee pain, it is possible that none of our other product candidates will ever obtain regulatory approval or that we will not be able to obtain regulatory approval for ZILRETTA in additional indications.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market ZILRETTA in additional indications or to market our other product candidates at all, which would harm our business, results of operations and prospects.

In addition, even if we were to obtain approval for other product candidates or for ZILRETTA in other indications, regulatory authorities may approve such product candidates or indications for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

Our product candidates may not receive regulatory approval despite success in clinical trials. Even if we successfully obtain regulatory approval to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies or for labeling supplements and other regulatory requests to be acted upon, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018 and ending on January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical government employees and stop critical activities. If repeated or prolonged government shutdowns occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, and negatively impact other government operations on which we rely, which could have a material adverse effect on our business.

The FDA granted marketing approval of ZILRETTA for the treatment of patients with OA pain of the knee, and we could face liability if a regulatory authority determines that we are promoting ZILRETTA for any off-label uses.

A company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from pharmaceutical companies or their employees, including sales representatives, with respect to off-label uses of products for which marketing clearance has not been issued. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of ZILRETTA and any future products, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. For example, as part of our promotion strategy for ZILRETTA we communicate certain results from our Phase 3 clinical trial and other clinical data that are consistent with, but not directly included in, the product label. While we believe our communication of this data is in accordance with FDA guidance and applicable laws, we cannot be certain that the FDA or other regulatory agencies will agree with our use of this data or our sales force may use such data in a way that is inconsistent with our policies. As a result, we may be subject to criminal and civil liability. In addition, our management's attention could be diverted to handle any such alleged violations. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of HHS, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug, and Cosmetic Act, or the FDCA, the federal False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

Any relationships with healthcare professionals, principal investigators, consultants, actual and potential customers, and third-party payers in connection with our current and future business activities are and will continue to be subject, directly or indirectly, to federal and state healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face criminal sanctions, civil penalties, administrative penalties, imprisonment, exclusion, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight, and curtailment or restructuring of our operations.

Our operations are directly or indirectly subject to various federal and state healthcare laws, including without limitation, fraud and abuse laws, false claims laws, marketing expenditure tracking and disclosure (or "sunshine") laws, government price reporting, and health information privacy and security laws. Our potential exposure under such laws increased significantly with the commercialization of ZILRETTA in the United States through our dedicated sales force. Our costs associated with compliance are also likely to increase. These laws may impact, among other things, our current activities with investigators and research subjects, as well as sales, marketing, promotion, manufacturing, distribution, pricing, discounting, customer incentive programs, physician speaker programs, and other business arrangements and activities. In addition, we may be subject to patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or arranging for the purchase, lease, or order of any good, item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform services involving the use or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, created under Section 6002 of the PPACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members;

- state, local, and foreign law equivalents of each of the above federal laws and regulations, such as anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers and entities, or marketing expenditures; state and local laws requiring the registration of pharmaceutical sales and medical representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA, thus complicating compliance efforts;

- the Foreign Corrupt Practices Act, or FCPA, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- state and federal government price reporting laws that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement, rebates and/or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts); and

- the European Union's General Data Protection Regulation ((EU) 2016/679), or GDPR, which went into effect in May 2018, and which introduces strict requirements for processing personal data of individuals within the EU.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices, including activities undertaken by third parties on our behalf, may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations. Moreover, while we do not bill third-party payers directly and our customers make the ultimate decision on how to submit claims, from time-to-time we may provide reimbursement guidance to patients and healthcare providers. If a government authority were to conclude that we provided improper advice and/or encouraged the submission of a false claim for reimbursement, we could face action against us by government authorities. If any of the physicians or other providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occurs, it could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside of the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

ZILRETTA is still subject to substantial, ongoing regulatory requirements, and our other product candidates may face future development and regulatory difficulties.

The FDA approved ZILRETTA only for the treatment of OA knee pain. If any other ongoing clinical studies of ZILRETTA are negative, the FDA could decide to withdraw approval, add warnings or narrow the approved indication in the product label.

ZILRETTA is, and, if approved, our other product candidates, will also be, subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the NDA. If we or a regulatory agency discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

We rely on third-party collaborators to assist us in meeting our reporting and related obligations. While we work closely with these third parties, we do not control all of their activities. If our third-party collaborators do not meet the relevant commitments, we may fail to meet our applicable regulatory requirements.

