

SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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

FORM 10-Q

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED September 30, 2021**

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
(State or Other Jurisdiction of
Incorporation or Organization)

10 Mall Road, Suite 301
Burlington, Massachusetts
(Address of Principal Executive Offices)

26-1388364
(I.R.S. Employer
Identification No.)

01803
(Zip Code)

(781) 305-7777

(Registrant's Telephone Number, Including Area Code)

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 Global Market

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
Non-accelerated filer
Emerging growth company

Accelerated filer
Smaller reporting 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

As of November 1, 2021, the registrant had 50,321,366 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 and per share amounts)

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 136,824	\$ 107,704
Marketable securities	5,229	67,576
Accounts receivable, net	29,375	30,025
Inventories	14,669	15,394
Prepaid expenses and other current assets	6,659	5,112
Total current assets	192,756	225,811
Property and equipment, net	19,480	19,538
Right-of-use assets	5,695	6,577
Total assets	<u>\$ 217,931</u>	<u>\$ 251,926</u>
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	\$ 7,492	\$ 6,928
Accrued expenses and other current liabilities	24,875	20,008
Deferred revenue	10,000	10,000
Operating lease liabilities	1,619	1,526
Current portion of long-term debt	—	16,806
Total current liabilities	43,986	55,268
Long-term operating lease liability, net	5,328	6,123
Long-term debt, net	80,087	44,114
2024 convertible notes, net	170,418	162,786
Other long-term liabilities	489	295
Total liabilities	300,308	268,586
Commitments and contingencies		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2021 and December 31, 2020 and 0 shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Stockholders' deficit		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 50,299,458 and 49,403,034 shares issued and outstanding, at September 30, 2021 and December 31, 2020, respectively	50	49
Additional paid-in capital	780,954	765,607
Accumulated other comprehensive loss	—	(11)
Accumulated deficit	(863,381)	(782,305)
Total stockholders' deficit	(82,377)	(16,660)
Total liabilities and stockholders' deficit	<u>\$ 217,931</u>	<u>\$ 251,926</u>

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues				
Product revenue, net	\$ 21,326	\$ 23,664	\$ 74,090	\$ 59,242
Operating expenses				
Cost of sales	3,727	5,130	14,791	12,887
Research and development	14,771	10,092	41,487	43,733
Selling, general and administrative	26,986	27,312	81,993	81,341
Total operating expenses	45,484	42,534	138,271	137,961
Loss from operations	(24,158)	(18,870)	(64,181)	(78,719)
Other (expense) income				
Interest income	54	62	531	584
Interest expense	(5,787)	(5,125)	(16,156)	(14,848)
Other expense	(421)	(457)	(1,270)	(581)
Total other (expense) income	(6,154)	(5,520)	(16,895)	(14,845)
Loss before income taxes	(30,312)	(24,390)	(81,076)	(93,564)
Income tax expense	—	248	—	495
Net loss	\$ (30,312)	\$ (24,638)	\$ (81,076)	\$ (94,059)
Net loss per common share, basic and diluted	\$ (0.60)	\$ (0.50)	\$ (1.62)	\$ (2.16)
Weighted average common shares outstanding, basic and diluted	50,265	49,298	50,027	43,563
Other comprehensive income (loss):				
Unrealized gains (losses) from available-for-sale securities, net of tax of \$0	2	(9)	11	(68)
Total other comprehensive income (loss)	2	(9)	11	(68)
Comprehensive loss	\$ (30,310)	\$ (24,647)	\$ (81,065)	\$ (94,127)

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

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

	Common Stock		Additional Paid-in- Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Value				
Balance at December 31, 2020	49,403	\$ 49	\$ 765,607	\$ (11)	\$ (782,305)	\$ (16,660)
Issuance of common stock, net of issuance costs	134		1,700			1,700
Issuance of common stock for equity awards, net of shares withheld for taxes	405	1	7			8
Stock-based compensation expense			4,640			4,640
Net loss					(28,556)	(28,556)
Other comprehensive income				1		1
Balance at March 31, 2021	49,942	\$ 50	\$ 771,954	\$ (10)	\$ (810,861)	\$ (38,867)
Issuance of common stock for equity awards, net of shares withheld for taxes	46		—			—
Employee stock purchase plan	118		921			921
Stock-based compensation expense			3,975			3,975
Net loss					(22,208)	(22,208)
Other comprehensive income				8		8
Balance at June 30, 2021	50,106	\$ 50	\$ 776,850	\$ (2)	\$ (833,069)	\$ (56,171)
Issuance of common stock for equity awards, net of shares withheld for taxes	193		(92)			(92)
Stock-based compensation expense			4,196			4,196
Net loss					(30,312)	(30,312)
Other comprehensive income				2		2
Balance at September 30, 2021	50,299	\$ 50	\$ 780,954	\$ —	\$ (863,381)	\$ (82,377)

	Common Stock		Additional Paid-in- Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Par Value				
Balance at December 31, 2019	38,361	\$ 38	\$ 648,391	\$ 62	\$ (668,599)	\$ (20,108)
Issuance of common stock for equity awards, net of shares withheld for taxes	201	1	8			9
Stock-based compensation expense			4,651			4,651
Net loss					(36,802)	(36,802)
Other comprehensive loss				(56)		(56)
Balance at March 31, 2020	38,562	\$ 39	\$ 653,050	\$ 6	\$ (705,401)	\$ (52,306)
Issuance of common stock, net of issuance costs	10,615	\$ 10	\$ 96,754			96,764
Issuance of common stock for equity awards, net of shares withheld for taxes	11	—	1			1
Employee stock purchase plan	82		891			891
Stock-based compensation expense			3,787			3,787
Net loss					(32,619)	(32,619)
Other comprehensive loss				(3)		(3)
Balance at June 30, 2020	49,270	\$ 49	\$ 754,483	\$ 3	\$ (738,020)	\$ 16,515
Issuance of common stock for equity awards, net of shares withheld for taxes	36		78			78
Stock-based compensation expense			4,959			4,959
Net loss					(24,638)	(24,638)
Other comprehensive loss				(9)		(9)
Balance at September 30, 2020	49,306	\$ 49	\$ 759,520	\$ (6)	\$ (762,658)	\$ (3,095)

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

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities		
Net loss	\$ (81,076)	\$ (94,059)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation	1,573	1,295
Amortization of right-of-use assets	1,315	1,224
Stock-based compensation expense	12,811	13,397
Provision for inventory	1,773	—
Non cash interest expense	540	518
Amortization (accretion) of premium (discount) on marketable securities	441	(18)
Loss on disposal of fixed assets	—	262
Loss on debt extinguishment	502	—
Amortization of debt discount and debt issuance costs	7,842	6,947
Premium paid on securities purchased	(54)	(534)
Changes in operating assets and liabilities:		
Accounts receivable	650	9,216
Inventory	(1,048)	(1,063)
Prepaid expenses and other current assets	(1,547)	(496)
Accounts payable	980	(6,693)
Accrued expenses and other current liabilities	4,992	216
Deferred revenue	—	10,000
Lease liabilities	(1,135)	(1,031)
Net cash used in operating activities	(51,441)	(60,819)
Cash flows from investing activities		
Purchases of property and equipment	(1,737)	(8,860)
Proceeds from sale of fixed assets	—	13
Purchases of marketable securities	(5,175)	(56,216)
Sale and redemption of marketable securities	67,146	54,398
Net cash provided by (used in) investing activities	60,234	(10,665)
Cash flows from financing activities		
Proceeds from borrowings under term loan	55,000	15,000
Payments on notes payable	(56,875)	—
Proceeds from revolving line of credit	20,000	20,000
Repayments of revolving line of credit	—	(15,000)
Proceeds from the offering of common stock	—	97,289
Proceeds from issuance of common stock (net of issuance costs)	1,700	—
Payments of public offering costs	(125)	(400)
Payment of debt issuance costs	(210)	—
Proceeds from the exercise of stock options (net of shares withheld for taxes)	(84)	88
Proceeds from employee stock purchase plan	921	891
Net cash provided by financing activities	20,327	117,868
Net increase in cash and cash equivalents	29,120	46,384
Cash and cash equivalents at beginning of period	107,704	82,253
Cash and cash equivalents at end of period	\$ 136,824	\$ 128,637
Non-cash operating, investing and financing activities		
Right-of-use asset obtained in exchange for operating lease obligation	433	—
Purchases of property and equipment in accounts payable and accrued expenses	15	870

Public offering costs in accounts payable and accrued expenses	—	125
Supplemental disclosures of cash flow information		
Cash paid for interest	6,483	6,042

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

Flexion Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Overview and Nature of the Business

Flexion Therapeutics, Inc. (“Flexion” 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, the most common form of 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 two pipeline programs focused on the local treatment of musculoskeletal conditions: FX201, an investigational IA gene therapy product candidate in clinical development for the treatment of OA, and FX301, a locally administered peripheral nerve block product candidate in clinical development for the control of post-operative 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 will 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 as to when, if ever, the Company will generate sales of ZILRETTA that are significant enough to achieve profitability or if the development efforts supporting the Company’s pipeline, including future clinical trials, will be successful.

Proposed Acquisition by Pacira BioSciences, Inc.

On October 11, 2021, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Pacira BioSciences, Inc., a Delaware corporation (“Pacira”), and Oyster Acquisition Company Inc., a Delaware corporation and wholly owned subsidiary of Pacira (“Purchaser”). Pursuant to the Merger Agreement, on October 22, 2021, Purchaser commenced a tender offer (the “Offer”) to purchase each issued and outstanding share of the Company’s common stock (the “Shares”) at an offer price of (i) \$8.50 per Share in cash, net of applicable withholding taxes and without interest, plus (ii) one non-transferable contractual contingent value right per Share, which will represent the right to receive one or more contingent payments up to \$8.00 in the aggregate, in cash, net of applicable withholding taxes and without interest, upon the achievement of specified milestones on or prior to December 31, 2030.

Promptly following the completion of the Offer, upon the terms and subject to the conditions of the Merger Agreement, Purchaser will merge with and into the Company (the “Merger”), with the Company continuing as the surviving corporation and as a wholly owned subsidiary of Pacira. The Merger Agreement contemplates that the Merger will be effected pursuant to Section 251(h) of the Delaware General Corporation Law, which permits completion of the Merger without a vote of the holders of common stock upon the acquisition by Purchaser of a majority of the aggregate voting power of common stock. As a result of the Merger, the Company will cease to be a publicly traded company.

The Merger Agreement contains customary representations and warranties. The Merger is expected to close before the end of the calendar year 2021, subject to the satisfaction or waiver of customary closing conditions, including, among others, that the number of Shares tendered in the Offer represent at least one Share more than 50% of the total number of Shares at the time of the expiration of the Offer. The Merger Agreement provides Pacira and the Company with certain termination rights and, under certain circumstances, may require the Company to pay Pacira a termination fee of \$18.0 million.

For additional information related to the Merger Agreement, refer to the Solicitation/Recommendation Statement on Schedule 14D-9 filed by the Company with the Securities and Exchange Commission on October 22, 2021, together with the exhibits and annexes thereto and as amended or supplemented from time to time.

The Company recorded acquisition-related costs of approximately \$0.7 million for each of the three and nine months ended September 30, 2021, primarily for outside legal and external financial advisory fees associated with the pending acquisition by Pacira. These costs were recorded in general and administrative expense in the Company’s condensed consolidated statements of operations and comprehensive loss in the respective reporting periods. Additional acquisition-related costs are expected to be incurred through the closing of the Merger.

Going Concern

The accompanying condensed consolidated financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the realization of assets and satisfaction of liabilities and commitments in the

normal course of business. The Company has incurred recurring losses and negative cash flows from operations. As of September 30, 2021, the Company had cash, cash equivalents, and marketable securities of approximately \$142.1 million.

The Company's operations have been and continue to be affected by the ongoing global pandemic of a novel strain of coronavirus ("COVID-19"). In March 2020, the World Health Organization declared COVID-19 a pandemic and recommended containment and mitigation measures worldwide. The COVID-19 pandemic has caused significant volatility and uncertainty, which could result in a prolonged economic downturn that has disrupted and is expected to continue to disrupt the Company's business. While there have been no material asset impairments recorded to date, any prolonged material future disruptions to the work of the Company's employees, suppliers, contract manufacturers, or vendors, or to the operations of physicians that administer ZILRETTA could negatively impact the Company's operations, availability of supplies, carrying value of assets, operating results, or cash flows.

The future viability of the Company is dependent on its ability to fund its operations through sales of ZILRETTA, and/or raising additional capital, such as through debt or equity offerings, as needed. The Company may not be able to obtain financing on acceptable terms, or at all. In particular, as a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility and disruptions, including declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any additional debt or equity financing more difficult, more costly, and more dilutive. 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/or reduce the scope of, or delay certain research and development activities, including the FX201 or FX301 programs, which could adversely affect its prospects.

In accordance with the amended and restated credit and security agreement described in Note 9, if the Company's liquidity decreases below \$100.0 million, the Company will need to comply with a minimum revenue covenant and all amounts received from customer collections will be applied to immediately reduce the Company's revolving credit facility. The minimum revenue covenant is set annually and is applied to the trailing six-months of net revenue and is determined based on the Company's approved forecast, as determined by the Lenders. The amended and restated credit and security agreement also has a material adverse event clause. If the minimum revenue covenant becomes applicable and the Company fails to comply with it, or a material adverse change as defined in the agreement occurs, the amounts due under the amended and restated credit and security agreement could be declared immediately due and payable, resulting in the Company immediately needing additional funds. As of September 30, 2021, the Company was in compliance with all financial covenants under the amended and restated credit and security agreement.

If the Company is unable to grow sales of ZILRETTA in future periods, it is possible that the Company may not maintain compliance with the revenue covenant, in the event it applies, in future periods, which would require the Company to repay its outstanding borrowings under the term loan and revolving credit facility. Given the recent decrease in revenue as compared to the Company's expectations, the Company expects that absent raising additional capital through financing or other transactions its cash balance is likely to decrease below \$100.0 million within the next twelve months, and the Company believes there is substantial risk that it would fail to meet the minimum revenue covenant at that time or shortly thereafter if demand for ZILRETTA does not increase in line with its expectations. If the Company is or expects to be subject to and unable to meet the minimum revenue covenant, the Company would plan to request a waiver from the lenders, although there can be no assurances that such a request would be granted or would not be conditioned on additional terms or concessions. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of one year after the date that the financial statements are issued.

Management's plans that would be intended to mitigate the conditions that raise substantial doubt about the Company's ability to continue as a going concern include reducing operating expenses through hiring and travel freezes, delaying, reducing, or ceasing all research and development activities outside of the ongoing clinical trials, reduction of certain external expenses, and elimination of non-essential operating expenses, requesting a waiver of the minimum revenue covenant from the lenders, and remaining opportunistic with respect to raising additional capital through financing or other transactions. However, as the Company is expecting to close the planned merger with Pacira prior to the end of 2021, none of the above actions have been taken or have been approved to be taken and therefore cannot be considered in management's going concern evaluation as a mitigating action.

The Company has concluded that without taking into consideration the planned Merger with Pacira, management's plans do not alleviate the substantial doubt about the Company's ability to continue as a going concern. As the planned Merger with Pacira has not occurred as of the issuance of these financial statements, it also cannot be considered within management's plans to alleviate the conditions raised around substantial doubt. As a result, in accordance with the requirements of ASC 205-40, management has concluded that it is required to disclose that substantial doubt exists about the Company's ability to continue as a going concern for one year from the date these financial statements are issued.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of September 30, 2021, and for the three and nine months ended September 30, 2021 and 2020, 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 that are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the SEC on March 10, 2021.

The information presented in the condensed consolidated financial statements and related notes as of September 30, 2021, and December 31, 2020, and for the three and nine months ended September 30, 2021 and 2020, is unaudited. The December 31, 2020, 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 and nine months ended September 30, 2021, are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2021, or any future period.

Recent Accounting Pronouncements

Accounting Standards Recently Issued

In August 2020, the FASB issued ASU No. 2020-06, ("ASU 2020-06"). The new standard simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. The new guidance reduced the number of accounting models for convertible debt and convertible preferred stock instruments and made certain disclosure amendments intended to improve the information provided to users. The guidance also amended the derivative guidance for the "own stock" scope exception, which exempts qualifying instruments from being accounted for as derivatives if certain criteria are met. Finally, the standard changed the way certain convertible instruments are treated when calculating earnings per share. The standard is effective for the Company for fiscal years, and the interim periods within those years, beginning after December 15, 2021, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2020-06 on the Company's condensed consolidated financial statements.

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 and nine months ended September 30, 2021, and the year ended December 31, 2020.

Revenue Recognition

On October 6, 2017, the U.S. Food and Drug Administration ("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 that 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.

Product Revenue, Net

The Company primarily sells ZILRETTA to specialty distributors and a specialty pharmacy, who then subsequently resell ZILRETTA to physicians, clinics, and certain medical centers or hospitals. The Company also contracts directly with healthcare providers and intermediaries such as Group Purchasing Organizations ("GPOs"). In addition, 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 that 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 that 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.

Service Fees and Allowances

The Company compensates its customers and GPOs 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 September 30, 2021, 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. Historically, the Company has received an immaterial amount of returns. In the third quarter of 2021, there was a significant increase in actual and expected product returns from specialty distributors of product that was never sold through to healthcare providers. This is due to the fact that the majority of product sold during the third quarter had between 3-4 months of expiry remaining. The vast majority of the returns related to product that was sold to the specialty distributors during the third quarter of 2021 and resulted in a \$2.0 million reduction of revenue in the third quarter of 2021. In addition, the Company increased its estimate of future returns relating to short-dated product, which resulted in an additional \$1.4 million reduction in revenue in the third quarter of 2021.

Chargebacks

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 U.S. 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 that 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 that remains in the distribution channel inventories at the end of each reporting period.

Purchaser/Provider Discounts and Rebates

The Company offers rebates to eligible purchasers and healthcare providers that are variable based on volume of product purchased. Rebates are based on actual purchase levels during the rebate purchase period. In the third quarter of 2021, the Company implemented an off-invoice discount ("OID") program whereby providers receive the discounted price immediately upon purchase, rather than having to wait until the end of the quarter for a rebate payment. Specialty distributors and other customers charge the Company for the difference between what they pay for the product (list price) and the net selling price after taking into account the OID. Chargeback amounts are generally determined at the time of resale to the eligible 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 commercial chargebacks consist of credits that the Company expects to issue for units sold to qualified healthcare providers but for which no chargeback has been submitted, and chargebacks that customers have claimed, but for which the Company has not yet issued a credit. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Other Incentives

Other incentives that 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 that 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 nine months ended September 30, 2021 and 2020:

<i>(In thousands)</i>	Service Fees, Allowances and Chargebacks	Government Rebates and Other Incentives	Product Returns	Purchaser/ Provider Discounts and Rebates	Total
Balance as of December 31, 2020	\$ 1,733	\$ 530	\$ 628	\$ 1,832	\$ 4,723
Provision related to sales in the current quarter	2,188	383	151	2,703	5,425
Credits and payments made	(1,969)	(266)	(9)	(1,832)	(4,076)
Adjustments related to prior period sales	—	—	(111)	—	(111)
Balance as of March 31, 2021	1,952	647	659	2,703	5,961
Provision related to sales in the current quarter	2,682	424	179	3,100	6,385
Credits and payments made	(2,527)	(311)	(86)	(2,711)	(5,635)
Adjustments related to prior period sales	(10)	—	—	—	(10)
Balance as of June 30, 2021	<u>\$ 2,097</u>	<u>\$ 760</u>	<u>\$ 752</u>	<u>\$ 3,092</u>	<u>\$ 6,701</u>
Provision related to sales in the current quarter	2,538	290	3,130	3,245	9,203
Credits and payments made	(2,859)	(401)	(1,331)	(5,182)	(9,773)
Adjustments related to prior period sales	—	—	291	—	291
Balance as of September 30, 2021	<u>\$ 1,776</u>	<u>\$ 649</u>	<u>\$ 2,842</u>	<u>\$ 1,155</u>	<u>\$ 6,422</u>
Balance as of December 31, 2019	\$ 1,847	\$ 248	\$ 402	\$ 1,656	\$ 4,153
Provision related to sales in the current quarter	1,590	254	114	526	2,484
Credits and payments made	(1,852)	(199)	(10)	(1,656)	(3,717)
Adjustments related to prior period sales	—	95	—	—	95
Balance as of March 31, 2020	1,585	398	506	526	3,015
Provision related to sales in the current quarter	1,417	133	98	892	2,540
Credits and payments made	(1,172)	(262)	(1)	(528)	(1,963)
Adjustments related to prior period sales	—	90	—	2	92
Balance as of June 30, 2020	<u>\$ 1,830</u>	<u>\$ 359</u>	<u>\$ 603</u>	<u>\$ 892</u>	<u>\$ 3,684</u>
Provision related to sales in the current quarter	2,270	265	136	1,314	3,985
Credits and payments made	(2,585)	(198)	(21)	(894)	(3,698)
Adjustments related to prior period sales	—	40	—	2	42
Balance as of September 30, 2020	<u>\$ 1,515</u>	<u>\$ 466</u>	<u>\$ 718</u>	<u>\$ 1,314</u>	<u>\$ 4,013</u>

License Agreement – On March 30, 2020, the Company entered into an exclusive license agreement with Hong Kong Tainuo Pharma Ltd. (“HK Tainuo”) and Jiangsu Tainuo Pharmaceutical Co. Ltd. (“Jiangsu Tainuo”), a subsidiary of China Shijiazhuang Pharmaceutical Co, Ltd., for the development and commercialization (other than manufacturing) of ZILRETTA in Greater China (consisting of mainland China, Hong Kong and Macau, and Taiwan). Under the terms of the agreement, HK Tainuo paid the Company an upfront payment of \$10.0 million, of which \$5.0 million was received as of June 30, 2020, and the remaining \$5.0 million was received as of September 30, 2020. The Company is also eligible to receive up to \$32.5 million in aggregate development, regulatory, and commercial sales milestone payments. All payments received from HK Tainuo are subject to applicable Hong Kong withholding taxes. HK Tainuo is responsible for the clinical development, product registration, and commercialization of ZILRETTA in Greater China, and Jiangsu Tainuo serves as the guarantor of HK Tainuo’s obligations and responsibilities under the agreement. The Company is solely responsible for the manufacture and supply of ZILRETTA to HK Tainuo for all clinical and commercial activities. The terms related to product manufacturing and supply, including pricing and minimum purchase requirements agreed to in the license agreement, will be covered by a separate supply agreement, which has not yet been finalized. All amounts owed to the Company are nonrefundable and non-creditable once paid. Unless terminated earlier in accordance with its terms, the license agreement continues in effect in perpetuity or as long as HK Tainuo or Jiangsu Tainuo continue to sell ZILRETTA in Greater China. Either party may terminate the agreement prior to expiration in the event of a material breach if not cured within 60 days from the date of notice of such breach (30 days in the case of payment obligations), or either party files for bankruptcy. The Company also has the right to terminate the agreement if HK Tainuo, Jiangsu Tainuo, or any affiliate of each commences any action or proceeding that challenges the validity, enforceability, or scope of any Company patent in Greater China. Upon any such termination, the license granted to HK Tainuo will

terminate and all know-how and patents will revert back to the Company. The Company concluded that the license and supply obligations were not distinct performance obligations, and therefore the transaction price will be recognized as revenue as the

Company's supply obligation is fulfilled over the term of the supply agreement, which has not yet commenced. No revenue was recognized associated with this contract as of September 30, 2021. The proceeds associated with the upfront payment have been recorded in short-term deferred revenue on the Company's condensed consolidated balance sheet as of September 30, 2021, as there is uncertainty around the timing of when the revenue will be recognized. The Company will re-evaluate the classification of deferred revenue when the supply agreement is finalized.

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 recognition and accrued expenses related to preclinical and clinical development 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.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations, and financial condition, including sales, expenses, reserves and allowances, clinical trials, research and development expenses, and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national, and international customers and markets. The Company has made estimates of the impact of COVID-19 within its financial statements, and there may be changes to those estimates in future periods.

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 convertible senior notes and term loan described below) 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 September 30, 2021 and December 31, 2020, and indicate the level of the fair value hierarchy utilized to determine such fair value:

<i>(In thousands)</i>	Fair Value Measurements as of September 30, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 108,686	\$ —	\$ —	\$ 108,686
Marketable securities	—	5,229	—	5,229
	<u>\$ 108,686</u>	<u>\$ 5,229</u>	<u>\$ —</u>	<u>\$ 113,915</u>

<i>(In thousands)</i>	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 79,148	\$ 6,832	\$ —	\$ 85,980
Marketable securities	—	67,576	—	67,576
	<u>\$ 79,148</u>	<u>\$ 74,408</u>	<u>\$ —</u>	<u>\$ 153,556</u>

As of September 30, 2021 and December 31, 2020, the Company's cash equivalents that are invested in money market funds are valued using Level 1 inputs based on quoted prices for identical securities in active markets. The Company's marketable securities are valued using Level 2 inputs and primarily rely 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 2021 credit facility with Silicon Valley Bank as agent, MidCap Financial Trust, and MidCap Funding XIII Trust (the "2021 term loan"), as well as a revolving credit facility. The amount outstanding on the 2021 term loan is reported at its carrying value in the accompanying balance sheet as of September 30, 2021. The Company determined the fair value of the 2021 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 2021 term loan was valued using Level 2 inputs as of September 30, 2021. The result of the calculation yielded a fair value that approximates its carrying value. The Company also concluded that the carrying value of the revolving credit facility approximates fair value because of the short-term maturity of this debt instrument.

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 \$179.8 million at September 30, 2021.

4. Marketable Securities

As of September 30, 2021 and December 31, 2020, the fair value of available-for-sale marketable securities by type of security was as follows:

(In thousands)	September 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 2,000	\$ —	\$ —	\$ 2,000
Corporate bonds	3,229	—	—	3,229
	<u>\$ 5,229</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,229</u>

(In thousands)	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 6,890	\$ —	\$ —	\$ 6,890
U.S. government obligations	9,997	1	—	9,998
Corporate bonds	50,700	2	(14)	50,688
	<u>\$ 67,587</u>	<u>\$ 3</u>	<u>\$ (14)</u>	<u>\$ 67,576</u>

As of September 30, 2021 and December 31, 2020, marketable securities consisted of \$5.2 million and \$67.6 million, respectively, of investments that mature within 12 months. There were no investments with maturities greater than 12 months as of September 30, 2021, and December 31, 2020. The Company assesses its available-for-sale marketable securities for impairment on a quarterly basis in accordance with ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. There were no material impairments of the Company's available-for-sale marketable securities measured and carried at fair value during the three and nine months ended September 30, 2021.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of September 30, 2021, and December 31, 2020:

(In thousands)	September 30, 2021	December 31, 2020
Prepaid expenses	\$ 6,065	\$ 4,346
Deposits	175	112
Interest receivable on marketable securities	18	246
Other	401	408
Total prepaid expenses and other current assets	<u>\$ 6,659</u>	<u>\$ 5,112</u>

6. Inventory

Inventory consisted of the following as of September 30, 2021, and December 31, 2020:

(In thousands)	September 30, 2021	December 31, 2020
Raw materials	\$ 2,831	\$ 4,287
Work in process	6,305	4,666
Finished goods	5,533	6,441
Total inventories	<u>\$ 14,669</u>	<u>\$ 15,394</u>

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. During the nine months ended September 30, 2021, the Company expensed \$5.2 million to cost of sales for unabsorbed manufacturing and overhead costs related to the operation of the United Kingdom facility at Patheon UK Limited. In addition, cost of sales for the three and nine months ended September 30, 2021, included charges of \$1.2 million and \$1.8 million, respectively, resulting from the write-down of short-dated ZILRETTA inventory that will not be sold prior to expiry.