If we fail to comply with applicable regulatory requirements for ZILRETTA or for any other approved product candidate, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;

- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

If we fail to develop, acquire or in-license other potential future product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop, acquire or in-license and commercialize a portfolio of potential future product candidates in addition to ZILRETTA. Our primary means of expanding our pipeline of product candidates is to select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current pipeline, or that otherwise fit into our development or strategic plans on terms that are acceptable to us, and/or develop improved formulations and delivery methods for existing FDA-approved products. Developing new formulations or delivery methods of existing or potential future product candidates or identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

Risks Related to Our Reliance on Third Parties

(*) We rely completely on third parties to manufacture our commercial supplies of ZILRETTA and our preclinical and clinical drug supplies for our other product candidates.

If we were to experience an unexpected loss of supply of ZILRETTA or our other product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience disruptions in commercial supply of ZILRETTA or delays, suspensions or terminations of clinical trials or regulatory submissions. We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers or other third-party manufacturers to manufacture our products and product candidates, including Patheon with respect to finished drug supplies of ZILRETTA, must obtain and maintain approval by the FDA. While we work closely with our third-party manufacturers on the manufacturing process for our products and product candidates, including quality audits, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our contract manufacturers or other third-party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both active drug substances and finished drug products. If our contract manufacturers or other third-party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities.

In addition, we have no control over the ability of our contract manufacturers or other third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve, or withdraws approval for, these facilities for the manufacture of our products and product candidates, we may need to find alternative manufacturing facilities, which would significantly impact our ability to commercialize, develop, or obtain or maintain regulatory approval for our products and product candidates.

We are particularly reliant on Patheon with respect to maintaining ZILRETTA manufacturing capacity. These Patheon facilities required approval from the FDA as a condition of regulatory approval for ZILRETTA, as we rely exclusively on Patheon for commercial supplies of ZILRETTA. In addition, because Patheon manufactures ZILRETTA in the United Kingdom, or U.K., it needs to maintain and update its facility license with the applicable U.K. regulatory agencies and any delay or inability to do so would delay or prevent Patheon from being able to produce commercial supplies of ZILRETTA. Furthermore, the manufacturing process for ZILRETTA is unique and involves specialized equipment and proprietary processes, which subjects us to heightened risks that Patheon will experience delays in the manufacturing process.

We also rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce ZILRETTA and our other product candidates for our clinical trials and commercial sales. There are a limited number of suppliers for raw materials that

we use to manufacture our products and product candidates and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials and ZILRETTA for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a contract manufacturer or other third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials for ZILRETTA or for any other approved products, there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our products, including ZILRETTA.

We expect to continue to depend on contract manufacturers or other third-party manufacturers for the foreseeable future. We have entered into long-term commercial supply agreements with our current contract manufacturers in order to maintain adequate supplies to manufacture finished ZILRETTA drug product. We may, however, be unable to enter into such agreements or do so on commercially reasonable terms for potential future product candidates, which could have a material adverse impact upon our business.

We rely on certain sole sources of supply for our products and product candidates and any disruption in the chain of supply may disrupt commercialization of ZILRETTA or cause delay in developing, obtaining approval for, and commercializing our products and product candidates.

Currently, we use the following sole sources of supply for manufacturing ZILRETTA: Farmabios SpA for TA, Evonik Corporation for PLGA, and Patheon for finished microspheres drug product. Because of the unique equipment and process for loading TA onto PLGA microspheres, transferring finished drug product manufacturing activities for ZILRETTA to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching ZILRETTA finished drug suppliers may involve substantial cost and could result in a failure to maintain adequate supplies of ZILRETTA. We expect that for the foreseeable future Patheon will be the only manufacturer qualified as a commercial supplier of ZILRETTA with the FDA. From time to time, commercial batches of ZILRETTA may fail to meet required specifications and be unavailable for commercial sale. If we experience multiple successive batch failures, or if supply from Patheon is otherwise interrupted, there could be a significant disruption in commercial supply. Any alternative vendor would need to be qualified through an NDA supplement, which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new ZILRETTA supplier is relied upon for commercial production.

Our other product candidates, including FX201, also rely on sole sources of supply for the preclinical and clinical supply of materials. The manufacturing processes for FX201 and our other product candidates are complex, and it may difficult or impossible to finalize appropriate processes for the scaled manufacture of the product candidates.