7. Property and Equipment, Net

Property and equipment, net, as of September 30, 2021, and December 31, 2020, consisted of the following:

<i>(In thousands)</i>	September 30, 2021	December 31, 2020
Computer and office equipment	\$ 1,215	\$ 1,203
Manufacturing equipment	12,656	12,297
Furniture and fixtures	609	609
Software	555	495
Leasehold improvements	1,177	1,157
Construction in progress	14,988	13,924
	<u>31,200</u>	<u>29,685</u>
Less: Accumulated depreciation	(11,720)	(10,147)
Total property and equipment, net	<u>\$ 19,480</u>	<u>\$ 19,538</u>

Depreciation for the three and nine months ended September 30, 2021, was approximately \$0.5 million and \$1.6 million, respectively, compared to \$0.5 and \$1.3 million, respectively, for the same periods in the prior year. No property and equipment was disposed of during the nine months ended September 30, 2021. The Company disposed of one piece of equipment during the nine months ended September 30, 2020, and recorded a loss on the disposal of \$0.3 million. As of September 30, 2021, construction in progress consisted primarily of equipment purchases related to the expansion of the Company's manufacturing capabilities at its contract manufacturer, Patheon U.K. Limited.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of September 30, 2021, and December 31, 2020:

<i>(In thousands)</i>	September 30, 2021	December 31, 2020
Research and development	\$ 2,972	\$ 1,856
Payroll and other employee-related expenses	10,189	10,674
Professional services fees	2,961	2,094
Accrued interest	2,943	1,464
Product revenue reserves	4,646	2,990
Other	1,164	930
Total accrued expenses and other current liabilities	<u>\$ 24,875</u>	<u>\$ 20,008</u>

9. Debt

Amended and Restated Credit and Security Agreement

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, to borrow up to \$30.0 million in term loans (the "2015 term loan"). On August 2, 2019, the Company terminated the credit and security agreement and concurrently entered into an amended and restated credit and security agreement (the "Existing Credit Agreement") with Silicon Valley Bank as agent, MidCap Financial Trust, Flexpoint MCLS Holdings, LLC, and the other lenders from time to time party thereto, providing for a term loan of \$40.0 million and a revolving credit facility of up to \$20.0 million, both of which mature on January 1, 2024. The Company concurrently borrowed the \$40.0 million term loan and used \$7.7 million of the proceeds to repay the remaining amount owed on the 2015 term loan.

On May 18, 2020, the Company borrowed \$15.0 million under a new term loan advance and immediately used the proceeds to repay an equal amount under the revolving credit facility, and the maximum principal amount of the revolving credit facility was reduced from \$20.0 million to \$5.0 million. The new term loan is subject to substantially the same terms, including interest rate, amortization, and maturity date, as the prior term loan under the credit facility.

On July 30, 2021, the Company entered into a second amendment (the "2021 Amended Credit Agreement") to the Existing Credit Agreement with Silicon Valley Bank, as agent and lender, MidCap Financial Trust, MidCap Funding XIII Trust, and the other lenders

from time to time party thereto (collectively, the “Lenders”), providing for a term loan facility of up to \$75.0 million, with \$55.0 million available at closing and an additional \$20.0 million (the “second tranche”) available upon positive Phase 1 clinical trial data in either of the Company’s two pipeline programs, FX201 and FX301, sufficient to initiate a Phase 2 clinical study, and a revolving credit facility of up to \$25.0 million, both of which mature on February 1, 2024, which may be extended to July 1, 2026, upon satisfaction of certain specified conditions set forth in the 2021 Amended Credit Agreement (the “Maturity Date”). The Company concurrently borrowed the \$55.0 million term loan (the “2021 term loan”), simultaneously used \$48.1 million of the proceeds to repay the outstanding term loan under the Existing Credit Agreement, and drew down \$20.0 million from the revolving

credit facility, bringing the total revolver balance to \$25.0 million. In connection with the repayment of the Existing Credit Agreement, the Company recorded a debt extinguishment loss of \$0.5 million primarily related to the write-off of the unamortized portion of the final payment, which was recorded as a component of interest expense on the statement of operations for the three and nine months ended September 30, 2021.

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 2021 Amended Credit Agreement. The Company also agreed not to encumber any of its intellectual property without the Lenders' prior written consent.

The 2021 Amended Credit Agreement contains certain representations, warranties, and covenants, including a minimum revenue covenant that will be in effect at any time the Company's liquidity (defined as cash, cash equivalents and marketable securities held with Silicon Valley Bank and certain accounts receivable as deemed eligible under the 2021 Amended Credit Agreement) is below \$100.0 million (if the second tranche is undrawn) or \$120.0 million (if the second tranche is drawn). Additionally, if the Company's liquidity is below \$100.0 million, all amounts received from customer collections will be applied immediately to reduce the revolving credit facility. The minimum revenue covenant, if it applies in the future, is applied to the trailing six-months of net revenue and is determined based on the Company's approved forecast, as determined by the Lenders.

The amended and restated credit and security agreement also has a material adverse event clause. If the minimum revenue covenant becomes applicable and the Company fails to comply with it, or a material adverse change as defined in the agreement occurs, the amounts due under the amended and restated credit and security agreement could be declared immediately due and payable. As of September 30, 2021, the Company was compliant with all financial covenants.

Term loan borrowings under the 2021 credit facility accrue interest monthly at a floating interest rate equal to the greater of (i) prime rate plus 2.75% or (ii) 6.0% per annum. Following an interest-only period of 24 months (if the second tranche is undrawn), or 36 months (if the second tranche is drawn), principal is due in equal monthly installments through Maturity Date. Upon the Maturity Date, the Company will be obligated to pay a final payment equal to 4.75% 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 September 30, 2021, the carrying value of the 2021 term loan was approximately \$55.1 million, all of which is presented as long-term debt in the Company's condensed consolidated balance sheet as of September 30, 2021. In connection with the planned merger with Pacira, the Company evaluated the terms of the 2021 Amended Credit Agreement and determined the agreement will require acceleration of payments upon a change of control.

The Company may prepay the term loan at any time by paying the outstanding principal balance, a final payment equal to 4.75% of the term loan amount, all accrued interest, and a prepayment fee of 3% of the outstanding term loan amount if repaid in the first year, 2% of the outstanding term loan amount if repaid in the second year, and 1% of the outstanding term loan amount if repaid in the third year of the loan; no prepayment fee is required thereafter.

As of September 30, 2021, annual principal and interest payments due under the term loan were as follows:

Year	Aggregate Minimum Payments <i>(in thousands)</i>
2021	568
2022	3,346
2023	10,907
2024	20,710
2025	19,587
Thereafter	13,523
Total	\$ 68,641
Less interest	(11,029)
Less unamortized portion of final payment	(2,525)
Total	\$ 55,087

Revolving Credit Facility

Borrowings under the 2021 Amended Credit Agreement revolving credit facility accrue interest monthly at a floating interest rate equal to the greater of (i) the Prime Rate plus 1.75% or (ii) 5.00%. In addition to paying interest on any amounts borrowed under the revolving credit facility, the Company may owe an unused revolving line facility fee equal to 0.25% per annum of the average unused

portion of the revolving line, multiplied by the difference between the total amount available to be borrowed (the “Revolving Commitment Amount”) and the greater of the average outstanding revolver balance and 25% of the Revolving Commitment Amount.

The Company may retire the revolving credit facility early, at any time, by paying the outstanding principal balance, all accrued interest, and a termination fee equal to 2% of the Revolving Commitment Amount if repaid in the first year, and 1% of the Revolving Commitment Amount if repaid in the second year; with no termination fee thereafter.

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 was 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 September 30, 2021, 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 and nine months ended September 30, 2021, was \$4.1 million and \$12.2 million, including \$2.4 million and \$7.2 million, related to amortization of the debt discount.

The table below summarizes the carrying value of the 2024 Convertible Notes as of September 30, 2021:

	<i>(in thousands)</i>
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	38,104
Carrying value 2024 Convertible Notes	<u>\$ 170,418</u>

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. Expected volatility is based on historical volatility of the Company's common stock. 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 and nine months ended September 30, 2021 and 2020, were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Risk-free interest rates	0.96 - 1.12%	0.47%	0.96 - 1.28%	0.47 - 1.79%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Expected term (in years)	6.0	6.0	6.0	6.0
Expected volatility	71.8 - 71.9%	72.5%	71.8 - 72.4%	65.4 - 72.5%

The following table summarizes stock option activity for the nine months ended September 30, 2021:

<i>(In thousands, except per share amounts)</i>	Shares Issuable Under Options	Weighted Average Exercise Price Per Share
Outstanding as of December 31, 2020	4,592	\$ 17.77
Granted	587	8.30
Exercised	(43)	3.40
Cancelled	(837)	18.81
Outstanding as of September 30, 2021	<u>4,299</u>	<u>\$ 16.42</u>
Options vested and expected to vest at September 30, 2021	<u>4,299</u>	<u>\$ 16.42</u>
Options exercisable at September 30, 2021	<u>3,302</u>	<u>\$ 17.91</u>

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 42,682 shares of the Company's common stock, with an aggregate intrinsic value of approximately \$386,138, were exercised during the nine months ended September 30, 2021.

At September 30, 2021 and 2020, there were options for the purchase of 4,299,337 and 4,753,623 shares of the Company's common stock outstanding, respectively, with a weighted average remaining contractual term of 6.0 years and 6.5 years, respectively, and with a weighted average exercise price of \$16.42 and \$17.74 per share, respectively.

The weighted average grant date fair value of options granted during the nine months ended September 30, 2021 and 2020, was \$5.28 and \$8.86 per share, respectively.

Restricted Stock Units

During the nine months ended September 30, 2021, the Company awarded 1,169,320 restricted stock units (“RSUs”) to employees at a weighted average grant date fair value of \$10.79 per share. The majority of 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.

Included in the 2021 RSU awards was a grant of 106,100 RSUs to the Company's chief executive officer. These RSUs have two performance conditions relating to achieving a certain revenue threshold for the year ending December 31, 2021, as well as progressing at least one of the Company's current pipeline assets. The number of shares ultimately eligible for vesting under the RSU award will depend upon the degree to which the performance conditions are achieved. The maximum number of shares that are eligible for vesting under the award is 159,150, which would be earned based on 150% achievement of the performance conditions. The portion of the RSUs eligible for vesting will vest in four substantially equal installments starting in 2022 upon confirmation of such performance metrics being achieved and thereafter on January 1 of the subsequent three years so that all of such shares will have vested on January 1, 2025, subject to the employee's continued employment with, or services to, the Company on each vesting date. As of September 30, 2021, the Company concluded that it was not probable that either performance condition would be met. Therefore, no expense has been recognized on these awards during the three and nine months ended September 30, 2021.

The following table summarizes the RSU activity for the nine months ended September 30, 2021:

<i>(In thousands, except per share amounts)</i>	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested balance as of December 31, 2020	2,193	\$ 14.15
Granted	1,169	10.79
Vested/Released	(626)	14.57
Cancelled	(490)	13.42
Nonvested Balance as of September 30, 2021	<u>2,246</u>	<u>\$ 12.45</u>

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 and nine months ended September 30, 2021 and 2020, as follows:

<i>(In thousands)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 1,166	\$ 1,403	\$ 3,469	\$ 4,692
Selling, general and administrative	3,030	3,556	9,342	8,705
Total	<u>\$ 4,196</u>	<u>\$ 4,959</u>	<u>\$ 12,811</u>	<u>\$ 13,397</u>

As of September 30, 2021, unrecognized stock-based compensation expense for stock options outstanding was approximately \$6.7 million, which is expected to be recognized over a weighted average period of 2.5 years. As of September 30, 2021, unrecognized stock-based compensation expense for RSUs outstanding was \$21.9 million, which is expected to be recognized over a weighted average period of 2.3 years.

11. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three and nine months ended September 30, 2021 and 2020:

<i>(In thousands, except per share amounts)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	\$ (30,312)	\$ (24,638)	\$ (81,076)	\$ (94,059)
Net loss:	<u>\$ (30,312)</u>	<u>\$ (24,638)</u>	<u>\$ (81,076)</u>	<u>\$ (94,059)</u>
Denominator:				
Weighted average common shares outstanding, basic and diluted	<u>50,265</u>	<u>49,298</u>	<u>50,027</u>	<u>43,563</u>
Net loss per share, basic and diluted	<u>\$ (0.60)</u>	<u>\$ (0.50)</u>	<u>\$ (1.62)</u>	<u>\$ (2.16)</u>

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:

<i>(In thousands)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Shares issuable upon conversion of the 2024 Convertible Notes	7,515	7,515	7,515	7,515
Stock options	4,676	4,986	4,579	4,946
Restricted stock units	2,301	2,058	2,350	1,485
Total	14,492	14,559	14,444	13,946

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”), for an initial term of 42 months. In June 2019, the Company amended the Lease to add additional square feet of office space and extend the term of the Lease through April 30, 2025 (the “Amended Lease”). As a result of the Amended Lease, the total rentable floor area is 41,873 square feet. Starting in August 2019, the Company’s minimum monthly lease payment is approximately \$108,000, which increases over the term of the Amended Lease. In addition to the base rent for the office space, the Company is responsible for its share of operating expenses and real estate taxes.

The lease cost for the Amended Lease (including the expense relating to the original Lease) for the three and nine months ended September 30, 2021, amounted to \$0.5 million and \$1.4 million for each of the three and nine months ended September 30, 2021 and 2020, respectively, and was included in operating expenses. As of September 30, 2021, the remaining lease term on the Amended Lease was 3.6 years, which includes the 18-month extension resulting from the amendment signed in June 2019.

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. The lease cost for the Woburn lease amounted to \$58,000 and \$150,000 for the three and nine months ended September 30, 2021 respectively, as compared to \$46,000 and \$139,000, respectively, for the same periods in the prior year, and was included in operating expenses.

In June 2021, the Company amended the Woburn lease to extend the term of the lease through February 29, 2024. Starting in March 2022, the Company’s minimum monthly lease payment will be approximately \$20,400, which increases over the term of the amended lease. The Company accounted for the amended lease as a modification that is not a separate contract from the original lease, as the amended lease does not contain any additional rights, and recorded an incremental right-of-use asset and lease liability of \$0.4 million, which represents the present value of the lease payments over the remaining lease term of 2.7 years, discounted at 8.4%. As of September 30, 2021, the remaining lease term on the Woburn lease, as amended, was 2.4 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 a 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.

In June 2019, the Company and Patheon amended the Manufacturing Agreement and the Technical Transfer Agreement. The amendment primarily modifies the compensation structure, which is comprised of base fees and per product fees the Company pays to Patheon and does not result in any additional rights of use. The Company accounted for the amendment as a lease modification that is not a separate contract from the original lease. As part of the modification, the Company reassessed whether the contract is or contains a lease and determined that there is an operating lease component for the use of dedicated manufacturing suites. The remainder of the consideration is allocated to the service component. The Company also reassessed the lease liability by calculating the present value of the remaining lease payments as of the modification date, discounted at 6.1%. The modification resulted in an increase to each of the lease liability and right of use asset of \$0.5 million.

In April 2020, the Company entered into a side letter amending the Manufacturing Agreement with Patheon pursuant to which the parties agreed that the Company would continue to pay the monthly base fee for maintaining the manufacturing suites, but minimum purchase obligations would be cancelled for 2020 as the Company temporarily suspended manufacturing activities for ZILRETTA due to COVID-19. The amendment did not change the amount of fixed consideration owed to Patheon over the life of the contract, nor did it grant the Company any additional rights of use. As such, there was no change in the accounting for the embedded lease as a result of this amendment. The Company restarted manufacturing activities at Patheon in the fourth quarter of 2020.

As of September 30, 2021, the remaining lease term on the Patheon lease was 6.1 years. The lease cost for the three and nine months ended September 30, 2021, amounted to \$61,000 and \$185,000, respectively, compared to \$58,000 and \$171,000, respectively, for the same periods in the prior year, and is included in inventory as part of manufacturing overhead.

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

<i>(In thousands)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Operating lease cost				
Operating lease cost included in operating expenses	\$ 525	\$ 513	\$ 1,552	\$ 1,540
Operating lease cost included in inventory	61	58	185	171
Total operating lease cost	586	571	1,737	1,711
Operating cash flows from operating leases	855	699	2,450	2,256

Maturities of lease liability due under these lease agreements as of September 30, 2021, were as follows:

Year	Operating Lease Obligations <i>(In thousands)</i>
2021	515
2022	2,087
2023	2,142
2024	1,975
2025	809
Thereafter	422
Present value of imputed interest	(2,115)
Total	\$ 5,835

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 was extended. The initial term of the agreement was five years, commencing

in July 2016. In May 2021, the Company entered into an amendment to the Supply Agreement that became effective on June 30, 2021. The total term of the Supply Agreement, as amended, is eight 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.

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, the Company made an upfront payment to GeneQuine of \$2.0 million. The upfront fee was attributed to the intellectual property acquired and recognized as research and development expense in December 2017 as the FX201 rights had not been commercially approved and had no alternative future use. In 2018, the Company paid GeneQuine \$750,000 for initiating a GLP toxicology study of FX201. In addition, the Company paid GeneQuine \$750,000 in November 2019 following the FDA acceptance of the Investigational New Drug (“IND”) application for FX201. The next milestone of \$2.5 million was achieved in March 2020, when the first patient was treated in the Phase 1 clinical trial. The Company may also be required to make additional milestone payments during the development of FX201, including up to \$4.5 million for the initiation of a Phase 2 proof of concept (“PoC”) clinical trial and, following successful PoC, up to an additional \$51.5 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. Milestone payments earned prior to regulatory approval of FX201 are 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 its estimated life. As of September 30, 2021, no other milestones under the arrangement were probable of being 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. In addition, in February 2020 the Company entered into a manufacturing agreement with another vendor for clinical trial supply of FX201 through Phase 3 clinical trials.

FX301-Related Agreements

In September 2019, the Company entered into a definitive agreement with Xenon Pharmaceuticals, Inc. (“Xenon”) that provides the Company with the global rights to develop and commercialize XEN402, Xenon’s Nav1.7 inhibitor known as funapide, formulated for extended release with a novel, Flexion proprietary thermosensitive hydrogel under the Company’s preclinical program known as FX301. The transaction was accounted for as an asset acquisition, as it did not qualify as a business combination. As part of the asset purchase transaction, the Company made an upfront payment to Xenon of \$3.0 million. The upfront fee was attributed to the intellectual property acquired and was recognized as research and development expense in September 2019 as the FX301 product candidate had not been commercially approved and had no alternative future use. The next milestone of \$0.5 million was achieved following the commencement of the GLP toxicology study. This milestone was recognized as research and development expense in the first quarter of 2020. The Company also paid \$1.0 million when the IND was cleared by FDA in February 2021 and \$2.0 million upon the initiation of the Phase 1b clinical trial in March 2021. These milestones were recognized as research and development expenses in the first quarter of 2021. The Company may also be required to make additional milestone payments during the development of FX301, including up to \$5.0 million through initiation of a Phase 2 PoC clinical trial and, following successful PoC, up to \$40.8 million in development and global regulatory approval milestone payments and up to an additional \$75.0 million in sales-related milestone payments. Future milestone payments earned prior to regulatory approval of FX301 would be recognized as research and development expense in the period when the milestone events become probable of being achieved. Future milestones earned subsequent to regulatory approval would be recognized as an intangible asset and amortized to expense over the estimated life of FX301. As of September 30, 2021, no other milestones under the arrangement were probable of being achieved. As part of the transaction, the Company became the direct licensee of certain underlying Xenon patents and other proprietary rights related to XEN402 for human applications. The Xenon agreement grants the Company an exclusive, royalty-bearing, world-wide right and license (with a right to sublicense) for human applications under its patents directly related to XEN402, with a similar royalty-free license to other Xenon proprietary rights directly related to XEN402. The agreement with Xenon includes a tiered royalty ranging from mid-single digits to low double digits that is based on aggregate annual net sales of FX301 and requires the Company to use reasonable efforts to develop FX301 according to timelines set out in the agreement.

Legal Proceedings

Between October 22, 2021, and November 10, 2021, eleven complaints were filed in federal court by purported stockholders of Flexion regarding the Merger. The first complaint was filed on October 22, 2021, in the United States District Court for the Southern District of New York and is captioned *Elaine Wang v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-08693. The second complaint was filed on October 28, 2021, in the United States District Court for the Southern District of New York and is captioned *Marc Waterman v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-08804 (S.D.N.Y filed October 28, 2021). The third complaint was filed on October 28, 2021, in the United States District Court for the Southern District of New York and is captioned *Melinda Turkington v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-08817. The fourth complaint was filed on November 1, 2021, in the United States District Court for the Southern District of New York and is captioned *Barbara Hart v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-08919. The fifth complaint was filed on November 1, 2021, in the United States District Court for the Southern

District of New York and is captioned *Lee Beary v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-08925. The sixth complaint was filed on November 2, 2021, in the United States District Court for the Southern District of New York and is captioned *Katherine Finger v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-09032. The seventh complaint was filed on November 2, 2021, in the United States District Court for the Eastern District of New York and is captioned *David Gruver v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-06106. The eighth complaint was filed on November 3, 2021, in the United States District Court for the Southern District of New York and is captioned *Theodore Meshover v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-09043. The ninth complaint was filed on November 4, 2021, in the United States District Court for the District of Delaware and is captioned *Sam Carlisle v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-01572-UNA. The tenth complaint was filed on November 4, 2021, in the United States District Court for the Eastern District of Pennsylvania and is captioned *Alex Ciccotelli v. Flexion Therapeutics, Inc., et al.*, Case No. 2:21-cv-04885. The eleventh complaint was filed on November 10, 2021, in the United States District Court for the District of Delaware and is captioned *James Murray v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-01590-UNA (collectively, the “Complaints”). The Complaints name as defendants Flexion and each member of Flexion’s board of directors (the “Flexion Defendants”). The *Waterman* complaint additionally names as defendants Pacira and Purchaser (the “Pacira Defendants”). The plaintiffs generally contend that the Solicitation/Recommendation Statement on Schedule 14D-9, filed on October 22, 2021, has omitted or misrepresented material information regarding the Merger. The *Hart* complaint additionally alleges that Flexion engaged in an insufficient sales process and that members of Flexion’s board of directors and Flexion’s management had conflicts of interest with Flexion’s stockholders. The Complaints allege violations of Section 14(d) and/or Section 14(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) against all Flexion Defendants and assert violations of Section 20(a) of the Exchange Act against the members of Flexion’s board of directors. The *Waterman* complaint additionally alleges violations of Section 14(d), Section 14(e), and Section 20(a) of the Exchange Act against the Pacira Defendants. The Complaints collectively seek, among other relief, (i) injunctive relief preventing the consummation of the transactions contemplated by the Merger Agreement; (ii) rescission and/or rescissory damages in the event the transactions contemplated by the Merger Agreement are consummated; (iii) other damages purportedly incurred on account of defendants’ alleged misstatements or omissions; (iv) disclosure of certain information requested by the plaintiffs; (v) declaratory relief stating defendants violated the Exchange Act; and (vi) an award of plaintiffs’ expenses and attorneys’ fees. The Flexion Defendants have been served with the *Wang* complaint and the *Hart* complaint, but have not been served with any of the other Complaints. On November 12, 2021, the Company filed a Schedule 14D-9/A containing certain supplemental disclosures in order to moot the claims alleged in the Complaints. The Flexion Defendants’ deadline to respond to the *Wang* complaint is December 27, 2021, and the Flexion Defendants’ deadline to respond to the *Hart* complaint is January 3, 2022.

Each of the Flexion Defendants and the Pacira Defendants intend to vigorously defend these actions. The Company believes that the Complaints are without merit and has not recorded an expense related to the outcome of these litigations because it is not yet possible to determine if a potential loss is probable nor reasonably estimable.

At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings.

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, 2020, and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed by us with the Securities and Exchange Commission, or SEC, on March 10, 2021.

Forward-Looking Statements

This discussion and analysis contains “forward-looking statements”—as defined in Section 21E of the Exchange Act—which are statements related to future, not past, events and 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 that 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. The forward-looking statements in this Quarterly Report on Form 10-Q, other than the statements regarding the proposed acquisition by Pacira BioSciences, Inc. ("Pacira"), do not assume the consummation of the proposed acquisition unless specifically stated otherwise.

Forward-looking statements include, without limitation, statements regarding the anticipated consummation and timing of the acquisition of Flexion by Pacira and payments that may be made upon the satisfaction of specified milestones, which are each based

on Pacira's and Flexion's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to Pacira's ability to complete the transaction on the proposed terms and schedule or at all; whether the tender offer conditions will be satisfied; whether sufficient stockholders of Flexion tender their shares in the transaction; the outcome of legal proceedings instituted against Flexion and/or others relating to the transaction; the failure (or delay) to receive the required regulatory approvals relating to the transaction; the possibility that competing offers will be made; risks related to future opportunities and plans for Flexion and its products, including uncertainty of the expected financial performance of Flexion and its products, including whether the milestones will ever be achieved; and the occurrence of any event, change, or other circumstance that could give rise to the termination of the acquisition agreement, as well as other risks related to Pacira's and Flexion's businesses detailed from time-to-time under the caption "Risk Factors" and elsewhere in Pacira's and Flexion's respective SEC filings and reports, including their respective Annual Reports on Form 10-K for the year ended December 31, 2020, and subsequent quarterly and current reports filed with the SEC.

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, the most common form of arthritis, referred to as OA.

On October 6, 2017, the U.S. Food and Drug Administration ("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 two pipeline programs focused on the local treatment of musculoskeletal conditions: FX201, which is an investigational IA gene therapy product candidate in clinical development for the treatment of OA, and FX301, an investigational NaV1.7 inhibitor product candidate in clinical development as a locally administered peripheral analgesic nerve block for control of post-operative pain.

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 September 30, 2021, we have 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.

Proposed Acquisition by Pacira BioSciences, Inc.

On October 11, 2021, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Pacira and Oyster Acquisition Company Inc., a Delaware corporation and wholly owned subsidiary of Pacira ("Purchaser"). Pursuant to the Merger Agreement, on October 22, 2021, Purchaser commenced a tender offer (the "Offer") to purchase each issued and outstanding share of our common stock (the "Shares") at an offer price of (i) \$8.50 per Share in cash, net of applicable withholding taxes and without interest, plus (ii) one non-transferable contractual contingent value right per Share, which will represent the right to receive one or more contingent payments up to \$8.00 in the aggregate, in cash, net of applicable withholding taxes and without interest, upon the achievement of specified milestones on or prior to December 31, 2030.

Promptly following the completion of the Offer, upon the terms and subject to the conditions of the Merger Agreement, Purchaser will merge with and into Flexion (the "Merger"), with Flexion continuing as the surviving corporation and as a wholly owned subsidiary of Pacira. The Merger Agreement contemplates that the Merger will be effected pursuant to Section 251(h) of the Delaware General Corporation Law, which permits completion of the Merger without a vote of the holders of our common stock upon the acquisition by Purchaser of a majority of the aggregate voting power of our common stock. As a result of the Merger, we will cease to be a publicly traded company.

The Merger Agreement contains customary representations and warranties. The Merger is expected to close before the end of the calendar year 2021, subject to the satisfaction or waiver of customary closing conditions, including, among others, that the number of Shares tendered in the Offer represent at least one Share more than 50% of the total number of Shares at the time of the expiration of

the Offer. The Merger Agreement provides Pacira and Flexion with certain termination rights and, under certain circumstances, may require us to pay Pacira a termination fee of \$18.0 million.

For additional information related to the Merger Agreement, refer to the Solicitation/Recommendation Statement on Schedule 14D-9 filed by the Company filed with the SEC on October 22, 2021, together with the exhibits and annexes thereto and as amended or supplemented from time to time. Please also see “Item 1A. Risk Factors—Risks Related to Our Pending Acquisition by Pacira.

Q3 2021 Commercial Performance

ZILRETTA net sales in the third quarter were \$21.3 million. We believe that our commercial performance reflects the adverse impacts of several key factors.

First, in August, we introduced a ZILRETTA price increase coupled with an “off-invoice discount” (OID) program intended to mitigate the impacts of the increase. As part of this program, providers have the ability to earn higher discounts in exchange for purchasing more units in each order. In conjunction with those changes, we revised the discount tiers such that the discounts offered at the lowest purchasing tiers were less than they were prior to the implementation of the OID program. Our goal was to incentivize higher purchasing volumes by healthcare practices; however, some accounts were reluctant to increase order sizes in amounts sufficient to obtain the more favorable cost recovery available in the higher discount tiers. We believe that this program had the unanticipated effect of causing accounts to purchase less product than we had forecast.

Second, COVID-19 and the emergence of the Delta variant resulted in reduced patient flows and restricted our Musculoskeletal Business Managers’ (MBMs) ability to access key office personnel. These restrictions were particularly acute in August and September as COVID cases spiked in a number of key regions.

Third, net sales in the quarter were reduced due to several unanticipated manufacturing batch failures in late 2020 and in the first half of 2021 that contributed to short-dated ZILRETTA inventory in the distribution channel, resulting in smaller order sizes by physician practices and product returns from specialty distributors. The product returns were a consequence of the drop in demand during the quarter. If demand had been in line with our forecast, significantly more inventory would have been consumed, and we anticipate that we would have avoided having short-dated product in the channel. We adjusted our manufacturing process to address the batch failures, and subsequent batches have fully met our product specifications and have been entered into the supply chain. These new batches have greater than 12 months of expiry remaining, which is consistent with the product dating that we were selling prior to the pause in manufacturing due to COVID-19.