These factors could cause the disruption of the commercialization of ZILRETTA; delay clinical trials, regulatory submissions, required approvals or commercialization of any of our other product or product candidates; cause us to incur higher costs; or prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required clinical or commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue in the event of a product stockout for ZILRETTA or any of our other product candidates that is approved and launched.

Manufacturing issues may arise that could increase product and regulatory approval costs or disrupt or delay commercialization.

As we scale up manufacturing of ZILRETTA and other product candidates, we may encounter product, packaging, equipment and process-related issues that may require refinement or resolution in order to proceed with our planned clinical trials or maintain regulatory approval for commercial marketing. In the future, we may identify impurities or other product related issues, which could result in increased scrutiny by regulatory authorities, suspensions of commercial activities or product recalls, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our products or product candidates.

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely upon and plan to continue to rely upon third-party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Council for Harmonization guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates may be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

(*) We may not be successful in establishing development and commercialization collaborations, which could adversely affect, and potentially prohibit, our ability to fully commercialize ZILRETTA or to develop our product candidates.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we are exploring collaborations with third parties that have more resources and experience. For example, we are exploring selective partnerships with third parties for ZILRETTA's development and commercialization outside of the United States. If we are unable to obtain a partner for ZILRETTA, we may be

unable to advance the development of ZILRETTA in territories outside of the United States, which may limit its market potential. In situations where we enter into a development and commercial collaboration arrangement for a product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such product candidate. If any of our product candidates, in addition to ZILRETTA, receives marketing approval, we may enter into sales and marketing arrangements with third parties with respect to otherwise unlicensed or unaddressed territories outside of the United States. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, or at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell ZILRETTA and any other future approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

We may not be successful in maintaining development and commercialization collaborations, and our partners may not devote sufficient resources to the development or commercialization of our products or product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop or commercialize certain of our products or product candidates and our financial condition and operating results.

Even if we are able to establish collaboration arrangements, any such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. If we partner with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated, and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development of a product or product candidate or research program under collaboration and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain.

We may become subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail. Conflicts may arise between us and partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the division of development or commercialization responsibilities or expenses, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a partner could act in its own self-interest, which may be adverse to our best interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our products or product candidates, and in turn prevent us from generating sufficient revenue to achieve or maintain profitability:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement;
- actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; or
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives and other technically qualified personnel in our industry, particularly in the greater Boston, Massachusetts area where our headquarters is located, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies for individuals with similar skill sets. In addition, failure

to succeed in the commercialization of ZILRETTA or clinical studies of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

(*) We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical trials and the sale of ZILRETTA and any other products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, or others coming into contact with our products or product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and perception of our products in the market;
- withdrawal or suspension of marketing approvals;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates;
- decreased demand for our products approved for commercial sale; and
- reputational harm.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action or mass tort lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If we collaborate with third parties to develop and commercialize products outside of the United States, a variety of risks associated with international operations could materially and adversely affect our business.

If we enter into agreements with third parties to market ZILRETTA, and if approved, our other product candidates, outside of the United States, we expect to be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- different government payer systems, multiple payer-reimbursement regimes or patient self-pay systems, and price controls;
- potential noncompliance with the FCPA, the U.K. Bribery Act 2010, or similar antibribery and anticorruption laws in other jurisdictions as well as various regulations pertaining to data privacy, such as the GDPR;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our commercial and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs, and the development of our product candidates could be delayed.

(*) If we fail to comply with applicable U.S. and foreign privacy and data protection laws and regulation, we may be subject to liabilities that adversely affect our business, operations and financial performance.

We are subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, HIPAA, and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information on covered entities, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of personal health information. In addition to HIPAA, numerous other federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, and storage of personal information.

We may also be subject to or affected by foreign laws and regulation, including regulatory guidance, governing the collection, use, disclosure, security, transfer and storage of personal data, such as information that we collect about employees, patients and healthcare providers in connection with clinical trials and our other operations in the U.S. and abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. For example, the EU has adopted the GDPR, which introduced strict requirements for processing personal data. The GDPR is likely to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and leverage information about them. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to 20 million euros or up to 4% of the annual global revenue. While companies are afforded some flexibility in determining how to comply with the GDPR's various requirements, it has and will continue to require significant effort and expense to ensure continuing compliance with the GDPR. Moreover, the requirements under the GDPR may change periodically or may be modified by European Union, or EU, national law, and could have an effect on our business operations if compliance becomes substantially costlier than under current requirements. It is possible that each of these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Any failure or perceived failure by us to comply with federal, state or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Business interruptions could delay us in the process of developing or commercializing our products and product candidates.

Our headquarters are located in Burlington, Massachusetts. We are vulnerable to natural disasters such as hurricanes, tornadoes and severe storms, as well as other events that could disrupt our operations. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Exposure to U.K. political developments, including the outcome of the referendum on membership in the European Union, could impact our suppliers and harm our business.

The U.K.'s referendum to leave the EU, or "Brexit," has caused and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the U.K.'s relationship with the EU. During this period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. The tax consequences of the U.K.'s withdrawal from the EU are uncertain as well. Brexit may also have a detrimental effect on our suppliers, which could, in turn, adversely affect our revenues and financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection, confidentiality agreements and proprietary know how, and intend to seek marketing exclusivity for any approved product, including ZILRETTA, in order to protect the intellectual property related to our products and product candidates, and to date we have three issued patents covering ZILRETTA in the United States.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights and our current or future licensors' or collaborators' patent rights are highly uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our products or product candidates in the United States, including through the inter-partes review process, or in other foreign countries. Even for our issued patents and if other patents do successfully issue, third parties may challenge their inventorship, ownership, validity, enforceability or scope in the courts or patent offices in the United States and abroad. This may result in such patents being narrowed or invalidated, which could limit our ability to stop others from using or commercializing similar or identical technologies or products, or limit the duration of the patent protection for our technologies and products. If this were to occur, early generic competition could be expected against ZILRETTA and potentially reduce the value of our product candidates in development. Also, a third party may challenge our rights to patents and patent applications that we license from third parties. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims.

If our patent applications with respect to ZILRETTA or our other product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop ZILRETTA or our other product candidates and threaten our ability to commercialize any resulting products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will not be found invalid and unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals for additional indications or in additional jurisdictions, the period of time during which we could market ZILRETTA or any product candidate under patent protection could be reduced. See "Business—Patents and Patent Applications" in our Annual Report on Form 10-K for additional information regarding our material patents and patent applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development process that involve proprietary know-how, information or technology that is not covered by patents. For example, we maintain trade secrets with respect to certain of the formulation and manufacturing techniques related to the TA-formulated PLGA microspheres in ZILRETTA, including those that relate to precise pharmaceutical release. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the U.S. Patent and Trademark Office, or U.S. PTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are commercializing or developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of ZILRETTA and/or our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any drug substance formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtain a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our products or product candidates, which could harm our business significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents, licensed patents or our other intellectual property. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. Accordingly, for such undetectable infringement or misappropriation our ability to recover damages will be negligible, and we could be at a market disadvantage because we may lack the resources of some of our competitors to monitor for and detect infringement. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in any patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in litigation proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from infringing on our intellectual property rights in all countries outside the United States, and competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Our owned or licensed patents directed to our product candidates may expire or have limited commercial life before the product candidate is approved for marketing in a relevant jurisdiction.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after our product candidates obtain regulatory approval, which may subject us to increased competition and reduce or eliminate our ability to recover our development costs. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Although we may be able to seek extensions of patent terms where available, including in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent, we cannot be certain that an extension will be granted, or if granted, what the applicable time period or the scope of patent protection afforded during any extended period will be. The applicable authorities, including the EMA, FDA, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We have in-licensed or acquired a portion of our intellectual property necessary to develop our product candidates, and if we fail to comply with our obligations under any of these arrangements, we could lose such intellectual property rights.

We are a party to and rely on several arrangements with third parties, which give us rights to intellectual property that is necessary for the manufacture of ZILRETTA and the development of FX201. In addition, we may enter into similar arrangements in the future. Our current arrangements impose various development, royalty and other obligations on us. If we materially breach these obligations or if our counterparts fail to adequately perform their respective obligations, these exclusive arrangements could be terminated, which would result in our inability to develop, manufacture and sell products that are covered by such intellectual property.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, you may not be able to resell your shares at a desired market price and you could lose all or part of your investment.