Pipeline Updates

ZILRETTA/FX006 (triamcinolone acetonide extended-release injectable suspension) - IA treatment for OA

ZILRETTA is the first and only extended-release IA therapy for patients confronting OA-related knee pain. In September 2021, we announced the inclusion of ZILRETTA in the American Academy of Orthopaedic Surgeons (AAOS) updated evidence-based clinical practice guidelines for the management of OA of the knee. The AAOS guidelines reflect a moderate recommendation for the use of intra-articular (IA) corticosteroids for patients with symptomatic OA of the knee. The recommendation follows a review of data from 25 studies assessing IA corticosteroids. Included in its rationale is a differential analysis of extended-release intra-articular steroid, of which ZILRETTA is the only available product, versus immediate-release IA corticosteroids, where AAOS analyses demonstrated that it can, “be used over immediate-release corticosteroids to improve patient outcomes.”

In addition to knee OA, we believe that ZILRETTA’s extended-release profile may also provide effective treatment for OA pain in other large joints, including the shoulder and in August results from the Phase 2 pharmacokinetic (“PK”) trial assessing the safety and general tolerability of ZILRETTA in OA of the shoulder were published in *Drugs in R&D*. PK and safety profiles of ZILRETTA were similar to those reported in Phase 3 studies of patients with knee OA. Plasma PK findings from this study were also consistent with the extended release of triamcinolone acetonide (“TA”) within the synovial fluid following an IA injection of ZILRETTA in the knee. Plasma PK data indicate the total and maximal exposure to TA was approximately two-thirds lower in patients treated with ZILRETTA compared to triamcinolone acetonide in crystalline suspension. With respect to our plans to initiate a registration study in shoulder OA by end of year, based on recent interactions with FDA, we are currently reassessing the proposed study design and determining the best path forward given FDA’s feedback.

At the American College of Rheumatology (ACR) annual meeting in November we presented data from our open-label Phase 3b trial assessing the effect of a single administration of ZILRETTA on synovitis in 129 patients with knee OA. In patients with knee OA and baseline synovitis (n=102), ZILRETTA significantly reduced synovial tissue volume at Week 6 (primary endpoint). These patients also reported improvements in WOMAC-A (pain), B (stiffness), and C (function) and KOOS-QoL scores through Week 24. ZILRETTA was well tolerated and there were no new or unexpected adverse events.

FX201 (humantakinogene hadenovec) – Locally Administered Gene Therapy for the Treatment of OA

FX201 is our novel, clinical stage, investigational IA gene therapy product candidate, which is designed to induce the production of interleukin-1 receptor antagonist (“IL-1Ra”), an anti-inflammatory protein. Preclinical data suggest that, following injection of FX201,

its genetic material is incorporated into local cells and IL-1Ra is expressed in response to inflammation in the joint tissues. Inflammation is a known cause of pain, and chronic inflammation is thought to play a major role in the progression of OA. By persistently suppressing inflammation, we believe that FX201 has the potential to both reduce pain and possibly modify disease progression. 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 May 2019, the U.S. Patent and Trademark Office issued patent number 10,301,647, which covers the composition of matter and method of use of FX201 in the treatment of OA with a term through January 2033.

In March 2020, we initiated a Phase 1 single ascending dose (“SAD”) study to evaluate the safety and tolerability of FX201 in patients with painful OA of the knee. The multicenter, open-label study is evaluating three doses (low, mid and high dose) of FX201 in cohorts of five to eight patients. In addition, in the first quarter of 2021, we expanded the trial to include up to 20 additional patients in both the low and mid dose treatment groups.

In June 2021, the SAD phase of the study was fully enrolled, and, as of November 1, 2021, 65 patients had been treated across all cohorts including the expansion groups. The most commonly observed treatment-related adverse events (“AEs”) observed in the trial have been pain, swelling, and effusion, and, in the second quarter, we made the strategic decision to investigate pretreatment with an intra-articularly administered immediate-release steroid prior to FX201 administration as a means to mitigate potential AEs. We expect to treat up to 38 patients with a pretreatment regimen. In October 2021, we presented initial data from the mid-dose cohort of the open-label FX201 Phase 1 single ascending dose phase of the trial in patients with knee OA via a poster at the 2021 European Society of Gene & Cell Therapy (ESGCT) annual meeting. Preliminary results indicate that seven of eight patients treated with the mid dose of FX201 experienced a reduction of pain and functional improvement from baseline out to Week 24. The mid dose of FX201 was generally well-tolerated in all eight patients with moderate-to-severe knee OA.

FX301 (funapide in a proprietary thermosensitive hydrogel) – Locally Administered NaV1.7 Inhibitor for the Treatment of Post-Operative Pain

In September 2019, we entered into a definitive agreement with Xenon Pharmaceuticals that provides us with the global rights to develop and commercialize XEN402, a NaV1.7 inhibitor, for control of post-operative pain. Our investigational product candidate, known as FX301, consists of funapide formulated for extended release from a Flexion proprietary thermosensitive hydrogel for administration as a peripheral nerve block for control of post-operative pain. Within minutes following injection, the thermosensitive formulation has been shown to transition from a liquid to a gel, an effect that we believe can provide local delivery of funapide near target nerves for up to a week. Unlike typical local anesthetics, the selective pharmacology of funapide has the potential to provide effective pain relief while preserving motor function. As such, we believe FX301 could enable ambulation, rapid discharge, and early rehabilitation following musculoskeletal surgery.

In a validated post-operative pain model in pigs, a single injection of FX301 provided both greater analgesic effect from 12 through 72 hours and a longer duration of effect through 72 hours compared to liposomal bupivacaine or placebo. In addition, treatment with FX301 did not significantly affect total walking distance in animals at 2 and 24 hours post-injection, whereas animals treated with liposomal bupivacaine experienced a significant reduction in total walking distance compared with baseline at 2 and 24 hours post-injection.

These data formed the basis of our IND application for FX301, which the FDA cleared in February 2021. In March 2021, we announced the treatment of the first patient in a Phase 1b proof-of-concept trial evaluating the safety and tolerability of FX301 administered as a single-dose, popliteal fossa block (a commonly used nerve block in foot and ankle-related surgeries) in patients undergoing bunionectomy. The Phase 1b randomized, double-blind, placebo-controlled study is being conducted in two parts, the SAD portion investigated FX301 at low and high doses of funapide administered at two volumes in four cohorts of patients undergoing bunionectomy. A total of 48 patients (12 patients per cohort), were randomized to receive either FX301 or placebo. A Safety Monitoring Committee reviewed data from each dose cohort before the study escalated into higher doses. In July 2021, we fully enrolled the SAD portion of the trial, and following an assessment of safety, systemic exposure and efficacy data by an internal review committee, we made the decision to expand the study. In the expansion cohort, an additional 36 patients will be randomized (1:1) to receive either FX301 at the selected dose (130 mg/low volume) or placebo to further assess the safety, tolerability, systemic exposure, and efficacy of FX301 as a single-injection analgesic nerve block adjacent to the sciatic nerve of the popliteal fossa. Based on the current pace of enrollment in the expansion cohort, we anticipate having data available in the first quarter of 2022.

Financial Overview

Revenue

Product 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.

License Revenue

On March 30, 2020, we entered into an exclusive license agreement with HK Tainuo and Jiangsu Tainuo, a subsidiary of China Shijiazhuang Pharmaceutical Co, Ltd., for the development and commercialization of ZILRETTA in Greater China (consisting of mainland China, Hong Kong and Macau, and Taiwan). Under the terms of the agreement, HK Tainuo paid us an upfront payment of \$10.0 million, of which \$5.0 million was received as of June 30, 2020, and the remaining \$5.0 million was received as of September 30, 2020. We are also eligible to receive up to \$32.5 million in aggregate development, regulatory, and commercial sales milestone payments. All payments received from HK Tainuo are subject to applicable Hong Kong withholding taxes. HK Tainuo is responsible for the clinical development, product registration, and commercialization of ZILRETTA in Greater China, and Jiangsu Tainuo serves as the guarantor of HK Tainuo's obligations and responsibilities under the agreement. We are solely responsible for the

manufacture and supply of ZILRETTA to HK Tainuo for all clinical and commercial activities. The terms related to product manufacturing and supply, including pricing and minimum purchase requirements agreed to in the license agreement, will be covered by a separate supply agreement. All amounts owed to us are nonrefundable and non-creditable once paid. We concluded that the license and supply obligations were not distinct performance obligations, and therefore the transaction price will be recognized as revenue as our supply obligation is fulfilled over the term of the supply agreement, which has not yet commenced. No revenue was recognized associated with this contract as of September 30, 2021.

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 (“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 expenses 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 a product candidate is recorded as research and development expense as incurred.

Our research and development expenses are expected to increase for the foreseeable future. While the duration of COVID-19 and its impact on our ability to conduct clinical development are highly uncertain, we expect that a return to normal operations will likely result in an increase in future research and development expenses. Specifically, our costs will increase as we conduct additional clinical trials for ZILRETTA, including our planned registration trial in shoulder OA, and conduct further development activities for our pipeline programs, including our on-going clinical trials of FX201 and FX301.

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 well as the status and timing of the Merger. 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 the product candidates in our pipeline.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel costs, including salaries, sales commissions, 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 selling, general, and administrative expenses will increase as compared to the prior year, including external marketing expenses and the operation of our field sales force.

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, our term loan facility, which, accrues interest at a floating interest rate equal to the greater of the prime rate as reported in the Wall Street Journal plus 2.75% or 6.0% per annum, and our revolving credit facility, which accrues interest at a floating interest rate equal to the greater of the prime rate as reported in the Wall Street Journal plus 1.75% or 5.0% per annum. Also included in interest expense is the amortization of the final payment on the 2021 term loan, the loss on debt extinguishment related to the 2019 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.

Other income (expense)

Other income (expense) consists of the amortization of premiums or accretion of discounts related to our marketable securities, realized gains (losses) on redemptions of our marketable securities, gains (losses) from foreign currency transactions, and the amortization of debt issuance costs on the 2024 Convertible Notes, which are being amortized over the term of the loan.

Provision for income taxes

The provision for income taxes consists of foreign withholding taxes related to our license agreement with HK Tainuo.

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, 2020, have the greatest potential impact on our financial statements, so we consider them to be our critical accounting policies and estimates. There were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2021.

RESULTS OF OPERATIONS

Comparison of the Three and Nine Months Ended September 30, 2021 and 2020

The following tables summarize our results of operations for the three and nine months ended September 30, 2021:

<i>(In thousands)</i>	Three Months Ended September 30,			
	2021	2020	Change	% Increase/ (Decrease)
Revenues:				
Product revenue, net	\$ 21,326	\$ 23,664	\$ (2,338)	(9.9)%
Operating expenses:				
Cost of sales	3,727	5,130	(1,403)	(27.3)%
Research and development	14,771	10,092	4,679	46.4%
Selling, general and administrative	26,986	27,312	(326)	(1.2)%
Total operating expenses	45,484	42,534	2,950	6.9%
Loss from operations	(24,158)	(18,870)	(5,288)	28.0%
Other (expense) income:				
Interest income	54	62	(8)	(12.9)%
Interest expense	(5,787)	(5,125)	(662)	12.9%
Other expense	(421)	(457)	36	(7.9)%
Total other (expense) income	(6,154)	(5,520)	(634)	11.5%
Loss before income taxes	(30,312)	(24,390)	(5,922)	24.3%
Income tax expense	—	248	(248)	NM
Net loss	\$ (30,312)	\$ (24,638)	(5,674)	23.0%

<i>(In thousands)</i>	Nine Months Ended September 30,			
	2021	2020	Change	% Increase/ (Decrease)
Revenues:				
Product revenue, net	\$ 74,090	\$ 59,242	\$ 14,848	25.1%
Operating expenses:				
Cost of sales	14,791	12,887	1,904	14.8%
Research and development	41,487	43,733	(2,246)	(5.1)%
Selling, general and administrative	81,993	81,341	652	0.8%
Total operating expenses	138,271	137,961	310	0.2%
Loss from operations	(64,181)	(78,719)	14,538	(18.5)%
Other (expense) income:				
Interest income	531	584	(53)	(9.1)%
Interest expense	(16,156)	(14,848)	(1,308)	8.8%
Other expense	(1,270)	(581)	(689)	118.6%
Total other (expense) income	(16,895)	(14,845)	(2,050)	13.8%
Loss before income taxes	(81,076)	(93,564)	12,488	(13.3)%
Income tax expense	—	495	(495)	NM
Net loss	\$ (81,076)	\$ (94,059)	12,983	(13.8)%

Product Revenue

The following table presents the adjustments deducted from gross product revenue to arrive at net product revenue for sales of ZILRETTA during the three and nine months ended September 30, 2021 and 2020:

<i>(In thousands, except for % of sales)</i>	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	% of Sales	2020	% of Sales	2021	% of Sales	2020	% of Sales
Product revenue, gross	\$ 30,825	100.0%	\$ 27,704	100.0%	\$ 95,283	100.0%	\$ 68,498	100.0%
Adjustments to product revenue, gross								

Provider discounts and rebates	(3,245)	(10.5)%	(1,329)	(4.8)%	(9,048)	(9.5)%	(2,757)	(4.0)%
Estimate of product returns	(3,421)	(11.1)%	(136)	(0.5)%	(3,640)	(3.8)%	(345)	(0.5)%
All other	(2,833)	(9.2)%	(2,575)	(9.3)%	(8,505)	(8.9)%	(6,154)	(9.0)%
Product revenue, net	<u>\$ 21,326</u>	<u>69.2%</u>	<u>\$ 23,664</u>	<u>85.4%</u>	<u>\$ 74,090</u>	<u>77.8%</u>	<u>\$ 59,242</u>	<u>86.5%</u>

Net product revenue for the three months ended September 30, 2021 and 2020, was \$21.3 million and \$23.7 million, respectively. The number of ZILRETTA units sold period-over-period increased, which resulted in an increase in net revenue of \$1.6 million, offset by

a decrease of \$3.9 million, which was attributable to a decrease in the net price per unit. The decrease in net price was due to an increase in returns of short-dated product, which resulted in a reduction of revenue of \$3.4 million for the three months ended September 30, 2021. The decrease in net price was also attributed to the increase in rebates and discounts offered to healthcare providers, partially offset by an increase in our gross sales price in the third quarter of 2021.

Net product revenue for the nine months ended September 30, 2021 and 2020, was \$74.1 million and \$59.2 million, respectively. The period-over-period increase was due to an increase in the number of ZILRETTA units sold, which resulted in an increase in net revenue of \$20.3 million, offset by a decrease of \$5.5 million, which was attributable to a decrease in the net price per unit primarily due to provider rebate offerings and other discounts and the aforementioned charge relating to product returns, partially offset by an increase in our gross sales price in the third quarter of 2021. Net revenue for the nine months ended September 30, 2020, included the adverse impact of COVID-19 on the operations of healthcare providers, which resulted in a material decline in net revenue as compared to our prior expectations.

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 \$3.7 million and \$5.1 million for the three months ended September 30, 2021 and 2020, respectively. For the three months ended September 30, 2021, cost of sales was comprised of \$1.8 million related to the actual cost of units sold and \$0.7 million of period costs and other adjustments. In addition, cost of sales for the three months ended September 30, 2021 included a charge of \$1.2 million related to the write-down of short-dated inventory that will not be sold prior to expiry. For the three months ended September 30, 2020, cost of sales was comprised of \$2.0 million related to the actual cost of units sold and \$3.1 million of unabsorbed overhead associated with the voluntary, temporary suspension of manufacturing activities at Patheon due to COVID-19 impacts on sales of ZILRETTA.

Cost of sales was \$14.8 and \$12.9 million for the nine months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021, costs of sales consisted of \$7.1 million related to the actual cost of units sold, \$5.2 million of unabsorbed manufacturing and overhead costs related to the operation of the facility at Patheon, \$1.8 million related to the write-down of short-dated inventory that will not be sold prior to expiry, and \$0.7 million of period costs and other adjustments. For the nine months ended September 30, 2020, cost of sales consisted of \$5.6 million related to the actual cost of units sold, \$6.5 million of unabsorbed manufacturing overhead, and \$0.8 million of period costs and adjustments.

Research and Development Expenses

<i>(In thousands)</i>	Three Months Ended September 30,			
	2021	2020	Change	% Increase/ (Decrease)
Direct research and development expenses by program:				
ZILRETTA	\$ 1,675	\$ 1,043	\$ 632	60.6%
FX201	3,358	831	2,527	304.1%
FX301	1,839	1,160	679	58.5%
Portfolio expansion	226	72	154	213.9%
Other	630	386	244	63.2%
Total direct research and development expenses	7,728	3,492	4,236	121.3%
Personnel and other costs	7,043	6,600	443	6.7%
Total research and development expenses	\$ 14,771	\$ 10,092	\$ 4,679	46.4%

<i>(In thousands)</i>	Nine Months Ended September 30,			
	2021	2020	Change	% Increase/ (Decrease)
Direct research and development expenses by program:				
ZILRETTA	\$ 4,319	\$ 8,188	\$ (3,869)	(47.3)%
FX201	6,715	5,789	926	16.0%
FX301	7,878	4,362	3,516	80.6%
Portfolio expansion	691	279	412	147.7%
Other	1,593	1,284	309	24.1%

Total direct research and development expenses	21,196	19,902	1,294	6.5%
Personnel and other costs	20,291	23,831	(3,540)	(14.9)%
Total research and development expenses	<u>\$ 41,487</u>	<u>\$ 43,733</u>	<u>\$ (2,246)</u>	<u>(5.1)%</u>

Research and development expenses were \$14.8 million and \$10.1 million for the three months ended September 30, 2021 and 2020, respectively. For the three months ended September 30, 2021, development expenses for ZILRETTA increased by \$0.6 million due to an increase in ZILRETTA life cycle management activities. Program expenses related to FX201 and FX301 increased by \$2.5 million

and \$0.7 million, respectively, due to an increase in clinical trial activity, and portfolio expansion-related expenses increased by \$0.4 million. Personnel and other costs also increased by \$0.4 million due to an increase in salary and other employee-related costs and stock-based compensation expense.

Research and development expenses were \$41.5 million and \$43.7 million for the nine months ended September 30, 2021 and 2020, respectively. The decrease in research and development expense of \$2.2 million was primarily due to a decrease of \$3.9 million in development expense for ZILRETTA due to a reduction in ZILRETTA life cycle management activities, and a decrease of \$3.5 million in salary and other employee-related costs and stock-based compensation expense related to lower headcount. Decreases were partially offset by an increase of \$0.9 million related to FX201 due to increased clinical trial activity in 2021, offset by the \$2.5 million milestone payment related to dosing the first human patient in the Phase 1 clinical trial that occurred in the first quarter of 2020 and an increase of \$3.5 million related to FX301, which is attributed to the achievement of certain development milestones, including the clearing of the IND by FDA and the initiation of the Phase 1b clinical trial, both of which occurred in the first quarter of 2021, and a \$0.7 million increase in costs related to our portfolio expansion.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$27.0 million and \$27.3 million for the three months ended September 30, 2021 and 2020, respectively. Selling expenses were \$17.8 million and \$19.3 million for the three months ended September 30, 2021 and 2020, respectively. The year-over-year decrease in selling expenses of \$1.5 million was primarily due to lower headcount, partially offset by the resumption of industry conferences and physician speaker programs and increase in business travel. General and administrative expenses were \$9.2 million and \$8.0 million for the three months ended September 30, 2021 and 2020, respectively, which represents an increase of \$1.2 million. The increase was largely attributable to acquisition costs related to the merger agreement with Pacira.

Selling, general and administrative expenses were \$82.0 million and \$81.3 million for the nine months ended September 30, 2021 and 2020, respectively. Selling expenses were \$55.7 million and \$56.5 million for the nine months ended September 30, 2021 and 2020, respectively. The year-over-year decrease in selling expenses of \$0.8 million was primarily due to lower headcount and a reduction in operating expenses, partially offset by the partial resumption of industry conferences and physician speaker programs and increases in business travel. General and administrative expenses were \$26.3 million and \$24.8 million for the nine months ended September 30, 2021 and 2020, respectively, which represents an increase of \$1.5 million. The year-over-year increase was largely attributable to acquisition costs related to the merger agreement with Pacira.

Other Income (Expense)

Interest income was \$0.1 million for each of the three months ended September 30, 2021 and 2020, respectively. Interest income was \$0.5 million and \$0.6 million for the nine months ended September 30, 2021 and 2020. The decrease in interest income was primarily due to a decrease in the average investment balance as well as a decrease in interest rates over the period.

Interest expense was \$5.8 million and \$5.1 million for the three months ended September 30, 2021 and 2020, respectively. Interest expense was \$16.2 million and \$14.8 million for the nine months ended September 30, 2021 and 2020, respectively. The increase in interest expense was attributed to the loss on debt extinguishment of \$0.5 million recorded in connection with the 2021 Amended Credit Agreement, which resulted in the partial repayment of the final payment owed on the prior term loan agreement, as well as an increase in the amortization of the debt discount on the 2024 Convertible Notes.

We recorded other expense of \$0.4 million for the three months ended September 30, 2021, compared to \$0.5 million for the three months ended September 30, 2020. Other expense was \$1.3 million and \$0.6 million for the nine months ended September 30, 2021 and 2020, respectively. The increase in other expense was primarily due to changes in the price of debt securities, resulting in increased amortization of premiums, as well as an increase in foreign currency losses due to exchange rate fluctuations.

Liquidity and Capital Resources

For the nine months ended September 30, 2021, we generated \$74.1 million in net product revenue. We have incurred significant net losses in each year since our inception, including net losses of \$113.7 million, \$149.8 million, and \$169.7 million, for fiscal years 2020, 2019, and 2018, respectively, and \$81.1 million for the nine months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of \$863.4 million. We anticipate that we will continue to incur losses over the next few years.

Since our inception through September 30, 2021, 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, including amounts from our initial and follow-on public offerings, as well as our term loan and revolving credit facility and our 2024 Convertible Notes issuance. This funding is necessary to support the commercialization of ZILRETTA and to perform the research and development activities required to develop

our other product candidates in order to generate potential future revenue streams. We may not be able to obtain financing on acceptable terms, or at all. In particular, as a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any additional debt or equity financing more difficult, more costly, and more dilutive.

We expect that our research and development expenses will increase in 2021 and beyond 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.

If the recent decrease in revenue as compared to our expectations continues, we anticipate that absent raising additional capital through financing or other transactions, our cash balance is likely to decrease below \$100.0 million within the next twelve months. If this occurs, under the terms of the 2021 Amended Credit Agreement, we would become subject to a minimum revenue covenant and we believe there is substantial risk that we would fail to meet the minimum revenue covenant at that time or shortly thereafter. If we become subject to the minimum revenue covenant and fail to comply with it, the lenders could elect to declare all amounts outstanding to be immediately due and payable. While we would expect to request a waiver from the lenders, there can be no assurances that such a request would be granted or would not be conditioned on additional terms or concessions, or that we would be able to raise additional capital to avoid application of the minimum revenue covenant. These conditions raise substantial doubt about our ability to continue as a going concern for a period of one year after the date that the financial statements are issued.

As of September 30, 2021, we had cash, cash equivalents, and marketable securities of \$142.1 million. Management believes that current cash, cash equivalents, and marketable securities on hand at September 30, 2021, and taking into account our plans to reduce operating expenses, request a waiver of the minimum revenue covenant from the lenders, and remain opportunistic with respect to raising additional capital through financing or other transactions, should be sufficient to fund operations for at least the next twelve months from the issuance date of these financial statements. However, as we are expecting to close the planned merger with Pacira prior to the end of 2021, none of the above actions have been taken or have been approved to be taken and therefore cannot be considered in Management's going concern evaluation as a mitigating action.

We have concluded that without taking into consideration the planned merger with Pacira, Management's plans do not alleviate the substantial doubt about our ability to continue as a going concern. As the planned merger transaction with Pacira has not occurred as of the issuance of these financial statements, it also cannot be considered within Management's plans to alleviate the conditions raised around substantial doubt. As a result, in accordance with the requirements of ASC 205-40, management has concluded that it is required to disclose that substantial doubt exists about our ability to continue as a going concern for one year from the date the financial statements included in this report are issued.

Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with an objective of capital preservation.

On July 30, 2021, we entered into a second amendment (the "2021 Amended Credit Agreement") to our Amended and Restated Credit and Security Agreement (the "Existing Credit Agreement") with Silicon Valley Bank, as agent and lender, MidCap Financial Trust, MidCap Funding XIII Trust, and the other lenders from time to time party thereto (collectively, the "Lenders"), providing for a term loan facility of up to \$75.0 million, with \$55.0 million available at closing and an additional \$20.0 million (the "second tranche") available upon positive Phase 1 clinical trial data in either of our two pipeline programs, FX201 and FX301, sufficient to initiate a Phase 2 clinical study, and a revolving credit facility of up to \$25.0 million, both of which mature on February 1, 2024, which may be extended to July 1, 2026, upon satisfaction of certain specified conditions set forth in the 2021 Amended Credit Agreement (the "Maturity Date"). We concurrently borrowed the \$55.0 million term loan (the "2021 term loan"), simultaneously used \$48.1 million of the proceeds to repay the outstanding term loan under the Existing Credit Agreement, and drew down \$20.0 million from the revolving credit facility, bringing the total revolver balance to \$25.0 million.

The 2021 Amended Credit Agreement contains certain representations, warranties, and covenants, including a minimum revenue covenant that will be in effect at any time our liquidity (defined as cash, cash equivalents and marketable securities held with Silicon Valley Bank and certain accounts receivable as deemed eligible under the 2021 Amended Credit Agreement) is below \$100.0 million (if the second tranche is undrawn) or \$120.0 million (if the second tranche is drawn). Additionally, if our liquidity is below \$100.0 million, all amounts received from customer collections will be applied immediately to reduce the revolving credit facility. The minimum revenue covenant, if it applies in the future, is applied to the trailing six-months of net revenue and is determined based on our approved forecast, as determined by the Lenders. If the revenue covenant becomes applicable and we fail to comply with it, the amounts due under the 2021 Amended Credit Agreement could be declared immediately due and payable.

Term loan borrowings under the 2021 Amended Credit Agreement accrue interest monthly at a floating interest rate equal to the greater of (i) the Prime Rate plus 2.75% or (ii) 6.00% per annum. Under the term loan credit facility, following an interest-only period ending on August 1, 2023 (if the second tranche is undrawn) or August 1, 2024 (if the second tranche is drawn), principal is due in equal monthly installments through the Maturity Date. We may prepay the term loan at any time by paying the outstanding principal balance, a final payment equal to 4.75% of the term loan amount, all accrued interest, and a prepayment fee of 3% of the outstanding term loan

amount if repaid in the first year, 2% of the outstanding term loan amount if repaid in the second year, and 1% of the outstanding term loan amount if repaid in the third year of the loan; no prepayment fee is required thereafter.

Revolving borrowings under the 2021 Amended Credit Agreement accrue interest monthly at a floating interest rate equal to the greater of (i) the Prime Rate plus 1.75% or (ii) 5.00% per annum. The revolving credit facility is co-terminus with the term loan credit facility. If the interest payment on the revolving credit facility is less than the amount of interest that would have been payable had we borrowed 25% of the total commitments under the revolving credit facility, or the Revolving Commitment Amount, then we will be required to pay the difference. We are also required to pay a facility fee in respect of the revolving credit facility equal to 0.5% of the

Revolving Commitment Amount payable at closing and 0.5% of the Revolving Commitment Amount payable on the first anniversary of closing. We may retire the revolving credit facility early, at any time, by paying the outstanding principal balance, all accrued interest, and a termination fee equal to 2% of the Revolving Commitment Amount if repaid in the first year, and 1% of the Revolving Commitment Amount if repaid in the second year; with no termination fee thereafter. To the extent any portion of the Revolving Commitment Amount is undrawn, we will be required to pay an “unused line fee” equal to 0.25% per annum of the average unused portion of the Revolving Commitment Amount, calculated on a calendar year basis as an amount equal to the difference between (i) the Revolving Commitment Amount and (ii) the greater of (A) 25.0% of the Revolving Commitment Amount, and (B) the average for the period of the daily closing balance of the Revolving Commitment Amount outstanding.