The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- the success or perceived success of the commercialization of ZILRETTA;
- failure to successfully develop and commercialize additional product candidates;
- changes in the structure of healthcare payment systems;
- adverse results or delays in clinical trials;
- inability to obtain additional funding;
- changes in laws or regulations applicable to our products or product candidates;
- inability to obtain adequate product supply for our products or product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent, product liability or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

The trading price of our common stock may also be dependent upon the valuations and recommendations of the analysts who cover our company. If our results do not meet these analysts' forecasts, the expectations of our investors or any financial guidance or expectations we provide to investors in any period, the market price of our common stock could decline. Our ability to meet analysts' forecasts (including revenue and profitability), investors' expectations and our own guidance or financial expectations is substantially dependent on our ability to increase sales of ZILRETTA and to successfully commercialize ZILRETTA in the United States. Because we are in the early stages of the ZILRETTA launch, we and the analysts who cover our company have limited ability to accurately predict future sales results, and actual results may differ materially from our expectations or those of such analysts.

In addition, the stock market in general, and the Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies like ours. Broad market and industry factors may continue to negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

As of December 31, 2018, our executive officers, directors and stockholders affiliated with our officers and directors beneficially owned approximately 15.4% of our voting stock. Therefore, these stockholders may have the ability to influence us through this ownership position. These stockholders may be able to determine or significantly influence all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control or significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We will continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

We completed our initial public offering on February 18, 2014. As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which require, among other things, that we file with the SEC annually, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation and filing of these reports. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and the Nasdaq Global Market have imposed various other requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity and/or convertible debt securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We may need significant additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities; our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2013 equity incentive plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2013 plan will automatically increase each year by 4% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2013 plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382, contains rules that limit the ability of a company that undergoes an ownership change to utilize its net operating losses, or NOLs, and tax credits existing as of the date of such ownership change. Under the rules, such an ownership change is generally any change in ownership of more than 50% of a company's stock within a rolling three-year period. The rules generally operate by focusing on changes in ownership among stockholders considered by the rules as owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from new issuances of stock by the company. We have experienced multiple ownership changes since our inception, however, based on the annual limitations calculated at each ownership change date, we expect that substantially all net operating loss carryforwards will be available to offset future taxable income. Approximately $0.3 million of NOLs are expected to expire unused. Future ownership changes as defined by Section 382 may further limit the amount of NOL carryforwards that could be utilized annually to offset future taxable income.

Under the newly enacted federal income tax law, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited and could be subject to future limitations under Section 382.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Additionally, our credit and security agreement with MidCap and Silicon Valley Bank contains covenants that restrict our ability to pay dividends. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder of such corporation for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

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

Recent sales of Unregistered Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit number	Description of document
3.1	Amended and Restated Certificate of Incorporation of Flexion (Exhibit 3.1, Current Report on Form 8-K, filed with the SEC on February 19, 2014).
3.2	Amended and Restated Bylaws of Flexion (Exhibit 3.2, Current Report on Form 8-K, filed with the SEC on February 19, 2014).
4.1	Form of Common Stock Certificate of Flexion (Exhibit 4.1, Registration Statement on Form S-1 (File No. 333-193233), as amended, filed with the SEC on January 29, 2014).
4.2	Indenture, dated May 2, 2017, by and between Flexion and Wells Fargo Bank, National Association, as trustee (Exhibit 4.1, Current Report on Form 8-K filed with the SEC on May 2, 2017).
4.3	Form of Note representing Flexion's 3.375% Convertible Senior Notes due 2024 (included as Exhibit A to the Indenture filed as Exhibit 4.1, Current Report on Form 8-K filed with the SEC on May 2, 2017).
4.4	Consent and Second Amendment to Credit and Security Agreement, dated April 24, 2017, between Flexion and MidCap Financial Trust, as administrative agent (Exhibit 4.3, Current Report on Form 8-K filed with the SEC on May 2, 2017).
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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

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 8, 2019

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

Date: May 8, 2019

By: /s/ David Arkowitz
David Arkowitz
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 31.1

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

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

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

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

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

4. 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 8, 2019

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

Exhibit 31.2

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

I, David A. Arkowitz., 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 8, 2019

/s/ David A. Arkowitz
David A. Arkowitz
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

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

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

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

Date: May 8, 2019

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

Date: May 8, 2019

/s/ David A. Arkowitz
David A. Arkowitz
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.