On November 4, 2020, we entered into a Distribution Agreement with Goldman Sachs & Co. LLC and Credit Suisse Securities (USA) LLC (collectively, the “Managers”) relating to the issuance and sale from time to time of up to \$100,000,000 of shares of our common stock. Under the terms of the Distribution Agreement, we will pay the Managers a commission of up to 3% of the gross sales price of any shares sold. As of September 30, 2021, 134,048 shares had been sold under the Distribution Agreement, for total net proceeds of \$1.7 million.

We are subject to a variety of specified liquidity and capitalization restrictions under the Merger Agreement. Unless we obtain Pacira’s prior written consent (which consent may not be unreasonably withheld, conditioned or delayed) and except (i) as required or expressly contemplated by the Merger Agreement, (ii) as required by applicable law or (iii) as set forth in the confidential disclosure schedule we delivered to Pacira, we may not, among other things and subject to certain exceptions and aggregate limitations, incur additional indebtedness, issue additional shares of our common stock outside of our equity incentive plans, repurchase our common stock, pay dividends, acquire assets, securities or property, dispose of businesses or assets, enter into material contracts or make certain additional capital expenditures.

The following table shows a summary of our cash flows for the nine months ended September 30, 2021 and 2020:

<i>(In thousands)</i>	Nine Months Ended September 30,	
	2021	2020
Cash flows used in operating activities	\$ (51,441)	\$ (60,819)
Cash flows provided by (used in) investing activities	60,234	(10,665)
Cash flows provided by financing activities	20,327	117,868
Net increase in cash and cash equivalents	\$ 29,120	\$ 46,384

Net Cash Used in Operating Activities

Operating activities used \$51.4 million of cash in the nine months ended September 30, 2021. Cash used in operating activities resulted primarily from our net loss for the period of \$81.1 million, partially offset by changes in our operating assets and liabilities of \$2.9 million and non-cash charges of \$26.7 million. Changes in our operating assets and liabilities consisted primarily of a \$0.7 million decrease in accounts receivable and an increase of \$6.0 million in accounts payable and accrued expense, partially offset by a \$1.5 million increase in prepaid expenses and other current assets, a \$1.0 million increase in inventory, and a \$1.1 million decrease in lease liabilities primarily due to principal lease payments. Our non-cash charges consisted primarily of \$12.8 million of stock-based compensation expense, \$7.8 million related to the amortization of the debt discount and debt issuance costs related to the 2024 Convertible Notes, \$1.3 million related to the amortization of right-of-use assets, \$1.6 million of depreciation, \$0.5 million of non-cash interest expense related to amortization of the final payment due on the 2021 term loan, \$0.4 million of amortization of premiums paid for the purchase of marketable securities, \$0.5 million related to the loss of debt extinguishment, and \$1.8 million related to the provision for inventory for the write-down of short-dated ZILRETTA inventory that is not expected to be sold prior to expiry.

Operating activities used \$60.8 million of cash in the nine months ended September 30, 2020. The cash flow used in operating activities resulted primarily from our net loss for the period of \$94.1 million, partially offset by changes in our operating assets and liabilities of \$10.1 million and non-cash charges of \$23.1 million. Changes in our operating assets and liabilities consisted primarily of a \$9.2 million decrease in accounts receivable, and a \$10.0 million increase in deferred revenue related to the license agreement with HK Tainuo, partially offset by a \$1.1 million increase in inventory, a \$0.5 million increase in prepaid expenses and other current assets, a decrease of \$6.5 million in accounts payable and accrued expenses and a \$1.0 million decrease in lease liabilities and other long-term liabilities primarily due to principal lease payments. Our non-cash charges consisted primarily of \$13.4 million of stock-based compensation expense, \$6.9 million related to the amortization of the debt discount and debt issuance costs related to the 2024 Convertible Notes, \$1.2 million related to the amortization of right-of-use assets, \$1.3 million of depreciation, \$0.5 million of non-cash interest expense related to amortization of the final payment due on the 2019 term loan and \$0.3 million related to the loss on disposal of fixed assets, partially offset by \$0.5 million of premiums paid for the purchase of marketable securities.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$60.2 million in the nine months ended September 30, 2021. Net cash provided by investing activities consisted primarily of cash received for the redemption and sale of marketable securities of \$67.1 million, partially offset by cash used to purchase marketable securities of \$5.2 million and capital expenditures of \$1.7 million, primarily relating to the purchase of equipment associated with the expansion of our manufacturing facilities at Patheon.

Net cash used in investing activities was \$10.7 million in the nine months ended September 30, 2020. Net cash used in investing activities consisted primarily of purchases of marketable securities of \$56.2 million and capital expenditures of \$8.9 million, primarily relating to the purchase of equipment associated with the expansion of our manufacturing facilities at Patheon. These expenses were partially offset by cash received for the redemption and sale of marketable securities of \$54.4 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$20.3 million for the nine months ended September 30, 2021, which consisted of \$55.0 million and \$20.0 million of additional term loan and revolving credit facility borrowings, respectively, under the 2021 Amended Credit Agreement, \$0.9 million related to employee stock purchases through our employee stock purchase plan, and \$1.7 million related to the net proceeds received from the sale of common stock under our Distribution Agreement. Increases were partially offset by a decrease of \$56.9 million of principal payments and partial repayment of the final payment under the 2019 term loan, \$0.2 million related the payment of debt issuance costs related to the 2021 Amended Credit Agreement, and \$0.1 million of public offering costs paid during the period.

Net cash provided by financing activities was \$117.9 million for the nine months ended September 30, 2020, of which \$97.2 million related to the net proceeds received from the offering of our common stock, partially offset by public offering costs paid during the period of \$0.4 million, \$0.1 million received from the exercise of stock options and \$0.9 million relating to employee stock purchases through our employee stock purchase plan, as well as \$20.0 million borrowed under the revolving credit facility associated with our 2019 term loan.

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 2020 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2020, other than as described in Notes 9, 12, and 13 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 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.

Term Loans

We have borrowed \$55.0 million in term loans under our 2021 Amended Credit Agreement. Term loan borrowings under the 2021 Amended Credit Agreement accrue interest monthly at a floating interest rate equal to the greater of (i) the Prime Rate plus 2.75% or (ii) 6.0% per annum.

Revolving Credit Facility

We have borrowed \$25.0 million under the revolving credit facility. Under the 2021 Amended Credit Agreement, borrowings under the revolving credit facility accrue interest monthly at a floating interest rate equal to the greater of (i) the Prime Rate plus 1.75% or (ii) 5.0% per annum. In addition to paying interest on any amounts borrowed under the revolving credit facility, we may in the future owe an unused revolving line facility fee equal to 0.25% per annum of the average unused portion of the revolving line, multiplied by the

difference between the total amount available to be borrowed (the “Revolving Commitment Amount”) and the greater of the average outstanding revolver balance and 25% of the Revolving Commitment Amount.

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 \$179.8 million at September 30, 2021.

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 September 30, 2021, we had \$2.5 million in liabilities denominated in British Pounds. A hypothetical 10% change in foreign exchange rates would result in a \$0.2 million change in the value of our liabilities. No other payables to vendors were denominated in currencies other than in U.S. dollars. As of September 30, 2021, we had \$2.6 million of cash denominated in British Pounds. A hypothetical 10% change in foreign exchange rates would result in a \$0.3 million 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.

In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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 September 30, 2021, the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2021, 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

Between October 22, 2021, and November 10, 2021, eleven Complaints were filed in federal court by purported stockholders of the Company regarding the Merger. The Complaints name the Flexion Defendants (defined above as the Company and each member of our board of directors) as defendants. The *Waterman* complaint additionally names as defendants the Pacira Defendants. The plaintiffs generally contend that the Solicitation/Recommendation Statement on Schedule 14D-9 that we filed on October 22, 2021, omitted or misrepresented material information regarding the Merger. The *Hart* complaint additionally alleges that we engaged in an insufficient sales process and that members of our board of directors and our management had conflicts of interest with stockholders of the Company. The Complaints allege violations of Section 14(d) and/or Section 14(e) of the Exchange Act against all Flexion Defendants, and assert violations of Section 20(a) of the Exchange Act against the members of our board of directors. The *Waterman* complaint additionally alleges violations of Section 14(d), Section 14(e), and Section 20(a) of the Exchange Act against the Pacira Defendants. The Complaints collectively seek, among other relief, (i) injunctive relief preventing the consummation of the transactions contemplated by the Merger Agreement; (ii) rescission and/or rescissory damages in the event the transactions contemplated by the Merger Agreement are consummated; (iii) other damages purportedly incurred on account of defendants' alleged misstatements or omissions; (iv) disclosure of certain information requested by the plaintiffs; (v) declaratory relief stating defendants violated the Exchange Act; and (vi) an award of plaintiffs' expenses and attorneys' fees. The Flexion Defendants have been served with the *Wang* complaint and the *Hart* complaint but have not been served with any of the other Complaints. On November 12, 2021, we filed a Schedule 14D-9/A containing certain supplemental disclosures in order to moot the claims alleged in the Complaints. The Flexion Defendants' deadline to respond to the *Wang* complaint is December 27, 2021, and the Flexion Defendants' deadline to respond to the *Hart* complaint is January 3, 2022. Each of the Flexion Defendants and the Pacira Defendants intend to vigorously defend these actions.

ITEM 1A. RISK FACTORS

As disclosed in "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed on March 10, 2021, there are a number of risks and uncertainties that may have a material effect on our business, financial condition, results of operations, and future growth prospects. There are also additional risks and uncertainties that we are unaware of that may become important factors that affect us, including as a result of the potential acquisition by Pacira. The following risk factors are either new or have changed materially from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2020. You should carefully review the risks described below and in our Annual Report on Form 10-K and in other reports we file with the Securities and Exchange Commission in evaluating our business.

Risks Related to Our Pending Acquisition by Pacira BioSciences, Inc.

The announcement and pendency of our agreement to be acquired by Pacira may have an adverse effect on our business, operating results, and our stock price and may result in the loss of employees, customers, suppliers, and other business partners.

On October 11, 2021, we entered into the Merger Agreement with Pacira and Purchaser, providing for the merger of Purchaser with and into Flexion, with Flexion surviving the Merger as a wholly owned subsidiary of Pacira. We are subject to risks in connection with the announcement and pendency of the Merger, including, but not limited to, the following:

- market reaction to the announcement of the Merger;
- changes in our business, operations, financial position, and prospects;
- market assessments of the likelihood that the Merger will be consummated;
- the amount of consideration offered per Share will not be increased to account for positive changes in our business, assets, liabilities, prospects, outlook, financial condition, or results of operations during the pendency of the Merger, including any successful execution of our current strategy as an independent company or in the event of any change in the market price of, analyst estimates of, or projections relating to, our common stock;
- potential adverse effects on our relationships with our existing and prospective customers, suppliers, and other business partners due to uncertainties about the Merger, including such customers, suppliers, and other business partners choosing to (i) delay, defer, or cease purchasing products or services from, or providing products or services to, us or the combined company;

(ii) delay or defer other decisions concerning us or the combined company; or (iii) otherwise seek to change the terms on which they do business with us or the combined company;

- we have incurred, and will continue to incur, significant costs, expenses, and fees for professional services and other transaction costs in connection with the Merger, and many of these fees and costs are payable by us regardless of whether the Merger is consummated;

- potential adverse effects on our ability to attract, recruit, retain, and motivate current and prospective employees who may be uncertain about their future roles and relationships with us following the completion of the Merger, and the possibility that our employees could lose productivity as a result of uncertainty regarding their employment following the Merger;
- the pendency and outcome of legal proceedings that have been and may be instituted against us or our board of directors, executive officers, and others relating to the transactions contemplated by the Merger Agreement, which could be time-consuming and expensive and delay or prevent the consummation of the Merger; and
- the possibility of disruption to our business, including increased costs and diversion of management time and resources that could otherwise have been devoted to other opportunities that may have been beneficial to us.

While the Merger is pending, we are subject to contractual restrictions that could harm our business, operating results, and our stock price.

The Merger Agreement includes restrictions on the conduct of our business prior to the completion of the Merger, generally requiring us to conduct our businesses in the ordinary course, consistent with past practice, and restricting us from taking certain specified actions absent Pacira's prior written consent, including, without limitation, restrictions on our ability to enter into contracts, acquire or dispose of assets, raise equity capital, incur indebtedness, or incur certain capital expenditures. We may find that these and other obligations in the Merger Agreement may delay or prevent us from or limit our ability to respond effectively to competitive pressures, industry developments, and future business opportunities that may arise, even if our management and board of directors think they may be advisable. These restrictions could adversely impact our business, operating results, and our stock price and our perceived acquisition value, regardless of whether the Merger is completed.

The failure to complete the Merger may adversely affect our business and our stock price.

Consummation of the Merger is subject to certain closing conditions, and a number of the conditions are not within our control and may prevent, delay, or otherwise materially adversely affect the completion of the transaction. We cannot predict with certainty whether and when any of the required closing conditions will be satisfied or if another uncertainty may arise and cannot assure you that we will be able to successfully consummate the proposed merger as currently contemplated under the Merger Agreement or at all. Such conditions include, among other things, (i) valid tender (without withdrawal) of Shares that represent at least one Share more than 50% of the then issued and outstanding Shares; (ii) subject to certain materiality qualifications, the continued accuracy of our representations and warranties, and our continued compliance with covenants and obligations (to be performed at or prior to the closing of the Merger); (iii) the absence of any continuing Material Adverse Effect (as defined in the Merger Agreement) on our business, assets, financial condition, or results of operations occurring after the date of the Merger Agreement; (iv) expiration or termination of any waiting periods applicable to the consummation of the Merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended; and (v) the absence of any legal restraints prohibiting the Merger and of certain legal proceedings brought by a governmental entity relating to the Merger. There can be no assurance that these conditions to the consummation of the Merger will be satisfied, or that the Merger will be completed on the proposed terms, within the expected timeframe or at all. If the Merger is not completed, we may be subject to negative publicity or be negatively perceived by the investment or business communities and our stock price could fall to the extent that our current stock price reflects an assumption that the Merger will be completed. Furthermore, if the Merger is not completed, we may suffer other consequences that could adversely affect our business and results of our operations, including, but not limited to, the filing of associated litigation, difficulties in raising additional capital or obtaining other financing, damage to relationships with vendors or customers, and loss of key personnel.

The Merger Agreement limits our ability to pursue alternative transactions, which could deter a third party from proposing an alternative transaction.

The Merger Agreement contains provisions that, subject to certain exceptions, limit our ability to (i) directly or indirectly, solicit, initiate, or knowingly facilitate or encourage (including by way of furnishing non-public information) any inquiry regarding, or the making of any proposal or offer that could reasonably be expected to lead to, an acquisition proposal; (ii) engage in, continue, or otherwise participate in any discussions or negotiations regarding, or furnish to any other person any information in connection with or for the purpose of knowingly encouraging or facilitating, an acquisition proposal; (iii) adopt, approve, or enter into any letter of intent, acquisition agreement, agreement in principle, or similar agreement with respect to an acquisition proposal or any proposal or offer that could reasonably be expected to lead to an acquisition proposal; or (iv) waive or release any person from, or fail to use reasonable best efforts to enforce, any standstill obligations relating to an acquisition proposal or any proposal or offer that could reasonably be

expected to lead to an acquisition proposal. It is possible that these or other provisions in the Merger Agreement, including a termination fee of \$18.0 million payable to Pacira under certain circumstances, might discourage a potential competing acquirer that might have an interest in acquiring all or a significant part of our outstanding common stock from considering or proposing an acquisition or might result in a potential competing acquirer proposing an overall lower per-share consideration amount than it might otherwise have proposed to offer.

If the Merger occurs, our stockholders will not be able to participate in any financial upside to our business after the Merger other than through the CVRs; if the required milestones under the CVRs are not achieved, stockholders will not realize any value from the CVRs.

Upon consummation of the Merger, each issued and outstanding share will be converted into the right to receive (i) \$8.50 per Share in cash, net of applicable withholding taxes and without interest, plus (ii) one non-transferable contractual contingent value right (“CVR”) per Share, which will represent the right to receive one or more contingent payments up to \$8.00 in the aggregate, in cash, net of applicable withholding taxes and without interest, upon the achievement of specified milestones pursuant to the terms of the Contingent Value Right Agreement in the form attached as Exhibit C to the Merger Agreement (the “CVR Agreement”). Following the consummation of the Merger, whether any of the milestones are achieved will be subject to Pacira’s commercially reasonable efforts and activities, over which our stockholders will have no control, and there is no guarantee that any of the milestones will be achieved. If none of the milestones specified in the CVR Agreement are achieved on or before December 31, 2030, no payment will be made under the CVRs, and the CVRs will expire valueless.

The tax treatment of the CVRs is unclear.

The U.S. federal income tax treatment of the CVRs is unclear. There is no legal authority directly addressing the U.S. federal income tax treatment of the receipt of, and payments (if any) under, the CVRs, and there can be no assurance that the Internal Revenue Service would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs.

Additional lawsuits may be filed against us and the members of our board of directors arising out of the proposed Merger, which may delay or prevent the proposed Merger.

Additional putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against us, our board of directors, Pacira, Pacira’s board of directors, and others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, and we may not be successful in defending against any such future claims. Lawsuits that may be filed against us, our board of directors, Pacira, or Pacira’s board of directors could delay or prevent the consummation of the Merger, divert the attention of our management and employees from our day-to-day business, and otherwise adversely affect us financially.

We will incur substantial transaction fees and costs in connection with the Merger.

As of September 30, 2021, we have incurred \$0.7 million of expenses and fees for professional services and other transaction costs in connection with the Merger and expect to continue to incur additional significant costs. A material portion of these expenses are payable by us whether or not the Merger is completed. While we have assumed that a certain amount of transaction expenses will be incurred, factors beyond our control could affect the total amount or the timing of these expenses. Many of the expenses that will be incurred, by their nature, are difficult to estimate accurately. These expenses may exceed the costs historically borne by us. These costs could adversely affect our business, financial condition, operating results, and cash flows.

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.

On August 2, 2019, we entered into an Amended and Restated Credit and Security Agreement with Silicon Valley Bank, MidCap Financial Trust, and Flexpoint MCLS Holdings, LLC, or the Credit Agreement, which provides for a term loan of \$40.0 million and a revolving credit facility up to \$20.0 million. We concurrently drew down the \$40.0 million term loan and used \$7.7 million of the proceeds to repay the remaining amount owed on our prior credit facility. In February 2020, we drew down \$20.0 million from the revolving credit facility. On May 18, 2020, we entered into an amendment to the Credit Agreement pursuant to which we borrowed \$15.0 million under a new term loan advance and immediately used the proceeds to repay an equal amount under the revolving credit facility, and the maximum principal amount of the revolving credit facility was reduced from \$20.0 million to \$5.0 million. On July 30, 2021, we entered into a second amendment, or the 2021 Amended Credit Agreement, to the Credit Agreement, which provides for a term loan of up to \$75.0 million, with \$55.0 million available at closing and an additional \$20.0 million, or the second tranche, available upon positive Phase 1 clinical trial data in either of our two pipeline programs, FX201 and FX301, sufficient to initiate a Phase 2 clinical study, and a revolving credit facility of up to \$25.0 million. We concurrently borrowed the \$55.0 million term loan, simultaneously used \$48.1 million of the proceeds to repay the previously outstanding term loan under the Credit Agreement, and drew down \$20.0 million from the revolving credit facility, bringing the total revolver balance to \$25.0 million. The 2021 Amended 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.

Under the 2021 Amended Credit Agreement we are subject to a minimum liquidity threshold, such that at any time our liquidity (defined as cash, cash equivalents, and marketable securities held with Silicon Valley Bank and certain accounts receivable as deemed eligible under the 2021 Amended Credit Agreement) is below \$100.0 million (if the second tranche is undrawn) or \$120.0 million (if the second tranche is drawn), we will become subject to a minimum revenue covenant. The minimum revenue covenant, if it applies in the future, is applied to the trailing six months of net revenue and is determined based on our approved forecast, as determined by the Lenders.

If the revenue covenant becomes applicable to us and we fail to meet it, the commitments under the 2021 Amended Credit Agreement could be terminated and any outstanding borrowings, together with accrued interest, under the 2021 Amended Credit Agreement could be declared immediately due and payable. Additionally, if our liquidity is below \$120.0 million, all amounts received from customer collections will be applied immediately to reduce the revolving credit facility. The restrictive covenants in the 2021 Amended 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 2021 Amended 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 2021 Amended Credit Agreement. In the case of a continuing event of default under the 2021 Amended 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 2021 Amended Credit Agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the 2021 Amended 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 the 2024 Convertible Notes are not redeemed or repurchased on or before their maturity date of May 1, 2024, we will be required to convert all or a portion of the amounts due under the 2024 Convertible Notes into common stock, which would cause our stockholders to experience additional dilution and could cause our stock price to fall. If specified bankruptcy, insolvency, or reorganization-related events of default occur, or if certain other events of default occur, including a default under the 2021 Amended Credit Agreement resulting in an obligation to repay the indebtedness, 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, including, but not limited to the consummation of the Merger, 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 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.

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 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.

General Business Risks

COVID-19 will likely continue to have an adverse impact on our clinical trials and further development of our pipeline.

COVID-19's impact on the healthcare industry is significant and has impacted our on-going clinical trials and may disrupt further development of our pipeline. For example, in April 2020, we temporarily suspended the active Phase 1 clinical trial evaluating the safety and tolerability of FX201. The decision was made in consideration of guidance from the FDA to ensure the safety of trial participants and minimize risk to trial integrity from disruptions caused by COVID-19. In addition, we decided to terminate the Phase 2 trial evaluating the efficacy of ZILRETTA in patients with shoulder OA and adhesive capsulitis, given the small number of patients enrolled in the trial, the uncertainty as to when we would be able to restart the study, and the costs required to maintain it in an inactive status. While we subsequently restarted our Phase 1 clinical trial of FX201 in late May 2020, intend to initiate a trial investigating ZILRETTA in patients with shoulder OA following our reassessment of the proposed study design, and have started clinical development of FX301, we cannot guarantee that COVID-19's impact or restrictions implemented by government agencies or healthcare facilities in response to COVID-19 will not force us to delay, suspend, or terminate these trials, and we cannot predict how access to, utilization of, and efficacy of COVID-19 vaccines may influence such impacts and restrictions. These impacts of COVID-19 will increase the costs of completing clinical development and delay our ability to obtain marketing approval for our pipeline product candidates and ZILRETTA for additional indications.

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

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 its approved indication. In addition, we must train our sales force to ensure that an appropriate and compliant message about ZILRETTA is being delivered. Due to the COVID-19 pandemic, our MBMs have been using a mix of in-person and virtual interactions with physicians to convey key information about ZILRETTA and aid physicians and their staff in prescribing and obtaining reimbursement for ZILRETTA. While we have attempted to maintain the effectiveness of our sales and marketing efforts, it may not be as effective as in the pre-COVID environment, as access to some providers remains limited. If we are unable to maintain an effectively trained sales force, equip them with compliant and effective materials, including medical and sales literature to help them appropriately inform and educate customers regarding the potential benefits and safety of ZILRETTA and its proper administration, and deploy them in an efficient and productive manner, our efforts to successfully commercialize ZILRETTA could be jeopardized, which would negatively impact our ability to generate product revenues.

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 any other products approved for sale 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 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.

For example, the Patient Protection and Affordable Care Act, as amended, or PPACA, 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 imposition of additional fees, an increase in required rebates and a change in their method of calculation, discounts to eligible beneficiaries under Medicare Part D, expanded discount eligibility for entities under the Public Health Service pharmaceutical pricing program, expansion of the range of existing manufacturer liabilities, expanded eligibility for Medicaid programs, additional reporting requirements, expansion of and enhanced penalties under fraud and abuse laws, and improved market access for follow-on biologic products. There have been legal and political challenges to PPACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the PPACA will remain in effect in its current form. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform efforts of the Biden administration will impact PPACA and our business. 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. It is also possible that additional governmental action is taken in response to COVID-19.

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 due to a variety of factors, including the following:

- success or perceived success of the commercialization of ZILRETTA;
- the impact and duration of COVID-19 and actions taken to mitigate its spread;
- inability to obtain approval for additional indications for 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 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, 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 have not yet fully commercialized ZILRETTA, we and the analysts who cover our company have limited ability to accurately predict future sales results, and actual results may differ materially from expectations.

In addition, the stock market in general, and the Nasdaq Global Market in particular, has experienced extreme price and volume fluctuations, and we have in the past experienced volatility that we believe has been unrelated or disproportionate to our operating performance. For example, during the first quarter of 2020, the closing price of our common stock ranged from \$5.53 to \$21.13 per share. Broad market and industry factors may continue to negatively affect the market price of our common stock, regardless of our operating performance. For example, there have been instances of groups of investors buying shares of a company's stock in order to drive up its market price, thereby causing traders who have bet that the stock price would fall and contracted to sell shares of that stock

with a plan to buy those shares after the share price has fallen (*i.e.*, those who have “shorted” the stock) to buy in as well to forestall even greater losses; this is known as a “short squeeze.” These short squeezes have caused extreme volatility in both the stock prices of the companies involved and in the market and have led to the shares of those companies trading at a significantly inflated price per share that is disconnected from the underlying value of the company. Many investors who have purchased shares in those companies at an inflated share price face the risk of losing a significant portion of their original investment, as in many cases the price per share has declined steadily as interest in those stocks has abated. While we do not believe that our common stock has been the target of a short squeeze, there can be no assurance that our common stock will not be impacted by unusual trading activity in the future or that the price of our common stock will not become significantly disconnected from our underlying value.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or the conversion of our debt securities, 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 such equity securities in one or more transactions at prices, under terms, and in a manner as we may determine from time to time. These sales may 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, we are 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 this plan automatically increases 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 reduce the size of any such increase. Currently, we plan to register the increased number of shares available for issuance under this plan each year. If our board of directors elects to increase the number of shares available for future grant by a significant amount each year, our stockholders would experience additional dilution, which could cause our stock price to fall.

If the 2024 Convertible Notes are not redeemed or repurchased on or before their maturity date of May 1, 2024, we will be required to convert all or a portion of the amounts due under the 2024 Convertible Notes into common stock, which would cause our stockholders to experience additional dilution and could cause our stock price to fall.

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
2.1*	Agreement and Plan of Merger, dated as of October 11, 2021, by and among Flexion Therapeutics, Inc., Pacira BioSciences, Inc., and Oyster Acquisition Company Inc. (Exhibit 2.1, Current Report on Form 8-K, filed with the SEC on October 12, 2021).
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).
10.1	Form of Tender and Support Agreement, dated as of October 11, 2021 (Exhibit 10.1, Current Report on Form 8-K, filed with the SEC on October 12, 2021).
10.2**	Manufacturing and Supply Agreement, dated July 31, 2015, by and between Flexion and Patheon UK Limited.
10.3**	Technical Transfer and Service Agreement, dated July 31, 2015, by and between Flexion and Patheon UK Limited.
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 Accounting and 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 Accounting and 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	Inline eXtensible Business Reporting Language (XBRL) Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Certain exhibits and schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Flexion agrees to furnish supplementally to the SEC a copy of any omitted exhibits or schedules upon request; provided that Flexion may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act.

** Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted by means of marking such portions with asterisks because Flexion has determined that the information is not material and would likely cause competitive harm to Flexion if publicly disclosed.

SIGNATURES

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

Flexion Therapeutics, Inc.

Date: November 12, 2021

By: /s/ Michael D. Clayman

Michael D. Clayman
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2021

By: /s/ Frederick W. Driscoll

Frederick W. Driscoll
Chief Financial Officer
(Principal Accounting and Financial Officer)

MANUFACTURING AND SUPPLY AGREEMENT

*** Certain Confidential Information Omitted - 1 -

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [*], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

MANUFACTURING AND SUPPLY AGREEMENT

This **MANUFACTURING AND SUPPLY AGREEMENT** (this “Agreement”) dated as of July 31, 2015 (the “Effective Date”) is made by and between Flexion Therapeutics, Inc., a Delaware corporation having its principal place of business at 10 Mall Road, Suite 301, Burlington, Massachusetts, United States (“Flexion”) and Patheon UK Limited, a company incorporated in England and Wales having its principal place of business at Kingfisher Drive, Covingham, Swindon, SN35BZ, United Kingdom (“Patheon”). Flexion, and Patheon are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

RECITALS

WHEREAS, Flexion has a commercial interest in the Manufacture (as defined herein) and commercialization of FX006 drug product, an extended-release formulation of triamcinolone acetonide (TCA) which is manufactured using the Flexion Manufacturing Process (the “Product”);

WHEREAS, Patheon has expertise and experience in manufacturing and packaging pharmaceutical products and is interested in providing Manufacturing services to Flexion in connection with the Product;

WHEREAS, in anticipation of this Agreement and the goods and services that Patheon will supply hereunder, the Parties are executing an agreement pursuant to which Patheon would undertake certain technical transfer and construction services in order to validate and scale up Flexion’s technology package and prepare Patheon’s facilities for the Manufacture of the Product (the “Technical Transfer Agreement”); and

NOW, THEREFORE, in consideration of the foregoing, the mutual promises and covenants of the Parties contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

ARTICLE I. DEFINITIONS

The following terms shall have the meanings set forth below. Unless the context indicates otherwise, the singular shall include the plural and the plural shall include the singular. Any term not defined hereunder shall have the meaning ascribed to such term in the Technical Transfer Agreement.

1.1 “Additional Services” means any services requested and approved by Flexion that supplement Patheon’s regular performance of the Services, as described in Schedule 2.1(a).

1.2 “Affiliate(s)” means, with respect to any Person, any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. For the purposes of this Section 1.2 only, a Person will be regarded as in control of another Person if such Person owns, or directly or indirectly controls, more than 50% of the voting securities (or comparable equity interests) or other

*** Certain Confidential Information Omitted - 2 -

ownership interests of the other Person, or if such Person directly or indirectly possesses the power to direct or cause the direction of the management or policies of the other Person, whether through the ownership of voting securities, by contract, or any other means whatsoever.

1.3 “Agreed Delivery Date” has the meaning set forth in Section 2.3(d).

1.4 “Agreement” has the meaning set forth in the Preamble hereto.

1.5 “API” means the active pharmaceutical ingredient Triamcinolone Acetonide, Micronised.

1.6 “Applicable Law” means applicable United States, Canadian, English and other foreign federal, state, and local laws, orders, rules, regulations, guidelines, standards, customs and ordinances, including, without limitation, those (to the extent they are applicable) of the FDA, Health Canada, the Medicines and Healthcare Products Regulatory Agency in the United Kingdom and other comparable foreign Regulatory Authorities, including the FDA Act.

1.7 “Base Fee” means the monthly fee paid by Flexion in consideration for the Services, as more specifically set forth in Schedule 2.1(a) of this Agreement. For the avoidance of doubt, Base Fees do not include Capital Expenditures (as defined in the Technical Transfer Agreement), Product Fees, Material Costs, or charges for Bill Back Items or Additional Services.

1.8 “Bill Back Items” means the items and services set forth in Schedule 2.1(a) that are used or necessary in connection with the Manufacture of the Products and which result in a nominal cost to Flexion.

1.8a “Certificate of Analysis” means a certificate evidencing the analytical tests conducted on a specific batch of Product or Material and setting forth, *inter alia*, the items tested, specifications, and test results.

1.9 “Certificate of Compliance” means a certificate stating that a specific batch of Product complies with the warranty set forth in Section 6.3.

1.11 “Change of Control” has the meaning set forth in Section 10.5A.

1.12 “Claim” has the meaning set forth in Section 9.3(a).

1.13 “Control” or “Controlled” means ownership or the right by a Party to assign or grant a license or sublicense under intellectual property rights to the other Party of the scope set forth herein, without breaching the terms of any agreement with a Third Party.

1.14 “Diligent and Reasonable Steps” has the meaning set forth in Section 6.4(a).

1.15 “Deficiency Notice” has the meaning set forth in Section 2.8(a).

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- 1.16 “Disclosing Party” has the meaning set forth in Section 1.90.
- 1.17 “Discretionary Manufacturing Changes” has the meaning set forth in Section 2.9(c).
- 1.18 “Effective Date” has the meaning set forth in the Preamble hereto
- 1.19 “EMA” means the European Medicines Agency.
- 1.20 “Equipment” means any equipment used in the Manufacture of the Product as more fully set forth in Section 2.9 herein.
- 1.21 “Existing Flexion Intellectual Property” has the meaning set forth in Section 5.1(a).
- 1.22 “Existing Patheon Intellectual Property” has the meaning set forth in Section 5.1(b).
- 1.23 “Expected Yield Rate” has the meaning set forth in Section 2.8(f).
- 1.24 “Expert” has the meaning set forth in Section 2.8(e).
- 1.25 “Exploit” means to make, have made, import, use, sell, offer for sale, receive or otherwise dispose of a product or process, including the research, development (including the conduct of clinical trials), registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, export, transport, distribution, promotion, or marketing of a product or process.
- 1.26 “Facility” means the facility of Patheon located at Kingfisher Drive, Swindon, Wiltshire SN3 5BZ, United Kingdom, or such other facility approved in accordance with Section 3.3(a).
- 1.27 “FDA” means the United States Food and Drug Administration and any successor organization thereto and all agencies under its direct control.
- 1.28 “FDA Act” means the Federal Food, Drug, and Cosmetic Act, as amended.
- 1.29 “FDA Approval Date” means the date of receipt of FDA approval allowing for Patheon’s manufacturing, testing, and packaging for the Product from the Phase I Filling Space and Phase II Manufacturing Space.
- 1.30 “Filing Party” has the meaning set forth in Section 3.15(a).
- 1.31 “Flexion” has the meaning set forth in the Preamble hereto.
- 1.32 “Flexion Assignors” has the meaning set forth in Section 5.1(m).

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1.33 “Flexion Improvements” has the meaning set forth in Section 5.1(e)(ii).

1.34 “Flexion Indemnified Parties” has the meaning set forth in Section 9.2.

1.35 “Flexion Manufacturing Equipment” has the meaning set forth in Section 2.9(a).

1.36 “Flexion Manufacturing Equipment Improvements” has the meaning set forth in Section 5.1(e)(i).

1.37 “Flexion’s Manufacturing Process” means the proprietary process owned or Controlled by Flexion for Manufacturing the Product, as disclosed by Flexion to Patheon, and each intermediate of the Product, as established as of the Effective Date, including without limitation, as set forth in the investigational new drug application filed with the FDA, and, when applicable, as set forth in the NDA as may be filed with, and approved by, the FDA.

1.38 “Flexion’s Manufacturing Process Improvements” has the meaning set forth in Section 5.1(e)(i).

1.39 “Flexion On Site Representative” has the meaning set forth in Section 3.4.

1.40 “Flexion Product Improvements” has the meaning set forth in Section 5.1(e)(i).

1.41 “Flexion Specification Improvements” has the meaning set forth in Section 5.1(e)(i).

1.41a “Flexion Specific Improvements” has the meaning set forth in Section 5.1(e)(i)

1.42 “Flexion-Supplied Materials” has the meaning set forth in Section 2.2(a).

1.43 “Forecast” has the meaning set forth in Section 2.3(a).

1.44 “GMP” means the current good manufacturing practices applicable from time to time to the Manufacturing of the Product, or any intermediate of the Product, pursuant to Applicable Law, including those promulgated under the FDA Act at 21 C.F.R. (chapters 210 and 211), and those promulgated under EC Directive 2003/94/EC, together with the latest FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time.

1.45 “Indemnification Claim Notice” has the meaning set forth in Section 9.3(a).

1.46 “Indemnified Party” has the meaning set forth in Section 9.3(a).

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- 1.47 “Indemnifying Party” has the meaning set forth in Section 9.3(a).
- 1.48 “Initial Draft” has the meaning set forth in Section 3.15(b).
- 1.49 “Initial Term” has the meaning set forth in Section 8.1.
- 1.50 “Key Personnel” has the meaning set forth in Section 2.1(f).
- 1.51 “Late Product” has the meaning set forth in Section 2.7(b).
- 1.52 “Letter Agreement” means the Letter Agreement between the Parties dated 1 May 2015.
- 1.53 “Long Term Forecast” has the meaning set forth in Section 2.3(b).
- 1.54 “Loss” means any claims, lawsuits, losses, damages, liabilities, penalties, costs, and expenses (including reasonable attorneys’ fees and disbursements).
- 1.55 “Maintenance” means the maintenance of Equipment and Facilities in satisfactory operating condition, including the performance of systematic inspection and service of Equipment pursuant to the applicable Standard Operating Procedures of Patheon, as reviewed and agreed to by Flexion (the “Equipment Standard Operating Procedures”), or the manufacturer’s terms of operation and recommended procedures.
- 1.56 “Make Good Costs” has the meaning set forth in Section 8.3(e).
- 1.57 “Manufacture” and “Manufacturing Services” means the manufacturing, processing, formulating, filling, sterilization, packaging, labelling, storage, handling, and quality control testing of Materials or of the Product.
- 1.58 “Manufacturing Suite IOQ” means the completion of the Phase I Filling Space and Phase II Manufacturing Space, including without limitation, the installation, qualification and operational qualification of the Equipment in each of the Phase I Filling Space and the Phase II Manufacturing Space, including the computer systems, utilities and manufacturing area enabling the initiations of technical transfer activities, as agreed to by the Parties and indicated by the delivery by Patheon to Flexion of the interim IOQ report for the Phase I Filling Space and Phase II Manufacturing Space.
- 1.59 “Manufacturing Services Termination Costs” has the meaning set forth in Section 8.3(g).
- 1.60 “Manufacturing Suite” means the manufacturing suite at the Facility capable of Manufacturing the Product pursuant to Flexion’s Manufacturing Process, whose footprint is set forth in Schedule 1.60, together with the areas identified in the plan attached as Schedule 1.60 as the areas for the bulk powder Manufacture and bulk vial filling, and, pursuant to the terms of Section 2.10, the Phase I Filling Space. The footprint of the Manufacturing Suite is diagrammatic in nature and is intended to generally depict the location

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and approximate size of current and future spaces allocated to Flexion. Such footprint may be amended during the Term of and pursuant to the Technical Transfer Agreement to be specifically adapted to the Manufacture of the Product, and the Parties shall agree upon the definitive footprint, taking into account parameters such as the exact design of the space, space classifications, code requirements, equipment, material, personnel, waste stream process flows, equipment sizing and utility requirements. For purposes of clarity, prior to the Phase III Manufacturing Suite Clearance Date (as defined in Section 2.10 herein), the definition of Manufacturing Suite shall include the Phase I Filling Space.

1.61 “Marketing Authorization” means an approved New Drug Application as defined in the FDA Act and the regulations promulgated thereunder, or any corresponding foreign application, registration, or certification, necessary or reasonably useful to market any Product in a country or regulatory jurisdiction other than the United States, including applicable pricing and reimbursement approvals, and all supplements and amendments thereto.

1.62 “Materials” means all API, excipients and processing aids, and processing, filling and packaging components, used in connection with the Manufacture of the Product and listed in Schedule 1.62, as amended prior to Product launch, based on the Parties’ most recent usage experience rate, and to reflect changes to the Specifications.

1.64 “Material Costs” has the meaning set forth in Section 2.2(a).

1.65 “Maximum Manufacturing Services Termination Costs” has the meaning set forth in Section 8.3(g).

1.66 Not used.

1.67 “NDA” means the new drug application for a product, including the Product, requesting permission to place a drug on the market in accordance with 21 C.F.R. Part 314, and all supplements filed pursuant to the requirements of the FDA, including all documents, data, and other information filed concerning such product that are necessary for FDA approval to market such product in the Territory.

1.68 “Non-Conforming Product” means (a) a batch of Product that fails, or is aborted during processing; or (b) a Product Manufactured by Patheon that fails to [...***...].

1.69 “Non-Filing Party” has the meaning set forth in Section 3.15(a).

1.69a “Non-Specific Improvement” has the meaning set forth in Section 5.1(e)(ii)

1.70 “PAI” has the meaning set forth in Section 3.8.

1.71 “Party” and “Parties” have the meanings set forth in the Preamble hereto.

1.72 “Patheon” has the meaning set forth in the Preamble hereto.

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1.73 “Patheon Assignors” has the meaning set forth in Section 5.1(l).

1.74 “Patheon Improvements” has the meaning set forth in Section 5.1(f)(ii).

1.75 “Patheon Indemnified Parties” has the meaning set forth in Section 9.1.

1.76 “Patheon Independent Manufacturing Equipment Improvements” has the meaning set forth in Section 5.1(f)(i).

1.77 “Patheon Manufacturing Equipment” has the meaning set forth in Section 2.9(a)(ii).

1.78 “Patheon Non-Applicable Inventions” has the meaning set forth in Section 5.1(f)(ii).

1.79 “Patheon Nonconformance” has the meaning set forth in Section 2.8(c).

1.80 “Patheon-Supplied Materials” has the meaning set forth in Section 2.2(a).

1.81 Not used.

1.82 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, or other similar entity or organization, including a government or political subdivision, department, or agency of a government.

1.83 “Phase I Filling Space”, “Phase II Manufacturing Space” and “Phase III Manufacturing Suite” shall each be as represented in Schedule 1.60. After the Phase III Manufacturing Suite Clearance Date, the Phase II Manufacturing Space shall be incorporate into the Phase III Manufacturing Suite.

1.84 “Phase I Filling Space Fee” has the meaning set forth in Schedule 2.1(a) at section II.

1.85 “Phase III Manufacturing Suite Clearance Date” has the meaning set forth in section 2.10(d).

1.86 “Phase III Option” has the meaning set forth in section 2.10 (b).

1.87 “Product” has the meaning set forth in the Recitals hereto in finished, unpackaged form, according to the Specifications, as the same may be amended from time to time.

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1.88 “Product Fee” has the meaning set forth in Section 2.4.

1.89 “Project Manager” and “Project Managers” have the meaning set forth in Section 3.4.

1.90 “Proprietary Information” means any information disclosed hereunder by one Party (the “Disclosing Party”) to another Party (the “Receiving Party”) (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party’s patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients or client confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional service proposals and information relating to composition and proprietary technology. In addition, all analyses, compilations, studies, reports or other documents prepared by any Party’s directors, officers, employees, advisers, agents, consultants, subcontractors, service partners, professional advisors, or representatives (collectively, “Representatives”) containing the Proprietary Information will be deemed to be Proprietary Information.

1.91 “Purchase Order” means a written purchase order that sets forth (a) the quantities of each presentation of Product to be delivered by Patheon to Flexion, (b) the requested delivery dates therefor, and (c) the size of the vials and bulk packaging to be used for such Product.

1.92 “Quality Agreement” has the meaning set forth in Section 3.1.

1.94 “Receiving Party” has the meaning set forth in Section 1.90.

1.95 “Regulatory Approval” means any and all approvals (including pricing and reimbursement approvals), licenses, registrations, or authorizations of any Regulatory Authority necessary to Exploit the Product in any country in the Territory, including any (a) approval of a Product, Marketing Authorization and supplements and amendments thereto; (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labelling approval; and (d) technical, medical, and scientific licenses.

1.96 “Regulatory Authority” means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities regulating or otherwise exercising authority with respect to the Exploitation of a Product in the Territory.

1.97 “Regulatory Filings” has the meaning set forth in Section 3.15.

1.98 “Regulatory Obligations” has the meaning set forth in Section 3.15.

1.99 “Remediation Period” has the meaning set forth in Section 8.2(a)(iii).

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- 1.100 “Replacement Entity” has the meaning set forth in Section 8.3(f).
- 1.101 “Reports” has the meaning set forth in Section 3.11.
- 1.102 “Required Manufacturing Changes” has the meaning set forth in Section 2.9(b).
- 1.103 “Scheduled Production Date” has the meaning set forth in Section 2.3(d).
- 1.104 “Services” means the (a) Manufacturing Services performed by Patheon under this Agreement and (b) the Transfer Services performed by Patheon pursuant to the Technical Transfer Agreement.
- 1.105 “Shipment Costs” has the meaning set forth in Section 2.8(c).
- 1.106 “Specifications” means the specifications for each presentation of Product (*i.e.*, the dosage forms in Schedule 1.82) given by Flexion to Patheon relating to the specifications of the Materials; the manufacturing specifications, directions and processes; the storage requirements; all environmental, health and safety information for the Product including material safety data sheets and the finished Product specifications, specifications for bulk and primary packaging and shipping requirements for the Product, as amended, modified, or supplemented from time to time.
- 1.107 “Steering Committee” has the meaning set forth in the Technical Transfer Agreement.
- 1.108 “Supplies” means various consumables / disposables used in small quantities for gowning, cleaning of Equipment and Manufacturing Suite, and in quality control testing of Materials and Product.
- 1.109 “Taxes” means all forms of taxation and statutory, governmental, state, federal, provincial, local, government or municipal charges, duties, imposts, contributions, levies, withholding or liabilities wherever chargeable and whether of the United Kingdom or any other jurisdiction (including for the avoidance of doubt, national insurance contributions in the United Kingdom) and any penalty, fine, surcharge, interest, charge, charges or costs thereto.
- 1.110 “Technical Transfer Agreement” has the meaning set forth in the Recitals.
- 1.111 “Term” has the meaning set forth in Section 8.1.
- 1.112 “Territory” means [...***...] and other territories agreed by the Parties pursuant to Section 2.2(h) from time to time.
- 1.113 “Third Party” means a Person who is neither a Party nor an Affiliate of a Party.

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1.114 “Third Party Losses” means Losses incurred as a result of claims brought by Third Parties.

1.115 “Transfer Services” has the meaning set forth in Section 1.64 of the Technical Transfer Agreement.

1.116 “TUPE” has the meaning set forth in Section 8.3(f).

1.117 “VAT” has the meaning set forth in Section 4.4(c).

1.118 “Yield” has the meaning set forth in Section 2.8(f).

1.119 “Yield Reimbursement Payment” has the meaning set forth in Section 2.8(f).

ARTICLE II. MANUFACTURING SERVICES

2.1 Supply Obligations.

(a) Subject to the terms and conditions hereof and in consideration for the payments set forth in Schedule 2.1(a), Patheon shall provide the Manufacturing Services and shall supply the Product [...***...] to Flexion. Flexion agrees to purchase from Patheon such quantities of Product as Flexion may order, in its discretion, in accordance with the terms herein during the Term.

(b) Pursuant to the Technical Transfer Agreement, Flexion will develop and Patheon will confirm Flexion’s Manufacturing Process. Flexion’s Manufacturing Process is the Proprietary Information of Flexion, as further clarified in Article V.

(c) Patheon shall Manufacture all Products delivered hereunder (i) in accordance with the Specifications, this Agreement, the Quality Agreement, and (ii) in compliance with GMP and all other Applicable Law.

(d) Patheon shall ensure that sufficient numbers of adequately educated and experienced staff are retained at the Facility in order to Manufacture evenly throughout the year the volumes of Product set out in the Forecast. Patheon shall perform all activities necessary to maintain a GMP compliant status of the manufacturing lines and areas of the Facility applicable to the Manufacture of the Product.

(e) Flexion reserves the right to request replacement of any personnel assigned by Patheon to perform the Services hereunder. If Patheon disagrees with such request and the Parties cannot reach resolution on Flexion’s request for replacement, such request will be discussed by the Steering Committee pursuant to the procedures set forth in Exhibit 2.7 of the Technology Transfer and Services Agreement.

(f) Patheon shall perform the Services under the direction of key personnel of Patheon to a project for the duration of the project (“Key Personnel”). Key Personnel include the Project Manager, Operational Manager, Quality Manager or other personnel reasonably agreed-to by the Parties. Patheon shall provide information on the qualifications and background of all proposed Key Personnel prior to such Key Personnel’s commencement of activities under this Agreement on Patheon’s behalf. Patheon will not remove Key Personnel without Flexion’s prior written consent (not to be unreasonably withheld, conditioned or delayed) except in the event of such Key Personnel’s promotion, resignation, incapacity or death, or termination for cause. Patheon will use commercially reasonable efforts to minimize turnover in Key Personnel, and will provide [...***...] business days’ notice to Flexion, whenever practical, of any changes to the Key Personnel, at which point, both Parties shall discuss and reasonable agree on a suitable replacement.

2.2 Materials, Bill Back Items and Additional Services.

(a) All Materials necessary for the Manufacture of the Product are set forth in Schedule 1.62. Patheon shall source all of the Materials set forth on Schedule 1.62 under the heading “Patheon Supplied Materials (“Patheon-Supplied Materials”), and such Materials will be invoiced to Flexion monthly at the time of purchase by Patheon, at cost plus an [...***...] handling fee, in accordance with the invoicing procedure set forth in ARTICLE IV (“Material Costs”). Flexion will purchase, and ship to Patheon in accordance with Schedule 1.62 under the heading “Flexion Supplied Materials” (“Flexion-Supplied Materials”) unless otherwise agreed to by the Parties. Patheon shall store, handle, and protect the Materials with a reasonable level of care, which shall include taking all reasonable precautions to ensure that the Materials are not subject to contamination, deterioration, destruction, or theft. Patheon shall keep adequate records of its usage of the Materials during the Term.

(b) Flexion acknowledges that Patheon is required under GMP to follow certain verification and approval processes for all vendors used by Patheon in the procurement of Materials. In the event that Flexion requests Patheon to procure Materials from a vendor that is not currently verified by Patheon, Flexion will be liable for Patheon’s fees for the performance of the initial audit and verification activities by Patheon under this Section 2.2(b) as an Additional Service.

(c) Flexion will, at its sole cost and expense, deliver to Patheon the Flexion-Supplied Materials to the Facility DDP (Incoterms 2010) at no cost to Patheon at least [...***...] days before the Scheduled Production Date, in sufficient quantities for Patheon to Manufacture the desired quantities of Product and to ship Product by the Agreed Delivery Date. If the Flexion-Supplied Materials are not received [...***...] days before the Scheduled Production Date, Patheon may delay the shipment of Product for a period of time proportionate to such delay. All shipments of Flexion-Supplied Materials, if required, will be accompanied by Certificate(s) of Analysis from the Material manufacturer or Flexion, confirming its

compliance with the Material's specifications. Flexion will obtain the proper release of the Flexion-Supplied Materials from the applicable customs agency and/or Regulatory Authority. Flexion or Flexion's designated broker will be the "Importer of Record" for Flexion-Supplied Materials imported to the Facility. Flexion-Supplied Materials will be held by Patheon on behalf of Flexion as set forth in this Agreement. Title to Flexion-Supplied Materials will at all times remain the property of Flexion. Any Flexion-Supplied Materials received by Patheon will only be used by Patheon to perform the Manufacturing Services or associated activities necessary to perform the Manufacturing Services (e.g. media fills or validation runs).

(d) Flexion and Patheon will agree upon a minimum inventory level of Patheon-Supplied Materials required to support the Manufacture of the Product based on the last Forecast received by Patheon from Flexion. Patheon will keep on hand all Materials necessary to support the Manufacture of the Product based on such agreed-upon minimum inventory levels.

(e) Patheon will provide sufficient storage capacity to support storage of the required quantity of Materials pursuant to Section 2.2 of this Agreement for up to the longer of [...***...] or the amount of time set forth next to the applicable Material on Schedule 1.62 herein. Patheon will also provide sufficient storage capacity to support storage of Product for up to [...***...] post Manufacture [...***...]. Any additional storage, or storage of Materials (either Flexion-Supplied Materials or Patheon-Supplied Materials) or Product beyond the applicable period stated herein, will be subject to the mutual agreement of the Parties. For any such additional storage, Flexion will pay Patheon £[...***...] per pallet, per month for storing any Materials or Product. Storage of Materials or Product that contain controlled substances or require refrigeration will be charged at £[...***...] per pallet per month. Storage fees are subject to a one pallet minimum charge per month. [...***...] will be liable for all risk or loss of damage to stored Materials or Product to the extent such damage was caused by [...***...]s, or its subcontractor's or vendors', [...***...]. Patheon shall store the Product according to GMP, any applicable storage guidelines stipulated by Flexion and agreed by Patheon and the provisions under the Quality Agreement.

(f) Bill Back Items will be charged to Flexion at Patheon's cost plus a [...***...]% handling fee. Patheon shall invoice Flexion monthly for any Bill Back Items used in connection with the Manufacture of the Products during the preceding month in accordance with ARTICLE IV. Patheon may only invoice Bill Back Items that have been quoted to and approved in writing by Flexion's Project Manager, or otherwise mutually agreed to by the Parties in advance.

(g) If Flexion is interested in having Patheon perform Additional Services, Flexion will provide Patheon with a written request containing sufficient detail to enable Patheon to provide Flexion with a quote and proposal to provide such Additional Services. Patheon may only invoice for Additional Services that have been quoted to and approved in writing by an authorized person

of Flexion and that have been agreed in writing by the Parties in a Change of Scope Agreement. Where a rate for Additional Services has been specified in Schedule 2.1 (a), such rates are calculated as at 1st January, 2015. These fees will be adjusted on 1st January of each year (first review [...***...]) to reflect any increase in the UK Consumer Price Index: All Items Index published by the Office for National Statistics (as published at www.ons.gov.uk, specific details are located at <http://www.ons.gov.uk/ons/rel/cpi/consumer-price-indices> during the previous 12 months (based on the average of the monthly changes over the 12-month period). Patheon shall invoice Flexion monthly for any Additional Services performed by Patheon during the preceding month in accordance with ARTICLE IV.

(h) If Flexion decides to have Patheon perform Manufacturing Services for the Product for a Territory outside the [...***...], then Flexion will inform Patheon of the additional requirements for each new country and Patheon will prepare a quotation for consideration by Flexion of any additional costs for the Product destined for each new country. The agreed additional requirements and change over fees will be set out in a written amendment to this Agreement.

(i) Patheon-Supplied Materials.

(i) Patheon will purchase all Patheon-Supplied Materials. Flexion understands and acknowledges that Patheon will rely on Flexion's Purchase Orders and Forecasts in ordering the Patheon-Supplied Materials required to meet the Purchase Orders. In addition, Flexion understands that to ensure an orderly supply of Patheon-Supplied Materials, Patheon may want to purchase Patheon-Supplied Materials in sufficient volumes to meet the production requirements for Products during part or all of the Forecast or to meet the production requirements of any longer period agreed to by Patheon and Flexion. Accordingly, Flexion authorizes Patheon to purchase Patheon-Supplied Materials to satisfy the Manufacturing Services requirements for Products for the first [...***...] contemplated in the most recent Forecast. Patheon may make other purchases of Patheon-Supplied Materials to meet Manufacturing Services requirements for longer periods if agreed to in writing by the Parties. Flexion will give Patheon written authorization to order Patheon Supplied Materials for any launch quantities of Product request by Flexion which will be considered a Purchase Order when accepted by Patheon. Flexion will reimburse Patheon for any destruction costs, as mutually agreed to in good faith, of any Patheon-Supplied Material ordered by Patheon under Purchase Orders or under Section 2.2(i) that are not included in finished Products Manufactured for Flexion within [...***...] after the forecasted month for which the purchases have been made (or for a longer period as the Parties may agree). If any non-expired Patheon-Supplied Materials are used in Products subsequently manufactured for Flexion, Flexion will receive credit for any costs of those Patheon-Supplied Materials previously paid to Patheon by Flexion.

2.3 Forecasting, Order, and Delivery of Products.

(a) No later than [...***...] prior to the anticipated FDA Approval Date and thereafter at least [...***...] prior to the [...***...] of each [...***...] during the Term, Flexion shall deliver to Patheon a written good faith [...***...] month forecast, calculated by month, estimating the quantities of each presentation of Product that Flexion expects to purchase from Patheon during such period (each, a “Forecast”). If Patheon is unable to accommodate any portion of the Forecast, it will notify Flexion and the Parties will agree on any revisions to the Forecast. Flexion shall update the Forecast on or before the [...***...] of each [...***...] on a rolling forward basis. Flexion shall use commercially reasonable efforts to also update the Forecast prior to the next [...***...] deadline if it determines that the volumes estimated in the most recent Forecast have changed by more than [...***...] percent [...***...]). The most recent Forecast will prevail. Except as set forth in Section 2.3(c) below, each Forecast shall be non-binding and shall be used by Patheon for planning purposes only.

(b) Commencing on [...***...], Flexion will give Patheon a written non-binding [...***...]-year forecast for strategic purposes, of the volume of Product Flexion then anticipates to purchase from Patheon for each year during such period (the “Long Term Forecast”). The Long Term Forecast will thereafter be updated every six months (as of June 1 and December 1) during the Term. If Patheon is unable to accommodate any portion of the Long Term Forecast, it will notify Flexion and the Parties will agree on any revisions to the Long Term Forecast.

(c) [...***...]. Flexion will issue Purchase Order(s) to purchase and, when accepted by Patheon, for Patheon to Manufacture and deliver the forecasted quantity or a quantity greater than the forecasted quantity of the Product for each such [...***...] period, provided that the delivery lead time must be at least [...***...] days from the date of Patheon’s acceptance of the Purchase Order pursuant to clause (d) below. The quantities of Products ordered in Purchase Orders will be firm and binding on Flexion and may not be reduced by Flexion. Unless otherwise stated herein, expedited Purchase Orders will be subject to additional fees.

(d) Patheon shall accept all Purchase Orders for Product that are issued consistent with the terms of this Agreement. Patheon shall accept in writing any Purchase Order by sending an acknowledgement to Flexion within [...***...] business days of its receipt of the Purchase Order. The acknowledgement will include, subject to confirmation from Flexion, the delivery date for the Product ordered which shall be approximately [...***...] days from the date of Patheon’s acceptance of the Purchase Order (“Agreed Delivery Date”) and the scheduled date of production for such Products (“Scheduled Production Date”) for the purposes of Section 2.2(c). The Agreed Delivery Date may be amended by agreement of the Parties or as set forth in Section 2.2(c). If Patheon fails to

acknowledge receipt of a Purchase Order within the [...***...] business day period, the Purchase Order will be deemed to have been accepted by Patheon.

(e) Patheon shall deliver Product to Flexion [...***...] the Facility (as defined in Incoterms 2010) by the Agreed Delivery Date. All Product shall be packed for shipping in accordance with the Specifications. Title and risk of loss to Product shall pass to Flexion (or a designated Flexion Affiliate) [...***...]. Each delivery of Product shall be accompanied by a Certificate of Analysis and a Certificate of Compliance and such other documents as may be required pursuant to the Quality Agreement. The costs of all freight, insurance, handling fees, taxes, and other costs associated with the shipment of Product, as well as export licenses, import license, and customs formalities for the import and export of goods will be borne by [...***...]. Patheon shall endeavour to make all deliveries of Product hereunder utilizing stock rotation based on expiration dating, with Product expiring earliest delivered first, save that a failure to comply with this requirement shall not be grounds for Flexion to reject any Product. Flexion shall collect shipments reasonably promptly from the Facility following notification of availability for delivery from Patheon. Storage of Product will be as described in Section 2.2(e). Patheon will, in accordance with Flexion's instructions and as agent for Flexion, at Flexion's risk, arrange for shipping to be paid by Flexion. Flexion will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement.

(f) If Flexion cancels any Purchase Order after receipt thereof by Patheon, Flexion will pay Patheon [...***...]% of the Product Fee for the Purchase Order.

2.4 Product Fees. The purchase price for all Products Manufactured hereunder (the "Product Fee") shall be as set forth on Schedule 2.1(a). Patheon shall invoice Flexion for all quantities of Product Manufactured and ready for collection by Flexion not previously invoiced in accordance with Purchase Orders. All Product Fees will be due and payable in accordance with the invoicing procedures set forth in ARTICLE IV.

2.5 Base Fees. Patheon will invoice Flexion monthly in advance for the Base Fee and any Phase I Filling Space Fee set forth Schedule 2.1(a). All Base Fees and Phase I Filling Space Fees will be due and payable in accordance with the invoicing procedures set forth in ARTICLE IV.

2.6 Product Fee Adjustment. The Parties shall use commercially reasonable efforts to reduce, through operating efficiencies, the cost of Manufacture of the Products during the Term and the benefits of such reduction in costs shall be shared equally by the Parties. The Product Fee stated herein is calculated as at the 1st January 2015. Starting on the [...***...], the Product Fee shall be adjusted annually to reflect any increase in the UK Consumer Price Index: All Items Index published by the Office for National Statistics (as published at www.ons.gov.uk, specific details are located at <http://www.ons.gov.uk/ons/rel/cpi/consumer-price-indices/>) during the preceding twelve (12)

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months (based on the average of the monthly changes over the 12-month period). Schedule 2.1(a) shall be deemed amended pursuant to the terms hereof. The Product Fee is subject to adjustment if, after [...***...] from the FDA Approval Date, (i) Flexion does not submit Purchase Orders for at least [...***...] vials of Product per calendar year, in which case the Product Fee may increase by an amount reasonably sufficient for Patheon to absorb its increased costs, and (ii) Flexion submits Purchase Orders for more than [...***...] vials of Product per calendar year, in which case the Product Fee may decrease for the volumes of Product exceeding [...***...] vials per calendar year as reasonably agreed-on by the Parties in order to adjust for additional volume discounts and economies of scale.

2.7 Failure or Inability to Supply Product.

(a) Patheon shall ensure that Product is Manufactured and delivered to Flexion on a timely basis consistent with the terms of this Agreement (including the Forecast and Purchase Order procedures set forth in Section 2.3). In the event that Patheon, at any time during the Term, shall have reason to believe that it will be unable to supply Flexion with the full quantity of Product forecasted to be ordered or actually ordered by Flexion in a timely manner and in conformity with the warranty set forth in Section 6.3 (whether by reason of force majeure or otherwise), Patheon shall notify Flexion thereof within [...***...] business days. Promptly thereafter, the Parties shall meet to discuss how Flexion shall obtain such full quantity of conforming Product. Compliance by Patheon with this Section 2.7(a) shall not relieve Patheon of any other obligation or liability under this Agreement, including any obligation or liability under clause (b) below. If Patheon's inability is partial, Patheon shall fulfill Purchase Orders with such quantities of Product as are available. In the event Patheon's inability to meet Purchase Orders or forecasts is due to a shortage of production capacity in the Manufacturing Suite, Patheon shall in addition to the foregoing requirements, promptly notify Flexion of such shortage of production capacity and the estimated date such shortage of production capacity is to end.

(b) If Patheon fails to Manufacture the full quantity of Product specified in a Purchase Order by the Agreed Delivery Date and in conformity with the warranty set forth in Section 6.3 (and such failure is directly due to the acts or omissions of Patheon where such acts or omission does not constitute a force majeure event pursuant to the terms of Section 10.2) ("Late Product"), and Patheon is unable to cure such failure within [...***...] days, in full and final settlement of such failure, Flexion, at its option, may (i) cancel the unfulfilled portion of such Purchase Order, in which event Flexion shall have no liability with respect to the portion of such Purchase Order so cancelled, or (ii) accept late delivery of all or any portion of the Product specified in such Purchase Order, in which event (A) Patheon shall pay all reasonable documented shipping costs for the expedited shipment of Product that are required in addition to the shipping costs for a non-expedited shipment (which shall be the responsibility of Flexion), and (B) the Product Fee otherwise payable by Flexion with respect to all Product delivered late but accepted by Flexion under such Purchase Order shall be reduced by [...***...]% per day for each day of delay after such Agreed Delivery Date, but not to exceed in aggregate an

amount equal to [...***...]% of the Product Fees of the Product delivered late (i.e., [...***...] days) per Purchase Order; provided that, sub-Section (ii) shall only apply after the Manufacture and delivery of the first [...***...] batches of commercial Product (including validation batches) pursuant to this Agreement, following which, if the Parties agree that the Manufacturing process is sufficiently robust to allow the Product to be delivered in a timely manner, this sub-Section (ii) shall be implemented. Any Product which is delivered to Flexion with less than [...***...] of expiry, assuming a product shelf life of [...***...], shall be considered Non-Conforming Product subject the provisions of Section 2.8(c); provided that, if the Product shelf life is not [...***...] (as set forth in the FDA approved label for the Product), the Parties shall mutually agree in good faith on the reasonably appropriate minimum amount of expiry a Product should have when delivered.

2.7 A. Batch Numbering and Expiration Dates: Each batch of the Product manufactured by Patheon will bear a unique lot number using Patheon batch numbering system. This number will be printed on the aluminium cap of the vial and will appear on all documents relating to the particular batch of Product and shall identify the date of manufacture for the batch of Product. Patheon will calculate the expiration date for the Product for each batch by adding the expiration period of the Product supplied by Flexion to the date of manufacture of each batch.

2.8 Non-Conforming Product.

(a) In the event Patheon discovers a potential Non-Conforming Product prior to delivery of such Product to Flexion, Patheon shall provide written notice to Flexion as soon as practicable describing in detail the Non-Conforming Product and the potential cause of such Non-Conforming Product. Flexion (or its shipping carrier) will perform a customary inspection of the Products Manufactured by Patheon on receipt. For the avoidance of doubt, such inspection will be limited to a visual inspection of the shipment-ready packaged Products (and associated shipping documentation) and Flexion will not be obliged to perform any testing of the Product. Flexion shall within (i) [...***...] days after delivery thereof by Patheon or (ii) within [...***...] days after Flexion discovers or is informed of a discovery of nonconformity that could not reasonably have been detected by the customary inspection on delivery (but not after the expiration date of the Product), give Patheon notice of any Non-Conforming Product (including a sample of such Non-Conforming Product, if applicable) (a “Deficiency Notice”). Subject to Flexion’s rights under 3.10 and 3.12, should Flexion fail to give Patheon the Deficiency Notice within the applicable [...***...] day period, then the delivery will be deemed to have been accepted by Flexion on the [...***...] day after delivery or discovery, as applicable. Patheon shall have no liability under this Section 2.8 for Nonconforming Product for which it has not received a Deficiency Notice within such applicable [...***...] day period.

(b) Patheon shall conduct a root-cause analysis to verify whether a Product constitutes a Non-Conforming Product and, if found, to determine the cause of such Non-Conforming Product (including by undertaking an appropriate evaluation of a Non-Conforming Product sample, as applicable). Flexion shall provide reasonable cooperation to Patheon in connection with any such root-cause analysis. Patheon shall notify Flexion in writing of its determination regarding whether the Product constitutes a Non-Conforming Product within [...***...] days after either discovery of the Non-Conforming Product or receipt of such Deficiency Notice from Flexion, as applicable. Such notification shall include Patheon's good faith determination of the cause of the Non-Conforming Product.

(c) "Patheon Nonconformance" shall mean (i) Patheon's failure to perform [...***...] pursuant to Section [...***...], and (ii) Patheon's failure to provide the [...***...] in accordance with the [...***...]. In the event of a Non-Conforming Product caused by a Patheon Nonconformance, Patheon, at Flexion's option, promptly shall (x) supply Flexion with a conforming quantity of Product at Patheon's expense (subject to Flexion supplying Patheon with Flexion-Supplied Materials and Patheon reimbursing Flexion for the actual costs of [...***...]) and reimburse Flexion for any incurred shipment costs in the event that the Non-Conforming Product was shipped from the Facility at the time of the discovery of the Patheon Nonconformance ("Shipment Costs"); or (y) reimburse Flexion for the applicable Product Fee (including the cost of any Patheon-Supplied Materials), the actual costs of the [...***...] and Shipment Costs with respect to such Non-Conforming Product (in each case, to the extent already paid by Flexion). For each of (x) and (y) above, Patheon's obligation to reimburse [...***...] shall be subject to the limitation of liability in Section 9.5(a) herein but Section 9.5(a) (1) shall not apply in relation to the internal expenses incurred by Patheon to supply conforming Product to Flexion pursuant to (x), including the cost of any Patheon-Supplied Materials or any Shipment Costs, and (2) shall not apply to the reimbursement of the Product Fee pursuant to (y). For the avoidance of doubt, Flexion will not be liable for Product Fees for Non-Conforming Product caused by a Patheon Nonconformance.

(d) If the Non-Conforming Product was caused by any reason other than a Patheon Nonconformance or the cause of such non-conformance is not due to Patheon Nonconformance (where applicable, as may be determined by an Expert in accordance with 2.8(e), Flexion shall be liable for all expected Product Fees for such Non-Conforming Product, to the extent not already paid.

(e) If, following the root-cause analysis described in Section 2.8(b), Patheon notifies Flexion that it does not believe the Product is a Non-Conforming Product, or if the Parties disagree as to the cause of a Non-Conforming Product, the Parties shall first submit such dispute to the Project Managers for prompt resolution. If the Project Managers cannot resolve the dispute, the Parties shall submit the dispute to an independent expert or (if mutually agreed to by the

Parties) a testing lab, each as agreed by the Parties (a “Expert”) for evaluation, provided that both Parties shall be entitled to observe and obtain copies of all results of such evaluation. The Expert shall determine (i) whether the Product is a Non-Conforming Product and (ii) the cause of the Non-Conforming Product; provided that, if the cause of the Non-Conforming Product is undeterminable the Expert shall give an opinion as to the likely cause. Both Parties shall cooperate with the Expert’s reasonable requests for assistance in connection with its evaluation hereunder. The findings of the Expert shall be binding on the Parties, absent fraud or manifest error. The expenses of the Expert shall be borne (x) by Patheon if the testing confirms the Non-Conforming Product and the cause or likely cause is found to be a Patheon Nonconformance; (y) by Flexion if the testing confirms the Non-Conforming Product and the cause or likely cause is found not to be a Patheon Nonconformance or the cause or likely cause of such non-conformance is not identifiable; and (z) by the Party stating the Product was Non-Conforming in the event the testing concludes that the Product meets the warranty set forth in Section 6.3. Costs of dealing with Product Complaints and Inquiries will be dealt with in accordance with Section 3.10. Costs of recalls will be dealt with in accordance with Section 3.12. Patheon shall have no liability for any Non-conforming Product unless such Non-conforming Product is identified as being due to a Patheon Nonconformance (where applicable, as may be determined by an Expert in accordance with 2.8(e)).

(f) During its performance of the Manufacturing Services, Patheon is expected to produce a certain percentage of saleable batches of Product (the “Yield”). For the avoidance of doubt, Nonconforming Product arising from anything other than a Patheon Nonconformance is treated as good and saleable Product for the purposes of this Section 2.8(f). The Parties shall calculate and mutually agree on the expected Yield after each anniversary of the initial batch of commercial Manufacture of Product and based on at least [...***...] batches of Product (the “Expected Yield Rate”). In the event the actual Yield in any calendar year is more than [...***...]% lower than the then-current Expected Yield Rate for such calendar year, (i) Patheon and Flexion will engage in good faith discussions to agree to a remediation plan describing the steps to be taken to achieve the then-current Expected Yield Rate and (ii) Patheon will reimburse Flexion for [...***...] used by Patheon as a result of Patheon’s failure to meet the Expected Yield Rate in such batches (i.e., a pro-rated refund of [...***...] paid by Flexion and/or reimbursement to Flexion for the costs of any [...***...]) subject to the limitation of liability in Section 9.5(a) (the “Yield Reimbursement Payment”). In the event the actual Yield in any calendar year is more than [...***...]% greater than the then-current Expected Yield Rate for such calendar year, Patheon shall be entitled to reduce any Yield Reimbursement Payment to be made in the next calendar year by an amount equal to the excess Materials that would have been used by Patheon if the Yield for such calendar year was equal to the then-current Expected Yield Rate in such batches.

2.9 Equipment and Amendment of Product Specifications, Manufacturing Process, Equipment and Formulation.

(a) Equipment.

(i) “Flexion Manufacturing Equipment” shall mean process equipment necessary to Manufacture the bulk Product and shall consist of equipment for the bulk Manufacturing, vial preparation, fill/finish, and in-process control testing of the Product and its intermediates as more fully set forth on Schedule 2.9 attached hereto which must comply with all EU mandatory requirements including without limitation, Supply of Machinery (Safety) Regulations 2008 (UK Regulations, Secondary UK Legislation), Electrical equipment of machines (General requirements BS EN 60204-1:2006+A1:2009) (British Product Standards), Machinery Directive 2006/42/EC (European Union Directive), Low Voltage Directive (LVD) 2006/95/EC (European Union Directive), and Electromagnetic Compatibility (EMC) Directive 2004/108/EC (European Union Directive).

(ii) “Patheon Manufacturing Equipment” shall mean any equipment, other than the Flexion Manufacturing Equipment, necessary to Manufacture the Product including as more fully set forth in Schedule 2.9 attached hereto, waste handling systems and all building infrastructure and any and all improvements or additions made thereto, as approved in writing by Flexion.

(iii) Patheon, acting as Flexion’s agent, shall purchase the Flexion Manufacturing Equipment on Flexion’s behalf and pursuant to Flexion’s written instruction. The inclusion of items of Flexion Manufacturing Equipment in Schedule 2.9, as may be amended by agreement from time to time, shall constitute written instruction to purchase. Title to all Flexion Manufacturing Equipment will be held by Flexion unless otherwise set forth in Schedule 2.9. Title to all Patheon Manufacturing Equipment will be held by Patheon.

(iv) Patheon is authorized to use the Flexion Manufacturing Equipment solely for the purposes of performing the Manufacturing Services for Flexion.

(v) During the Term, Flexion shall be responsible for additions and replacement cost of any Flexion Manufacturing Equipment and Patheon Manufacturing Equipment.

(vi) During the Term, Patheon shall, at its sole cost and expense, subject to this subsection (vi), provide all Maintenance for the Equipment and Facilities. Notwithstanding the foregoing, with respect to the Flexion Manufacturing Equipment and Patheon Manufacturing Equipment, Maintenance does not include (A) the cost of spare parts, (B) Equipment breakdowns caused by any reason outside of Patheon’s reasonable control (other than breakdowns caused by Patheon’s negligence or failure to maintain the Equipment in accordance with the applicable Equipment Standard Operating Procedures of Patheon or the

manufacturer's terms of operation and recommended procedures), or (C) specialized maintenance services not within Patheon's technical expertise or that requires specialist equipment, in each case where Patheon is required to utilize a Third Party contractor. Patheon's costs associated with such spare parts and Third Party contractors will be reimbursed by Flexion as a Bill Back Item. Patheon shall not be liable for ordinary wear and tear of the Flexion Manufacturing Equipment or Patheon Manufacturing Equipment; Patheon shall only be liable for the repair or replacement of any damage caused to such Equipment where such damage arises due to its negligence or willful misconduct or its failure to maintain Equipment pursuant the applicable Equipment Standard Operating Procedures of Patheon or the manufacturer's terms of operation and recommended procedures. Throughout the Term of this Agreement, Patheon shall maintain property insurance on Flexion Manufacturing Equipment in the amount equal to the replacement value of such Equipment.

(b) For changes to the Specifications, Quality Agreement, Flexion's Manufacturing Process, the Equipment, the Services to be provided pursuant hereto or the formulation of the Product that are required by Applicable Law (collectively, "Required Manufacturing Changes"), Patheon and Flexion shall cooperate to promptly make such changes within the required timeline.

(c) For changes to the Specifications, Quality Agreement, Flexion's Manufacturing Process, the Equipment, the Services to be provided hereto or the formulation of the Product that are not Required Manufacturing Changes (collectively, "Discretionary Manufacturing Changes"), Patheon and Flexion must each agree to any Discretionary Manufacturing Changes and shall cooperate in making such changes, and each agrees that it shall not unreasonably withhold, condition or delay its consent to such Discretionary Manufacturing Changes.

(d) Notwithstanding the foregoing, all internal and external costs, including, without limitation, costs of obsolete Materials, work-in-process and Product (i) associated with Required Manufacturing Changes shall be borne by Flexion, and (ii) all such costs associated with Discretionary Manufacturing Changes shall be agreed between the Parties; provided that, in each case, all such costs shall be commensurate with costs common in the industry for the types of changes being made.

(e) In the event that Flexion changes the Specifications, Quality Agreement, Flexion's Manufacturing Process, the Equipment, the Services to be provided hereto or the formulation of the Product, or consents to any change by Patheon, Patheon shall provide to Flexion at Flexion's cost as an Additional Service any such documentation or other information with respect thereto as they relate to the Manufacturing Services as Flexion may reasonably request in order to obtain or maintain any Regulatory Approval or comply with GMP or other Applicable Law.

2.10 Phase I Filling Space Option.

(a) Prior to the Phase III Manufacturing Suite Clearance Date, Patheon shall provide the Manufacturing Services utilizing the Phase I Filling Space and Phase II Manufacturing Space. During this period, the Phase I Filling Space Fee set forth in Schedule 2.1(a) shall be payable if a period of [...***...] has elapsed after the date on which Flexion submitted for approval to the FDA or other applicable Regulatory Authority for the Manufacture of Product in the Phase III Manufacturing Suite for commercial sale in the Territory. The Phase I Filling Space Fee shall cease to be payable on the Phase III Manufacturing Suite Clearance Date unless Flexion exercises the Phase I Option.

(b) After the Phase III Manufacturing Suite Clearance Date, (1) Patheon will provide the Manufacturing Services set forth herein utilizing the Phase II Manufacturing Space and Phase III Manufacturing Suite and (2) Flexion shall have the option to elect to have Patheon continue to provide the Manufacturing Services utilizing the Phase I Filling Space for all or any portion of the remaining Term (the “Phase I Option”), provided that, (i) Flexion pays the Phase I Filling Space Fee set forth in Schedule 2.1(a) commencing after election of the Phase I Option, and (ii) the Phase I Option shall cease to be applicable if Flexion does not exercise the Phase I Option within [...***...] from Patheon’s notice to Flexion that [...***...]. After the Phase III Manufacturing Suite Clearance Date, Patheon shall have no obligation to provide the Manufacturing Services utilizing the Phase I Filling Space unless Flexion has exercised the Phase I Option in accordance with this Section 2.10(b).

(c) The extent of the use of the Phase I Filling Space for the Manufacturing Services shall be at Flexion’s sole discretion both prior to and after the Phase III Manufacturing Suite Clearance Date except that the Parties acknowledge that the Phase I Filling Space will [...***...] after the Phase III Manufacturing Suite Clearance Date. The Parties shall discuss and agree [...***...] in good faith but any associated costs or fees would be payable by [...***...].

(d) For purposes of this Section 2.10, the “Phase III Manufacturing Suite Clearance Date” shall mean the date upon which, in Flexion’s sole discretion, the FDA or other applicable Regulatory Authority, has approved or will allow the Product to be Manufactured in the Phase III Manufacturing Suite for commercial sale in the applicable Territory.

ARTICLE III. REGULATORY, ACCESS, AND OTHER MATTERS

3.1 Quality Agreement. Within [...***...] of the Effective Date, the Parties shall enter into a mutually agreed upon quality agreement (“Quality Agreement”). If there is any inconsistency between this Agreement and the Quality Agreement, the terms of the Quality Agreement shall control solely with respect to quality issues, and this Agreement shall control with respect to all other issues.

3.2 Release. All Product shall be released in accordance with the terms of the Quality Agreement.

3.3 Maintenance of Facility.

(a) Patheon shall Manufacture the Product [...***...] at the Facility, unless Flexion has granted prior written consent to Manufacture the Product at any other facility, such consent to be granted by Flexion in its sole discretion.

(b) Subject to Section 2.9(b)-(d), Patheon shall ensure that any and all necessary licenses, registrations, and Regulatory Authority approvals have been obtained in connection with the Facility and Equipment used in connection with the Manufacture of the Product by Patheon.

(c) Subject to Section 2.9, Patheon shall maintain the Facility and Equipment in a state of repair and operating efficiency consistent with the requirements of the Specifications, the Regulatory Approvals, Flexion’s Manufacturing Process, GMP, and all other Applicable Law. Prior to each use of Equipment in Manufacturing the Product, Patheon shall ensure that such Equipment is cleaned and consistent with any procedures reasonably established by Flexion and notified to Patheon, the Specifications, the Regulatory Approvals, Flexion’s Manufacturing Process, GMP, and all other Applicable Law. Without limitation of the foregoing, Patheon agrees to implement, in connection with the Manufacture of the Product, quality assurance and quality control procedures, including validation protocols and process change procedures that are reasonably satisfactory to Flexion.

(d) Patheon shall maintain in the Facility an adequate GMP and temperature controlled area for the Product, all intermediates thereof, and Materials used in Manufacturing the Product in accordance with the Specifications, the Regulatory Approvals, Flexion’s Manufacturing Process, any risk mitigation plan, the Quality Agreement, GMP, and all Applicable Law. All Product, intermediates and Materials (as applicable) shall be held by Patheon in a GMP and temperature controlled area (on a separate pallet and SAP reference from other products) until delivery to Flexion.

(e) Patheon shall only use qualified disposal services or sites that have appropriate environmental and operating permits and are in compliance with the Quality Agreement and Applicable Law.

3.4 Flexion On Site Representatives; Project Managers. For so long as Patheon is obliged to Manufacture and supply the Products for Flexion, Flexion shall have the right at all times throughout the Term to have [...***...] representatives present (or other number as reasonably requested by Flexion after discussion by the members of the Steering Committee) (each, a “Flexion On Site Representative”) in that portion of Patheon’s Manufacturing facilities that is being used to Manufacture the Product or store Materials to observe the procedures and processes used to Manufacture the Product. Subject to the following sentence, such representatives shall have full access to the Manufacturing Suite and to all non-financial records that relate to the Product, the Materials and Bill Back Items. Patheon shall provide reasonable (semi-permanent) on-site accommodations at the Facility for the Flexion On Site Representatives (e.g., office space). For the avoidance of doubt, the term “non-financial records” as used in this Agreement does not include the Reports (defined in Section 3.11 below). Flexion On Site Representatives shall be appropriately trained by Flexion (e.g. GMP training) and shall observe at all times Patheon’s policies and procedures (as amended from time-to-time) as they pertain to the Facility, including policies relating to health and safety and compliance with GMP, and comply with all reasonable directions of Patheon in relation to the same; provided that Flexion is given notice of such policies and given a reasonable period of time to review and implement such policies. Patheon may refuse or limit in its sole discretion at any time admission to the Facility by any Flexion On Site Representative who fails to observe such policies or comply with such reasonable directions. For the avoidance of doubt, Flexion On Site Representatives shall have (i) no management authority over any Patheon employee and (ii) no authority to conclude contracts on behalf of Flexion. Patheon and Flexion will each appoint a project manager (each, a “Project Manager” and, together, the “Project Managers”), who will meet as needed to resolve any issues or problems arising in the performance of this Agreement. Flexion’s Project Manager may be one of the Flexion On Site Representatives.

3.5 Notification of Regulatory Inspections. Patheon shall notify Flexion by telephone within [...***...], and in writing within [...***...], after learning of any proposed or unannounced visit or inspection of any part of the Facility by any Regulatory Authority, including the Occupational Safety and Health Administration or any equivalent governmental agencies of the country of Manufacture, and shall permit Flexion or its agents to be present at the Facility to support Patheon during such visit or inspection if it, directly or indirectly relates to the Product or Manufacturing Suite or may reasonably be expected to adversely affect the Product or the Manufacturing Suite. For the avoidance of doubt the responsibility for conducting the inspection rests with Patheon. Flexion personnel will be permitted to take part in the inspection where this participation is directly requested either by the authorized agent of the Regulatory Authority or by Patheon. Patheon shall provide to Flexion in so far as it, directly or indirectly, affects the Product or the Manufacturing Suite or may reasonably be expected to adversely affect the Product or the Manufacturing Suite, either a copy of any report and other written communications received from such Regulatory Authority in connection with any visit or inspection, including the Form 483 observations and responses or any equivalent form under Applicable Law. Such copy or summary shall be provided to Flexion within [...***...] business days of Patheon’s receipt thereof (and may be redacted as Patheon acting reasonably deems necessary to protect the confidentiality of matters not affecting, or not reasonably likely to affect, the Product or the Manufacturing Suite which are confidential to Patheon or to other clients of Patheon). Flexion shall have the right to review and comment on

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any communications with such Regulatory Authority pertaining to such inspection as set forth in Section 3.15.

3.6 Manufacturing Records. Patheon shall maintain, or cause to be maintained, (a) all records necessary to comply with GMP and all other Applicable Law relating to the Manufacture of Product, (b) all Manufacturing records, standard operating procedures, equipment log books, batch records, laboratory notebooks, and all raw data relating to the Manufacturing of the Product, and (c) such other records as Flexion may reasonably require in order to ensure compliance by Patheon with the terms of this Agreement. The template, form and style of all records referred to herein are the exclusive property of Patheon; Flexion Proprietary Information and all Product-specific related information contained in these records shall be deemed Proprietary Information of Flexion and be retained for such period as may be required by GMP and all other Applicable Law or for such longer period as Flexion may reasonably require.

3.7 Compliance with Applicable Laws. Patheon shall comply and shall cause each of subcontractors and its Materials and Bill Back Items suppliers to comply with the Quality Agreement, GMP and Applicable Law in carrying out the Manufacturing of the Product and its other duties and obligations under this Agreement. Should during the Term of this Agreement a change or changes in Applicable Law lead to Patheon (a) providing services not originally contemplated by Patheon, or (b) incurring increased costs in order to comply with said change or changes, any such services or costs (to the extent pertaining to the Product or related to Flexion's Manufacturing Process or Flexion Manufacturing Equipment) shall constitute an Additional Service subject to mutual written agreement of the Parties.

3.8 Compliance Audits. Flexion and its designated representatives shall have the right to audit all applicable non-financial records of Patheon for the purpose of determining Patheon's compliance with the obligations set forth in this Agreement and the Technical Transfer Agreement, including Sections 2.2(a) and 6.2 of this Agreement, and the terms of any Purchase Order. Such audit right shall include the right to inspect: (a) the Materials used in the Manufacture of the Product, (b) the holding facilities for such Materials and Product, (c) the Equipment used in the Manufacture of the Product, (d) all non-financial records relating to the Manufacturing Suite and the Manufacturing of the Product (subject to any other restrictions set forth in this Agreement) and (e) all other documentation set forth in the Quality Agreement. Flexion shall provide Patheon with reasonable prior advance notice of its intention to conduct such audit and the Parties will determine a mutually agreeable date for such audit. Flexion shall include no more than [...***...] of Flexion's representatives in each such audit, with each such audit lasting no more than [...***...] days without Patheon's prior written consent. Flexion may exercise its audit rights under this Section 3.8 no more than [...***...] per calendar year; provided that, in the event any of the following circumstances arise, Flexion may elect and Patheon shall permit Flexion to conduct additional audits in a timely manner: (i) where there is the occurrence of a condition or event relating to the Materials or any Product which constitutes a serious health risk; (ii) where either Party has received correspondence or a report from a Regulatory Authority pointing out a deficiency in the Product by or on behalf of Patheon; (iii) where the Specifications have not been complied with or there is otherwise evidence that compliance with the Specifications is at risk; or (iv) in the event of a recall related to the Product. The Steering Committee will discuss the findings of any audit conducted by Flexion under this

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Section 3.8 and shall mutually agree upon a plan to remedy any issues identified by Flexion in such audit and Patheon shall use commercially reasonable efforts to implement such plan in a timely manner. Patheon will support the first Product approval, including its inspection if required, of the FDA or equivalent regulatory launch for other jurisdictions (where applicable) (a “PAI”) (including one mock-readiness review and efforts conducted with Flexion representatives in advance of such inspection). Patheon will be prepared for the successful completion of the PAI with respect to the Manufacturing of the Product at the Facility a minimum of [...***...] in advance of the anticipated date of the PAI and Patheon will cooperate with Flexion to prepare for and to complete the PAI in accordance with guidelines and requirements set forth by the applicable Regulatory Authority. Additional support (including, without limitation, subsequent regulatory launches or Product approval inspections/resulting reports for other jurisdictions) will be subject to additional fees.

3.9 Inventory Reviews. Without limiting the foregoing, Flexion shall have the right, with Patheon’s assistance, to conduct an annual inventory count of the Materials and of the Products. Following an audit or inventory, Flexion may discuss its observations and conclusions with Patheon, and Patheon shall promptly implement such corrective actions after notification thereof by Flexion. In the event the Parties are unable to agree upon whether or not corrective actions are necessary, such dispute shall be resolved pursuant to the terms of Section 10.9.

3.10 Product Inquiries and Complaints.

(a) With respect to Products Manufactured by Patheon, each Party will promptly (as may be further defined in the Quality Agreement) submit to the other Party any Product safety and efficacy inquiries, Product quality complaints, and adverse drug event reports received by such Party, together with all available evidence and other information relating thereto, in accordance with procedures to be agreed upon by the Parties. Except as otherwise required by, or to comply with, Applicable Law or the terms of this Agreement, Flexion, as the Party holding the applicable Regulatory Approval, will be responsible for investigating and responding to all such inquiries, complaints, and adverse events regarding the Product, and reporting to the FDA or any other Regulatory Authority.

(b) Pursuant to a reported complaint or adverse drug event pertaining to the Products Manufactured by Patheon, if the nature of the reported complaint or adverse drug event requires testing, Patheon will, upon Flexion’s request and approval, perform analytical testing of corresponding Product complaint or retention samples and provide the results thereto to Flexion as soon as reasonably practicable, but no later than [...***...] days after Flexion’s request. Such testing shall be performed using approved testing procedures as set forth in the applicable Regulatory Approval or the Quality Agreement. If such analytical testing concludes that the reported complaint or adverse drug event was the result of a Patheon Nonconformance, Patheon shall reimburse Flexion for [...***...] associated with such complaint or adverse drug event and incurred by Flexion with respect to such nonconforming Product, including [...***...]. Costs of recalls will be dealt with in accordance with

Section 3.12. If such analytical testing concludes that the reported complaint or adverse drug event was not the result of a Patheon Nonconformance, Flexion shall compensate Patheon for all costs associated with such complaint or adverse drug event and incurred by Patheon with respect to such nonconforming Product, including costs of recalls, market withdrawals, returns, and destruction.

(c) If the Parties disagree as to which Party is responsible, Patheon and Flexion representatives shall attempt to resolve such dispute. If the representatives cannot resolve such dispute within [...***...] days, the retention samples shall be submitted by Patheon and Flexion to an Expert and Section 2.8 shall apply.

3.11 Reports. Prior to the start of Patheon's commercial Manufacture of the Product (or as reasonably requested by Flexion prior to such date), Patheon and Flexion will work together in good faith to develop and agree upon Patheon's ordinary course reporting obligations. Such reports ("Reports") will include those reports as necessary for Flexion to (a) manage Product inventory; (b) manage its financial close and reporting; (c) monitor on-going Product and process performance for its internal analysis and reporting; and (d) comply with Applicable Law. Patheon will deliver such reports via electronic delivery methods, including by utilizing Patheon's existing IT systems as practicable.

3.12 Product Recalls.

(a) In the event (i) any Regulatory Authority issues a request, directive, or order that Product be recalled, (ii) a court of competent jurisdiction orders such a recall, or (iii) Flexion as holder of the applicable Regulatory Approval shall reasonably determine that Product should be recalled, withdrawn, or a field correction issued, the Parties shall take all appropriate corrective actions, and shall cooperate in the investigations surrounding the recall. In the event that Flexion determines that Product should be recalled, to the extent reasonably possible, Flexion shall consult with Patheon prior to taking any corrective actions. In the event of any Product recall, withdrawal, or field correction resulting from a Patheon Nonconformance, Patheon shall bear [...***...] associated with such recall, withdrawal, or field correction, which shall include [...***...] of the recalled Product and all other [...***...] incurred in connection with such recall, plus [...***...] incurred by Flexion with respect to such Product. In all other circumstances, all costs associated with any Product recall, withdrawal, or field correction shall be borne by Flexion.

(b) If there is any dispute concerning which Party's acts or omissions gave rise to such recall of Product, Patheon and Flexion representatives shall attempt to resolve such dispute. If the representatives cannot resolve such dispute within [...***...] days, the matter shall be submitted by Patheon and Flexion to an Expert and Section 2.8 shall apply.

3.13 Payment Audits.

(a) Upon [...***...] days' prior written notice, Flexion may audit any Third Party invoices subsequently invoiced to Flexion pertaining to Patheon's provision of Equipment, Materials, Bill Back Items and Additional Services hereunder; provided, however, that Flexion will not be entitled to more than one audit during any [...***...] period. Such audits will be conducted during normal business hours, without undue disruption to Patheon's business, and may be conducted by Flexion, or by an independent public accounting firm designated by Flexion who is bound by confidentiality obligations at least as stringent as those set forth in the Confidentiality Agreement. Except as hereinafter set forth, Flexion will bear the full cost of the performance of any such audit.

(b) If, as a result of any audit described in Section 3.13(a), it is shown that the payments or credits from one Party to the other under this Agreement with respect to the period of time audited were less than or more than the amount that should have been paid or credited, then the Parties will reconcile the amounts owed by each Party to the other. In addition, if such audit demonstrates that Patheon has overcharged Flexion hereunder by more than [...***...]% for the period audited, then Patheon will also reimburse Flexion for its documented reasonable out-of-pocket costs and expenses incurred in connection with the audit.

3.14 Subcontractors. Prior to subcontracting any of Patheon's obligations hereunder, Patheon will notify Flexion (1) in advance of engaging a proposed subcontractor that directly relates to the Manufacture of the Product and will obtain Flexion's prior written approval of each such subcontractor, and (2) within six (6) months, of all other subcontractors so engaged. The terms of any subcontract directly relating to the Manufacture of the Product will be in writing and will be consistent with this Agreement, including (i) the confidentiality obligations set forth in Article VII, (ii) the representations and warranties of Patheon in Section 6.3, and (iii) compliance with Applicable Law as required hereunder. No subcontracting will release Patheon from its responsibility for its obligations under this Agreement and Patheon will be responsible for the work and activities of each such subcontractor as they relate to performance of Patheon's obligations under this Agreement, including compliance with the terms of this Agreement.

3.15 Regulatory Filing Obligations. Except as otherwise set forth in this Agreement or the Technical Transfer Agreement, each Party will be responsible for all routine filings and communications with Regulatory Authorities ("Regulatory Filings") required with respect to such Party's Regulatory Obligations hereunder. "Regulatory Obligations" shall mean: (i) with respect to Flexion, any Regulatory Filings pertaining to the Product, Flexion's Manufacturing Process, and filling and packaging processes and procedures; and (ii) with respect to Patheon, any Regulatory Filings pertaining to the Facility, including in connection with a Facility inspection by a Regulatory Authority (*e.g.*, those described in Section 3.5). For the avoidance of doubt, Flexion shall have the sole responsibility and Regulatory Obligation for the filing of all documents with all applicable Regulatory Authorities, and to take any other actions that may be required, for the receipt of Regulatory Approval for the development or commercial manufacture of the Product. Flexion shall provide Patheon with a copy of any Regulatory Approval directly

relevant to this Agreement on request including any Regulatory Approval required for the storage, receipt or distribution of the Product by Flexion or its designee.

(a) Cooperation. Each Party (“Non-Filing Party”) will provide reasonable assistance and cooperation to the other Party (“Filing Party”) in the connection with the Filing Party’s Regulatory Obligations consistent with the terms of this Section 3.15 and the Non-Filing Party’s obligations under this Agreement. The Filing Party shall notify the Non-Filing Party in writing of any written communications received by the Filing Party from a Regulatory Authority related to the other Party’s Regulatory Obligations within [...***...] business days after receipt thereof. The Filing Party shall consult with the Non-Filing Party concerning the response of the Filing Party to each such communication, unless such filing is not relevant to the Non-Filing Party’s Regulatory Obligations.

(b) Verification of Data. Prior to filing any documents or communications with a Regulatory Authority that incorporate or uses data generated by the Non-Filing Party or otherwise relate to the Non-Filing Party’s Regulatory Obligations, the Filing Party will give the Non-Filing Party a draft of such document or communication (“Initial Draft”) to give the Non-Filing Party the opportunity to verify the accuracy and regulatory validity of such Initial Draft. The Non-Filing Party shall be given a minimum of [...***...] calendar days to review the Initial Draft, but the Parties may mutually agree to a different time for the review as needed under the circumstances. The Initial Draft may be redacted by the Filing Party as reasonably deems necessary to protect the confidentiality of matters not affecting the Non-Filing Party or which are confidential to the Filing Party or to other clients or customers of the Non-Filing Party. The Parties agree that in reviewing the Initial Draft, the Non-Filing Party’s role will be limited to verifying the accuracy of the description of its Regulatory Filing Obligations or accuracy of its data or information in the Initial Draft. Notwithstanding the forgoing, nothing in this Section 3.15(b) shall be deemed to limit a Party’s ability to make any filing with, or otherwise communicate with, any Regulatory Authority if such Party reasonably determines that such filing or communication is legally required and must be made in an expedited manner and consultation with the other Party as provided herein is not reasonably possible.

(c) Inaccuracies. If the Non-Filing Party determines that any of its data or information in the Initial Draft is inaccurate or any other errors relating to the Non-Filing Party’s Regulatory Obligations, the Non-Filing Party will notify Filing Party in writing of such inaccuracy and provide a recommendation to remediate the Initial Draft. Such notice shall also include documentation and data sufficient to substantiate the Non-Filing Party’s claim that the Initial Draft is inaccurate to the Filing Party’s reasonable satisfaction. The Non-Filing Party shall provide comments to the Initial Draft no later than [...***...] days prior to the required filing date with the applicable Regulatory Authority. If the Non-Filing Party does not provide comments or notify the Filing Party of inaccuracies within such [...***...] day period, the Non-Filing Party will be deemed to have approved any data or language related to its Regulatory Obligations in the Initial Draft. The

Filing Party shall be required to incorporate the Non-Filing Party's recommendations to the extent they directly relate to an error in the Non-Filing Party's data or information or the Non-Filing Party's Regulatory Filing Obligations. The Parties will work together in good faith to resolve any inaccuracies contained in the Initial Draft as soon as practicable under the circumstances to prevent a delay or postponement of such filing (or any related inspections by such Regulatory Authority to which the filing relates). Any on-going disagreement regarding the Deficiencies shall be escalated to the Steering Committee for resolution on an expedited basis.

(d) Responsibilities. Patheon shall deliver a copy of the final version of the filing to Flexion at least [...***...] days prior to the required filing date. Flexion shall deliver a copy of the final version of the filing to Patheon promptly after the required filing date. Subject to the foregoing, the Non-Filing Party will not assume any responsibility for the accuracy of any other materials submitted by the Filing Party to a Regulatory Authority in connection with this Agreement. Except as otherwise set forth in this Agreement or the Technical Transfer Agreement, the Filing Party is solely responsible for the preparation and filing of any materials required by a Regulatory Authority with respect to such Party's Regulatory Filing Obligations hereunder and any relevant costs will be borne by the Filing Party.

ARTICLE IV. FEES AND INVOICING

4.1 General. (a) Patheon shall invoice Flexion for all applicable fees and charges incurred by Patheon as set out in this Agreement or the Technical Transfer Agreement. (b) All invoices shall be sent electronically to [...***...]. Payment shall be due thirty (30) days after receipt by Flexion of an undisputed invoice. All payments from Flexion to Patheon hereunder shall be in British Pounds (GBP).

4.2 Late Fees. In relation to all invoices issued by Patheon pursuant to this Agreement, if Flexion fails to make any payment due to Patheon by the due date for payment, then, without limiting Patheon's remedies under ARTICLE VIII or at law, Patheon may charge interest on past due accounts at [...***...]% per month which is equal to an annual rate of [...***...]%.

4.3 Disputed Invoices. If Flexion disputes any portion of an invoice, (a) Flexion shall provide Patheon with written notice of the disputed portion within [...***...] business days of receipt by Flexion of Patheon's invoice and its reasons therefor and shall not be obliged to pay such disputed portion unless and until such disputed portion is determined to be due and owing, and (b) Patheon shall cancel such invoice and issue a new invoice reflecting the undisputed invoiced amount, which shall be paid by Flexion within [...***...] days. The Parties shall use good faith efforts to resolve the dispute regarding the disputed amount promptly, and if the Parties agree that a balance is due, Patheon shall issue an invoice for such balance, and payment shall be due [...***...] days after receipt of such invoice. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control.

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4.4 Taxes.

- (a) Subject to (b) and (c) below, Patheon will bear all Taxes however designated as a result of the provision of the Services under this Agreement.
- (b) Flexion acknowledges that it will be responsible for all Taxes that arise in respect of the following:
- (i) The acquisition of the Flexion-Supplied Materials.
 - (ii) The acquisition of the Flexion Manufacturing Equipment.
- (c) Any payment due under this Agreement for the provision of Services to Flexion by Patheon is exclusive of value added or equivalent tax in any other jurisdiction, including any related interest and penalties (hereinafter all referred to as “VAT”). If any VAT is payable on a Service supplied by Patheon to Flexion under this Agreement, this VAT will be added to the invoice amount and will be for the account of (and reimbursable to Patheon by) Flexion. Where applicable, Patheon will use its reasonable commercial efforts to ensure that its invoices to Flexion are issued in such a way that these invoices meet the requirements for deduction of input VAT by Flexion, to the extent permitted by law to do so.
- (d) Flexion acknowledges that all amounts due in respect of any fees payable by Flexion under this Agreement shall be paid in full without any set-off, counterclaim, deduction or withholding in respect of any Tax liabilities.

ARTICLE V. INTELLECTUAL PROPERTY

5.1 Ownership.

- (a) Flexion shall maintain ownership and Control of all of its technology and intellectual property rights existing prior to the Effective Date (“Existing Flexion Intellectual Property”).
- (b) Patheon shall maintain ownership and Control of all of its technology and intellectual property rights existing prior to the Effective Date (“Existing Patheon Intellectual Property”).
- (c) Existing Flexion Intellectual Property shall include and Flexion shall own all right, title, and interest in and to (i) the Product, (ii) the Specifications, and (iii) Flexion’s Manufacturing Process.
- (d) Existing Patheon Intellectual Property shall include and Patheon shall own all right, title, and interest in and to the Patheon Manufacturing Equipment as of the Effective Date.

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(e) Flexion shall own all right, title, and interest in and to, all intellectual property (specifically including inventions and patents and patent applications therefor) with respect to, and any data with respect to:

(i) (A) any improvement of, modification of, change of, enhancement of, new indication for, new formula for, new formulation for, new ingredients for, new dosage for, new dosage strength for, new means of delivery for, or new labelling or packaging for, the Product (“Flexion Product Improvements”); (B) any improvement of, modification of, change of, or enhancement of the Specifications (“Flexion Specification Improvements”); (C) any improvement of, modification of, change of, enhancement of, new process for, new procedure for, or new step related to Flexion’s Manufacturing Process (“Flexion Manufacturing Process Improvements”); and (D) any improvements of, modification of, change of or enhancement of Flexion Manufacturing Equipment (the “Flexion Manufacturing Equipment Improvements”) in each of case (A), (B), (C) and (D) , (1) that is developed, conceived, or created after the Effective Date specifically as a result of or in connection with this Agreement, including Patheon’s Manufacturing of the Product hereunder, (2) whether or not patentable, (3) whether developed, conceived, or created by employees of, or consultants to, Flexion or Patheon, alone or jointly with each other or with permitted Third Parties (including permitted sublicensees and subcontractors), and (4) that has specific applicability, meaning it does not have applicability to products other than the Product, to the Product, Specifications, Flexion’s Manufacturing Process or the Flexion Manufacturing Equipment as applicable (together the Flexion Specification Improvements, Flexion Product Improvements, Flexion’s Manufacturing Process Improvements and the Flexion Manufacturing Equipment Improvements shall be referred to as the “Flexion Specific Improvements”);

(ii) any improvement of, modification of, change of, enhancement of manufacturing, processing, formulating, filling, labelling or packaging technology or equipment which is (x) developed, conceived, created, generated or derived after the Effective Date by Patheon, alone or jointly with Flexion or other permitted Third Parties (including permitted sublicensees) specifically as a result of or in connection with this Agreement, and (y) of generic application to the Product, meaning it has application to or utility in relation to a range of products which includes the Product (“Non-Specific Improvement”)(the Flexion Specific Improvements and the Non-Specific Improvements are together “Flexion Improvements”); and

(iii) any inventions, know how or other intellectual property developed, conceived, or created by Flexion, alone or jointly with Third Parties (other than Patheon or its Affiliates, or their respective employees and consultants), in the course of conducting activities outside the scope of this Agreement and without any use of any Existing Patheon Intellectual Property, Patheon Independent Manufacturing Equipment Improvements and/or Patheon Non-Applicable Inventions (as defined hereunder).

(f) Patheon shall own all right, title, and interest in and to, all intellectual property (specifically including inventions and patents and patent applications therefor) with respect to, and any data with respect to:

(i) any improvement of, modification of, change of, enhancement of Patheon's Manufacturing Equipment, (1) that is developed, conceived, or created as a result of or in connection with this Agreement, including Patheon's Manufacturing of the Product hereunder, (2) whether or not patentable, (3) whether developed, conceived, or created by employees of, or consultants to, Flexion or Patheon, alone or jointly with each other or with permitted Third Parties (including permitted sublicensees), and (4) that is of generic application rather than a specific solution that only has applicability to the Product, ("Patheon Independent Manufacturing Equipment Improvements");

(ii) any inventions, know how or other intellectual property developed, conceived, or created by Patheon, alone or jointly with Flexion or other permitted Third Parties (including permitted sub-licensees), in the course of conducting activities under the scope of this Agreement where such inventions know how or other intellectual property have no applicability to the Product, the Specifications, Flexion's Manufacturing Process or the Flexion Manufacturing Equipment ("Patheon Non-Applicable Inventions") (together the Patheon Independent Manufacturing Equipment Improvements and the Patheon Non-Applicable Inventions are together "Patheon Improvements"); and

(iii) any inventions, know how or other intellectual property developed, conceived, or created by Patheon, alone or jointly with Third Parties, in the course of conducting activities outside the scope of this Agreement and without any use of any Existing Flexion Intellectual Property or Flexion Specific Improvements.

(g) Patheon shall, and shall cause its Affiliates to, promptly disclose in writing and in reasonable detail to Flexion any Flexion Improvements developed, conceived, or created by employees, consultants, or subcontractors of Patheon or its Affiliates, alone or jointly with employees, consultants or subcontractors of Flexion or its Affiliates. Such written notice will be treated as the Proprietary Information of Flexion hereunder.

(h) Flexion shall, and shall cause its Affiliates to promptly disclose in writing and in reasonable detail to Patheon any potential Patheon Improvement and any Flexion Non-Specific Improvements developed, conceived, or created by employees, consultants, or subcontractors of Flexion or its Affiliates, alone or jointly with employees, consultants, or subcontractors of Patheon or its Affiliates. Such written notice in relation to Patheon Improvements will be treated as the Proprietary Information of Patheon hereunder.

(i) The Specifications, Flexion's Manufacturing Process, and any and all information or material related to the Existing Flexion Intellectual Property, and Flexion Improvements shall constitute Proprietary Information of Flexion,

which shall be deemed the disclosing Party with respect to such Proprietary Information and shall be subject to the provisions of Article VII of this Agreement.

(j) Patheon's Manufacturing Equipment and any and all information or material related to the Existing Patheon Intellectual Property and Patheon Improvements shall constitute Proprietary Information of Patheon, which shall be deemed the disclosing Party with respect to such Proprietary Information.

(k) Patheon shall, and shall cause its Affiliates, to disclose in writing and in reasonable detail to Flexion prior to the implementation of any such Patheon Improvement or Non-Specific Improvement into the Manufacturing Services or any potential Patheon Improvements or Non-Specific Improvements and Flexion shall, in its sole discretion, decide whether such improvement shall be used in the Manufacture of the Product. Such written notice will be treated as the Proprietary Information of Patheon hereunder.

(l) Patheon agrees to, and hereby does, and shall cause each of its employees, consultants, and Affiliates (collectively with Patheon, the "Patheon Assignors") to assign to Flexion all right, title and interest in and to the Flexion Improvements developed, conceived or created by such Patheon Assignors, alone or jointly with others including all intellectual property rights associated therewith. Upon Flexion's request and at Flexion's sole expense, Patheon shall, and shall use commercially reasonable efforts to cause each Patheon Assignor to, assist Flexion or anyone Flexion reasonably designates in preparing, filing, prosecuting, obtaining, enforcing or defending patent, copyright or other intellectual property application or grant of right issuing therefrom in any and all countries in the world.

(m) Flexion agrees to, and hereby does, and shall cause each of its employees, consultants, and Affiliates (collectively with Flexion, the "Flexion Assignors") to assign to Patheon all right, title and interest in and to the Patheon Improvements developed, conceived or created by such Flexion Assignors, alone or jointly with others including all intellectual property rights associated therewith. Upon Patheon's request and at Patheon's sole expense, Flexion shall, and shall use commercially reasonable efforts to cause each Flexion Assignor to, assist Patheon or anyone Patheon reasonably designates in preparing, filing, prosecuting, obtaining, enforcing or defending patent, copyright or other intellectual property application or grant of right issuing therefrom in any and all countries in the world.

5.2 Licenses.

(a) Flexion hereby grants to Patheon a fully paid-up worldwide, non-exclusive license, under Flexion's entire right, title, and interest in and to the Existing Flexion Intellectual Property for Patheon to Manufacture the Products solely pursuant to the terms of this Agreement.

(b) Flexion hereby grants to Patheon a fully paid-up worldwide, non-exclusive license, under Flexion's entire right, title, and interest in

and to the Flexion Improvements, in each case to make Products solely pursuant to the terms of this Agreement.

(c) Flexion hereby grants to Patheon a perpetual, irrevocable, fully paid-up worldwide, exclusive license, with the right to grant sub-licences, under Flexion's entire right, title, and interest in and to the Non-Specific Improvements for the manufacture, use, sale or supply of any and all products, except Excluded Products or any and all products which, at any time, are owned by or exclusively licensed to Flexion.

In addition, Flexion grants to Patheon a perpetual, irrevocable, fully paid-up worldwide, co-exclusive license, with the right to grant sub-licences, under Flexion's entire right, title, and interest in and to the Non-Specific Improvements for the manufacture, use, sale or supply of any and all products which, at any time, are owned by or exclusively licensed (in terms of the right of Flexion to sell such products) to Flexion except Excluded Products.

Accordingly, notwithstanding anything to the contrary herein, Flexion retains:

(i) co-exclusively with Patheon, rights to the Non-Specific Improvements for the manufacture, use, sale or supply of any and all products which, at any time, are owned by or exclusively licensed (in terms of the right of Flexion to sell such products) to Flexion, and

(ii) exclusively, any and all rights to the Non-Specific Improvements for the manufacture, use, sale or supply of Excluded Products;

provided that, in either case (i) or (ii),

- (1) Flexion may only sublicense its rights to Non-Specific Improvements to a Third Party in conjunction with the license or assignment by Flexion of rights to manufacture, use, sell or supply a therapeutic product that is, or were prior to the assignment, owned by or exclusively license (in terms of the right of Flexion to sell such products) to Flexion; and
- (2) other than with respect to permitted assignments of this Agreement under Section 10.5A herein Flexion shall not assign or otherwise transfer its right to Non-Specific Improvements without the prior written consent of Patheon. In the event that Flexion wishes to assign any Non-Specific Improvement(s) to an Affiliate, Patheon and Flexion shall enter into a novation agreement with that Flexion Affiliate, to novate the rights and obligations hereunder in respect of such Non-Specific Improvement(s) only.

For the purposes of this Section 5.2(c), “Excluded Products” means any product which comprises as its active agent [...***...]. For the avoidance of doubt, co-exclusive means that only Patheon (and its authorised sub-licensees) and Flexion (and its authorised sub-licensees) has rights in relation to the Non-Specific Improvements, such rights and the scope and nature of authorised sub-licensees being as expressly set out in this clause 5.2(c) and no wider.

5.3 Technology Transfer. Upon the request of Flexion at any time during the [...***...] period prior to expiry of this Agreement, Patheon shall, at Flexion’s cost (i) promptly disclose to Flexion or its designee any Patheon Improvement, (ii) have its representatives meet with representatives of Flexion or its designee to enable Flexion or such designee to Manufacture the Product, and (iii) provide such other assistance as Flexion may reasonably request to enable Flexion or such designee to Manufacture the Product. Flexion shall reimburse Patheon for its fees and all documented out-of-pocket expenses reasonably incurred by Patheon in connection with such technology transfer. Patheon will provide a quotation for the services which Flexion requires pursuant to this Section 5.3 as Additional Services and on acceptance by Flexion of the same, Patheon will provide the services stated therein.

5.4 Third Party Litigation. In the event that, during the Term, any Third Party institutes against Patheon any action that alleges that the Manufacture of the Product hereunder in accordance with the terms hereof infringes the intellectual property rights held by such Third Party, then, as between Patheon and Flexion, and subject to Flexion indemnifying and defending and holding harmless Patheon in relation to such action pursuant Section 9.1(a)(iv) herein, Flexion, at its sole expense, shall have the sole obligation to contest and assume discretion and control of the defense of such action, including the right to settle such action on terms determined by Flexion; provided, however, that in no event may Flexion agree to the entry of any equitable or injunctive relief that is binding on Patheon and its Affiliates without Patheon’s prior written consent, not to be unreasonably withheld or delayed. Patheon, at Flexion’s expense, shall use all commercially reasonable efforts to assist and cooperate with Flexion as reasonably request by Flexion in such action.

5.5 Licenses of Rights to Intellectual Property. The licenses granted by the Parties hereunder shall be deemed to be licenses of rights to “intellectual property” as defined Section 101 of the United States Bankruptcy Code and, in connection therewith, each Party shall have the rights set forth in Section 365(n) of the United States Bankruptcy Code in the event of any rejection or proposed rejection of this Agreement in any bankruptcy proceeding.

ARTICLE VI. REPRESENTATIONS AND WARRANTIES

6.1 Representations and Warranties of Each Party. Each Party hereby represents and warrants to the other Party as follows:

(a) Such Party (i) is duly formed and in good standing under the laws of the jurisdiction of its formation, (ii) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and

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(iii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other similar laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

(b) Except for the FDA's approval of Patheon's manufacturing, testing, and packaging for the Product from the Manufacturing Suite, all necessary consents, approvals, and authorizations of all Regulatory Authorities, other governmental authorities, and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

(c) The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not and will not conflict with or violate any requirement of Applicable Law or any provision of the articles of incorporation, bylaws limited partnership agreement, or other constituent document of such Party and (ii) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

6.2 Additional Representations, Warranties and Covenants, of Patheon. Patheon warrants, represents and covenants, that:

(a) (i) it has facilities, personnel, experience, and expertise sufficient in quality and quantity to perform the obligations hereunder, (ii) it shall perform its obligations in conformity with GMPs where applicable, (iii) it will comply with the Quality Agreement and comply with all agreed upon quality assurance, quality controls, and review procedures in the performance of its obligations hereunder and (iv) during the Term, the Facility will remain operational and qualified for the purpose of the Manufacture of Product under the terms of this Agreement;

(b) it has, as of the Effective Date observed and complied, and shall, during the Term and at its cost (subject to Sections 2.9(b)-(d) and Section 3.7), observe and comply, with all then-current Applicable Laws, including federal, state, and local laws, orders, regulations, rules, customs, and ordinances now in force or that may hereafter be in force, pertaining to the Facility and the performance of the Manufacturing Services and including, without limitation, (i) labor laws, orders, regulations, rules, customs, and ordinances of the country of Manufacture and (ii) those issued by the FDA pertaining to the Manufacturing Services and the Facility (but not those pertaining solely to non-Manufacturing matters relating to the Product, compliance with which shall be the responsibility of

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Flexion), and any laws, orders, regulations, rules, or ordinances issued in addition to, as a supplement to or as a replacement of Applicable Laws;

(c) none of it, its Affiliates, nor any Person under its direction or control, has ever been, nor will it engage suppliers which have to its actual knowledge, after due inquiry, been, (i) debarred or convicted of a crime for which a person can be debarred, under Section 335(a) or 335(b) of the FDA Act, or any equivalent Applicable Law of the country of Manufacture, (ii) threatened to be debarred under the FDA Act or any equivalent Applicable Law of the country of Manufacture or (iii) indicted for a crime or otherwise (to its actual knowledge after due inquiry) engaged in conduct for which a person can be debarred under the FDA or any equivalent Applicable Law of the country of Manufacture, and Patheon agrees that it will, within [...***...], notify Flexion in the event it receives notification of any such debarment, conviction, threat or indictment. Should Patheon become aware of any actual or suspected noncompliance with the foregoing, Patheon will notify Flexion in writing of such issue within [...***...]. For the purpose of this Section 6.2, suppliers and subcontractors engaged by Patheon to undertake the Manufacture of the Product shall be deemed to be under Patheon's direction or control;

(d) none of it, its Affiliates, nor any Person under its direction or control is currently excluded from a federal or state health care program under Sections 1128 or 1156 of the Social Security Act, 42 U.S.C. §§ 1320a-7, 1320c-5 or any equivalent Applicable Law of the country of Manufacture, as may be amended or supplemented;

(e) none of it, its Affiliates, nor any Person under its direction or control is otherwise currently excluded from contracting with the U.S. federal government or the government of the country of Manufacture;

(f) none of it, its Affiliates, nor any Person under its direction or control is otherwise currently excluded, suspended, or debarred from any U.S. or foreign governmental program;

(g) it shall immediately notify Flexion if, at any time during the Term, Patheon, its Affiliates, or any Person under its direction or control is convicted of an offense that would subject it or Flexion to exclusion, suspension, or debarment from any U.S. or foreign governmental program; and

(h) agrees to keep the Equipment free from all liens and encumbrances.

(i) it will not enter into any agreement or arrangement with any other Person that would prevent its ability to perform its obligations hereunder.

6.3 Warranty. Patheon warrants that, at the time of delivery of Product to Flexion: (a) such Product will have been Manufactured in accordance with the [...***...]; (b) such Product will be in conformity with the

[...***...] in accordance with the [...***...] set out therein and will conform with the [...***...] therefor provided pursuant to Section [...***...]; (c) title to such Product will pass to Flexion as provided herein free and clear of any security interest, lien, or other encumbrance; (d) such Product will not be adulterated or misbranded within the meaning of the FDA Act as a result of a Patheon Nonconformance; and (e) such Product will not be articles that, under the provisions of the FDA Act, may not be introduced into interstate commerce as a result of a Patheon Nonconformance.

6.4 Additional Representations and Warranties of Flexion. Flexion warrants and represents that:

(a) Non-Infringement.

(i) (1) as of the Effective Date, it or its Affiliates Control all issued patents and pending patent applications set forth on Schedule 6.4(a), which patents and applications are necessary for performance of the Manufacturing Services; and (2) it has the right to authorize Patheon to use and exploit such issued patents and pending patent applications to perform the Manufacturing Services in accordance with the terms and conditions hereof;

(ii) as of the Effective Date, to the actual knowledge of Flexion's management team, having taken all Diligent and Reasonable Steps to ascertain the same, that there are no facts or circumstances that would cause Flexion to conclude that the performance of the Manufacturing Services, in accordance with the terms and conditions hereof and using Flexion's Manufacturing Process, or the manufacture, use, supply or other disposition of the Product by Patheon as may be required to perform its obligations under this Agreement, will result, in the infringement or misappropriation of any Third Party's intellectual property rights;

(iii) as of the Effective Date, Flexion or its Affiliates Control and have the right to lawfully disclose the Specifications to Patheon and to authorize Patheon to use the Specification to perform the Manufacturing Services;

(iv) as of the Effective Date, there are no actions or other legal proceedings pending against Flexion and/or its Affiliates concerning the infringement of Third Party intellectual property rights related to any of the Specifications, Flexion's Manufacturing Process, any of the Materials, or the sale, use, or other disposition by Flexion of any Product made in accordance with the Specifications.

For the purposes of part (ii) above, "Diligent and Reasonable Steps" means such steps as would normally be taken by a company of the same size and nature as Flexion for a product of similar market potential at a similar stage of its product life, when utilizing sound and reasonable business practice.

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(b) Quality and Compliance.

(i) during the Term, the Specifications for all Products conform to all applicable GMPs and Applicable Laws;

(ii) during the Term, the Products, if labelled and manufactured in accordance with the Specifications and in compliance with the Quality Agreement, applicable GMPs and Applicable Laws may be lawfully sold and distributed in every jurisdiction in which Flexion markets the Products; and

(iii) during the Term, on the date of shipment to Patheon, any Flexion-Supplied Materials will conform to the specifications for the Flexion-Supplied Materials that Flexion has given to Patheon and the Flexion-Supplied Materials will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

(c) Flexion agrees that, as a pre-condition to the adding of any country to the Territory pursuant to section 2.2(h), Flexion shall repeat the warranties above as at the date on which the country is added to the Territory.

6.5 DISCLAIMER. THE FOREGOING EXPRESS WARRANTIES SET FORTH IN THIS ARTICLE VI ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT, AND ALL OTHER WARRANTIES ARE HEREBY DISCLAIMED AND EXCLUDED BY EACH PARTY.

6.6 Legal Compliance.

(a) Patheon confirms that all licences, registrations and Regulatory Authority approvals to be obtained by Patheon pursuant to this Agreement and the Technical Transfer Agreement shall be obtained in a lawful and ethical manner.

(b) Patheon has not and shall not cause Flexion or its subsidiaries or affiliates to be in violation of any applicable U.S. export or import control or customs law or regulation, U.S. sanctions or embargoes, the U.S. Foreign Corrupt Practices Act of 1977 (as amended) (“FCPA”), the U.S. Travel Act, the UK Bribery Act of 2010 (the “UK Bribery Act”), anti-corruption and anti-kickback laws and regulations, any applicable anti-corruption laws or regulations of another country, or any other applicable law or regulation. In relation to Flexion’s business, Patheon has not and shall not directly or indirectly offer, pay, solicit, or accept any bribes, kickbacks, or other improper payments/benefits to or from any party, including, but not limited to, any employee, representative, or official of the Flexion, any government, or any state-affiliated entity. Patheon has not and shall not offer, pay, solicit, or accept any rebates or refunds in connection with the Product or Flexion’s business without informing and obtaining the written approval of Flexion in advance and ensuring that such rebate/refund is compliant with all applicable laws and regulations. Patheon

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has in good faith provided to Flexion accurate and complete due diligence information and materials regarding Patheon and its employees and Affiliates in response to requests by Flexion. In relation to the performance of this Agreement, Patheon shall fully cooperate with Flexion in ensuring compliance with the FCPA, the UK Bribery Act and all other applicable laws and regulations.

(c) Flexion may suspend its performance under this Agreement if Flexion reasonably suspects that Patheon has or will violate the FCPA, the UK Bribery Act or any other applicable law or regulation. Patheon shall reasonably cooperate with Flexion with any audit or questioning related thereto.

(d) Patheon understands and acknowledges that a violation of the FCPA, the UK Bribery Act or any of the terms of this Section 6.6 by Patheon or its employees, agents, or contractors shall constitute a [...***...] for the purpose of Section [...***...] of this Agreement.

ARTICLE VII. CONFIDENTIALITY

7.1 Confidentiality Obligations.

(a) Subject to the provisions of clauses (b), (c) and (d) below, at all times during the Term and for seven (7) years following the expiration or termination thereof, the Receiving Party (i) shall keep completely confidential and shall not publish or otherwise disclose any Proprietary Information furnished to it by the Disclosing Party, except to those of the Receiving Party's Representatives or Affiliates to perform such Party's obligations hereunder (and who shall be advised of the Receiving Party's obligations hereunder and who are bound by confidentiality obligations with respect to such Proprietary Information no less onerous than those set forth in this Agreement) and (ii) shall not use Proprietary Information of the Disclosing Party directly or indirectly for any purpose other than performing its obligations or exercising its rights hereunder. The Receiving Party shall be jointly and severally liable for any breach by any of its Representatives of the restrictions set forth in this Agreement.

(b) The Receiving Party's obligations set forth in this Agreement shall not extend to any Proprietary Information of the Disclosing Party:

(i) that is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of a Receiving Party or its Representatives or Affiliates;

(ii) that is received from a Third Party without restriction and without breach of any agreement between such Third Party and the Disclosing Party;

- (iii) that the Receiving Party can demonstrate by competent evidence was already in its possession without any limitation on use or disclosure prior to its receipt from the Disclosing Party;
- (iv) that is generally made available to Third Parties by the Disclosing Party without restriction on disclosure; or
- (v) that the Receiving Party can demonstrate by competent evidence was independently developed by the Receiving Party without reference to the Proprietary Information of the Disclosing Party.

(c) Each Party may disclose Proprietary Information to the extent that such disclosure is:

(i) made in response to a valid order of a court of competent jurisdiction or other governmental body of a country or any political subdivision thereof of competent jurisdiction; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Proprietary Information and/or documents that are the subject of such order be held in confidence by such court or governmental body or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Proprietary Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in such response to such court or governmental order;

(ii) otherwise required by law or regulation, including the rules and regulations of any securities authority or stock exchange on which such Party's or its Affiliate's securities are traded, as determined in good faith by counsel for the Receiving Party and acting in accordance with Section 10.10;

(iii) made in connection with the filing or prosecution of patent rights as permitted by this Agreement;

(iv) made in connection with the enforcement of such Party's rights under this Agreement and in performing its obligations under this Agreement;

(v) made in connection with the prosecution or defense of litigation as permitted by this Agreement;

(vi) made to Affiliates, actual and potential licensees and sublicensees, employees, consultants or agents of the Receiving Party who have a need to know such information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided, in each case, that any such Affiliate, actual or potential licensee or sublicensee, employee, consultant or agent agrees to

be bound by terms of confidentiality and non-use comparable in scope to those set forth herein; and

(vii) made to Third Parties in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by reasonable obligations of confidentiality and non-use; and

(viii) with respect to disclosure by Flexion, made to Regulatory Authorities in connection with obtaining and maintaining any Marketing Authorization.

(d) The Parties rights and obligations regarding the filing of this Agreement with any securities authority or with any stock exchange on which securities issued by a Party or its Affiliate are traded are set forth in Section 10.10.

(e) Subject to Patheon's obligations with any Regulatory Authority, upon expiration or termination of this Agreement, each Party, at the request of the other, shall return all data, files, records and other materials in its possession or control containing or comprising the other Party's Proprietary Information; provided that each Party may retain a copy of any Proprietary Information of the other Party required in order to permit a Party to exercise its rights pursuant to clause (c) above.

7.2 Injunctive Relief. Each Party acknowledges that a breach by either Party of the this ARTICLE VII may not reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party may be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to apply for preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of this ARTICLE VII; provided, however, that no specification in this Agreement of a specific legal or equitable remedy will be construed as a waiver or prohibition against the pursuing of other legal or equitable remedies in the event of such a breach. Each Party agrees that the existence of any claim, demand, or cause of action of it against the other Party, whether predicated upon this Agreement, or otherwise, will not constitute a defense to the enforcement by the other Party, or its successors or assigns, of the covenants contained in this ARTICLE VII.

ARTICLE VIII. TERM AND TERMINATION

8.1 Term. This Agreement shall commence as of the Effective Date and, unless earlier terminated in accordance with the terms hereof, shall expire on the tenth (10th) anniversary of the FDA Approval Date (the "Initial Term"). Notwithstanding, by mutual agreement the Parties may commence discussions three (3) years prior to the end of the Initial Term with a view to extending the Initial Term for such period or periods as may be agreed (collectively, the Initial Term and any extensions thereof, the "Term").

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8.2 Termination. In addition to any other provision of this Agreement expressly providing for termination of this Agreement, this Agreement may be terminated as follows:

(a) Flexion may terminate this Agreement:

(i) at any time by giving Patheon one (1) month prior written notice in the event that for efficacy or safety reasons the Product is withdrawn permanently or, if not yet approved, the Product is barred from further development (in either case for reasons outside of the reasonable control of Flexion) in the United States or any other market in a country or countries of the Territory that represent eighty percent (80%) or more of Flexion's overall Product sales including without limitation: (A) if any Regulatory Authority causes the clinical hold or permanent withdrawal of the Product, (B) failure to receive Marketing Authorization in the United States, (C) failure of the Product to achieve its primary endpoint or key secondary endpoints with respect to either of the ongoing (as of the Effective Date) Phase 2(b) and Phase 3 clinical trials, or (D) safety data which Flexion determines may have a materially adverse impact on use of the Product.

(ii) for convenience, at any time (x) prior to the FDA Approval Date, with three (3) months written notice to Patheon, and (y) after the FDA Approval Date, by giving twenty four (24) months prior written notice to Patheon; or

(iii) at any time upon written notice in the event of any material default by Patheon in the performance of any of its obligations hereunder, which material default has not been cured by Patheon within ninety (90) days after receiving written notice thereof ("Remediation Period"), provided that Patheon shall continue performing hereunder pursuant to the terms of Section 8.4 below. Flexion's right to terminate this Agreement for a particular breach under this Section 8.2(a)(iii) may only be exercised for a period of one hundred twenty (120) days following the expiry of the Remediation Period (where the breach has not been remedied) and, if the termination right is not exercised during this period, then Flexion will be deemed to have waived its right to terminate this Agreement for such breach. For purposes of clarity, the Parties agree that a "material default" of Patheon shall have occurred if (A) Patheon shall have delivered Non-Conforming Product caused by Patheon Nonconformance with respect to three (3) batches in any one calendar year, or (B) the Facility and/or the Manufacturing Suite violates GMP or other Applicable Law preventing the ability to continue the Manufacturing of Product for at least six (6) months.

(b) Patheon may terminate this Agreement at any time upon written notice in the event of (i) any material default by Flexion in the performance of any of its obligations hereunder, which default has not been cured by Flexion within ninety (90) days after receiving written notice thereof; or (ii) Flexion's default of its payment obligations in accordance with ARTICLE IV which default has not been cured by Flexion within fifteen (15) days after receiving written notice thereof; provided, however, that, if Flexion fails to cure such payment default,

Patheon may not terminate without first providing a second notice to the attention of Flexion's Chief Executive Officer and an additional fifteen (15) day cure period.

(c) This Agreement may be terminated at any time by either Party immediately upon written notice to the other Party (A) pursuant to Section 10.2 in the event of a force majeure that remains uncured for the period provided in Section 10.2, or (B) if the other Party shall file in any court or agency, pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for arrangement or for the appointment of a receiver or trustee of the other Party or of its assets, or if the other Party proposes a written agreement of composition of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is consented to by such Party or is not dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a Party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

(d) Either Party may terminate this Agreement by giving three (3) months' notice to the other Party if a permanent injunction is granted pursuant to a Third Party claim for intellectual property infringement in either the United Kingdom and/or the United States preventing the further sale, promotion or marketing of the Product in such country as applicable.

(e) This Agreement will automatically terminate should either Flexion or Patheon exercise its right to terminate the Technical Transfer Agreement (but not in the event of an expiration of such agreement as set forth in Section 8.2 thereof) prior to the FDA Approval Date, in which case, any payment to Patheon will be made in accordance with the Technical Transfer Agreement.

8.3 Effect of Termination.

(a) The expiration or termination of this Agreement shall be without prejudice to any rights or obligations of the Parties that may have accrued prior to such termination, and the provisions of Sections 2.8 (in respect of Product on the market at the date of termination of this Agreement), 3.5, 3.6, 3.8, 3.10, 3.12, 3.13, 5.1, 5.2(c), 5.5, 6.3, 6.5, 8.3 and 8.4 and ARTICLE I (to the extent definitions are used in other surviving sections pursuant to this Section 8.3(a)), ARTICLE IV, ARTICLE VII, ARTICLE IX, and ARTICLE X; provided that, Section 3.8 shall only survive for a period of [...***...] days after expiration or termination of this Agreement in respect of deviations that occurred before termination or expiration and continue to be relevant shall survive the expiration or termination of this Agreement. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

(b) Upon expiration or termination of this Agreement, subject to the Parties' obligations under Section 8.4 below, each Party, at the request of the

other, shall return all data, files, records, and other materials in its possession or control containing or comprising the other Party's Proprietary Information.

(c) Upon expiration or termination of this Agreement for any reason, subject to the Parties' obligations under Section 8.4 below, (i) all submitted but unfilled Purchase Orders with respect to which Patheon has (1) not begun Manufacture of Product shall be cancelled, or (2) begun Manufacture of the Product shall be completed, unless otherwise agreed (ii) Flexion shall remove all Flexion Manufacturing Equipment and Materials from the Facility within [...***...] days of such termination under all sections other than Section 8.2(a)(iii) and within [...***...] days [...***...] of a termination by Flexion pursuant to Section 8.2(a)(iii) that is not reasonably disputed by Patheon, failing which Flexion will pay a fee equivalent to the aggregate monthly Base Fee for the Manufacturing Suite for each month or part month the Flexion Manufacturing Equipment or Materials remain at the Facility after [...***...] days or [...***...] days, as applicable, from such termination.

(d) Upon expiration or termination of this Agreement, subject to the Parties' obligations under Section 8.4 below, (i) Flexion shall purchase from Patheon at Patheon's cost, all unpaid Material Costs and Bill Back Items which were ordered, purchased, produced or maintained by Patheon in contemplation of the Manufacture of the Product in accordance with Section 2.2; (ii) Flexion shall pay Patheon any earned but unpaid Product Fees, including those under any outstanding Purchase Order as described in Section 8.3(c); (iii) Flexion shall pay for any earned (through the month of such expiration or termination) but undisputed and unpaid Base Fees, Phase I Filling Space Fees or Additional Services; and (iv) Flexion shall pay all due and outstanding invoices under ARTICLE IV.

(e) Upon expiration or termination of this Agreement for any reason other than by [...***...] pursuant to Section [...***...] that is not reasonably disputed by [...***...], subject to the Parties' obligations under Section 8.4 below, Flexion shall pay to Patheon all and any removal and Make Good Costs associated with the removal of the Flexion Manufacturing Equipment from the Facility as agreed to in good faith by the Parties. "Make Good Costs" means the reasonable costs required to repair the Facility and return it to a clean, safe and useable area based on the repair of damage caused by the installation or removal of Flexion Manufacturing Equipment. In relation to termination of this Agreement by [...***...] pursuant to Section [...***...], Flexion shall pay any Make Good Costs that are required in relation to and to the extent that any damage that is caused to the Facility as a result of the negligence of Flexion or its agent or a failure to materially comply with the reasonable written instructions of Patheon in the removal of Flexion Manufacturing Equipment.

(f) The Parties understand and believe that the expiration or termination of this Agreement for any reason shall not constitute a "relevant transfer" as defined by and pursuant to Regulation 3(1)(b) of the Transfer of Undertakings (Protection of Employment) Regulations 2006 ("TUPE"). If, contrary

to the Parties' understanding and belief, TUPE does apply on the expiration or termination of this Agreement to the transfer of any employee or subcontractor of Patheon to Flexion or to any person who, after expiration or termination of this Agreement, provides to Flexion services similar to the Manufacturing Services and/or the Additional Services ("Replacement Entity") then:

- (i) without prejudice to Flexion's obligations under Section 8.3(g) below, following termination or expiry of this Agreement other than by [...***...] pursuant to Section [...***...], Flexion shall indemnify Patheon for and against all claims, costs, expenses or liabilities arising, incurred or suffered by Patheon in relation to any claim made by or in respect of any person employed or formerly employed by Patheon for which it is alleged Flexion and/or any Replacement Entity may be liable by virtue of TUPE, provided that this indemnity shall not apply if and to the extent that, (A) the aggregate amount payable by Flexion pursuant to this Section 8.3(f)(i) and Section 8.3(g) exceeds the Maximum Manufacturing Services Termination Costs; or (B) any such claim, cost, expense or liability arises as a result of a failure by Patheon to comply with its applicable obligations under TUPE.
- (ii) if (A) this Agreement has been terminated by [...***...] pursuant to Section [...***...], or (B) this Agreement terminates or expires under any other circumstances and the aggregate amount payable by Flexion pursuant to Section 8.3(f)(i) and Section 8.3(g) exceeds the Maximum Manufacturing Services Termination Costs, Patheon shall indemnify Flexion for and against all claims, costs, expenses or liabilities arising, incurred or suffered by Flexion and/or any Replacement Entity in relation to any claim made by or in respect of any person employed or formerly employed by Patheon for which it is alleged Flexion and/or any Replacement Entity may be liable by virtue of TUPE provided that this indemnity shall not apply if and to the extent that any such claim, cost, expense or liability arises as a result of a failure by Flexion or the Replacement Entity to comply with its applicable obligations under TUPE.

(g) Subject to the Parties' obligations under Section 8.4 below, Flexion shall pay to Patheon the following costs ("Manufacturing Services Termination Costs"): (i) upon expiration or termination of this Agreement, all reasonable actual costs incurred by Patheon to complete activities associated with such completion, expiry or termination including, without limitation, disposal fees that may be payable for any Materials and supplies owned by Flexion to be disposed of by Patheon; and (ii) upon expiration or termination of this Agreement other than by [...***...] pursuant to Section [...***...], all and any direct costs and expenses or termination or cancellation fees payable by Patheon as a consequence of or arising from the termination of this Agreement, to include but not limited to, all and any reasonable redundancy costs of employees employed by

Patheon to work solely or mainly in providing the Services and/or Manufacturing the Product, all and any termination costs in relation to subcontractors and agency staff working solely or mainly in providing the Services and/or Manufacturing the Product and any termination or cancellation fees payable to Third Party suppliers. Patheon will use commercially reasonable efforts to mitigate the Manufacturing Services Termination Costs and reallocate available resources. Patheon will further provide Flexion with documentation in order to substantiate the Manufacturing Services Termination Costs. Notwithstanding anything in this Section 8.3(g), Flexion's aggregate liability for the Manufacturing Services Termination Costs (under both this Agreement and the Technical Transfer Agreement combined) shall be limited to the payment to Patheon of the first £[...***...] (the "Maximum Manufacturing Services Termination Costs").

(h) Flexion acknowledges that no Patheon Competitor (being a Person that derives greater than [...***...]% of its revenues from performing contract pharmaceutical or biopharmaceutical development or commercial manufacturing services) will be permitted access to the Facility.

(i) In relation to any representatives of Flexion that are permitted access to the Facility pursuant to Section 8.3 or 8.4, Flexion shall ensure that such representatives are appropriately trained by Flexion (e.g. GMP training) and shall observe at all times Patheon's policies and procedures (as amended from time-to-time) as they pertain to the Facility, including policies relating to health and safety and compliance with GMP, and comply with all reasonable directions of Patheon in relation to the same; provided that Flexion is given notice of such policies and given a reasonable period of time to review and implement such policies. Patheon may refuse or limit in its sole discretion at any time admission to the Facility by any of Flexion's representatives who fail to observe such policies or comply with such reasonable directions.

(j) The Parties agree that if any fees or charges are duplicated under Section 8.11 of the Technical Transfer Agreement, Flexion shall only be obligated to make such payment once.

8.4 Transition Assistance.

(a) Upon the delivery by either Party of a notice of termination of this Agreement for any reason, upon the request of Flexion, and subject to terms set forth in this Agreement including this Section 8.4(a), (i) Patheon shall provide Flexion with the reasonable assistance of its staff and reasonable access to its other internal resources to provide Flexion with a reasonable level of technical assistance and consultation to transfer the Manufacture and the regulatory qualification of the Product to a supplier of Flexion's election, provided that Flexion will reimburse Patheon for its fees and all documented costs and out-of-pocket expenses incurred

in connection with such assistance (Patheon would provide a quotation for the services which Flexion requires pursuant to this Section 8.4 as Additional Services and on acceptance by Flexion of the same, Patheon will provide the services stated therein) and (ii) Patheon will provide the deliverables set forth on Schedule 8.4(a) hereto subject to payment of the fees and costs to be paid by Flexion as described above.

(b) Upon the delivery by [...***...] of a notice of termination of this Agreement pursuant to Section [...***...] (but not including the giving of notice of termination following an extension to this Agreement pursuant to this Section 8.4(b)), if requested by Flexion in writing given at the same time as the giving of such notice of termination including the term of such additional supply, Patheon shall supply the Products pursuant to the terms of this Agreement for a period not to exceed a maximum of [...***...] from the delivery of a notice of termination. For the avoidance of doubt, the termination date of this Agreement shall be deemed the date upon which the Parties have completed their obligations under this Section 8.4. Flexion acknowledges that, during such transition assistance period, no Patheon Competitor (being a Person that derives greater than [...***...]% of its revenues from performing contract pharmaceutical or biopharmaceutical development or commercial manufacturing services) will be permitted access to portions of the Facility other than those dedicated to the Manufacture of the Product.

ARTICLE IX. INDEMNIFICATION

9.1 Flexion Indemnification Obligations. Flexion shall indemnify Patheon, its Affiliates, and their respective directors, officers, employees, and agents (the “Patheon Indemnified Parties”), and defend and save each of them harmless, from and against any and all (a) Third Party Losses incurred by any of them in connection with, arising from, or occurring as a result of (i) the breach by Flexion of any of its obligations under this Agreement; (ii) the breach or inaccuracy of any representation or warranty made by Flexion in this Agreement, (iii) any negligence or willful misconduct by Flexion or any of its Affiliates, (iv) any claim made by any Person that the Manufacture and supply of the Product in accordance with the terms hereof infringes or misappropriates the patent, trademark, or other intellectual property rights of such Person, and (v) any product liability claim made by any Person with respect to any Product Manufactured in accordance with the terms hereof, except to the extent liability is based on a Patheon Nonconformance or (b) any Loss incurred by any of them as a direct result of and to the extent of the negligence or willful misconduct of the Flexion On Site Representatives at the Facility except, in each case, for those Losses for which Patheon has an obligation to indemnify the Flexion Indemnified Parties pursuant to Section 9.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses and provided, however, that Flexion will not be required to indemnify the Patheon Indemnified Parties with respect to any such Loss hereunder to the extent the same is caused by any breach of contract, negligent act or omission, or intentional misconduct by any Patheon Indemnified Parties. For the avoidance of doubt, the parties acknowledge that Patheon has not and will not conduct any freedom to operate searches in relation to the Product and/or Flexion’s Manufacturing Process nor reviewed any third party patents in relation thereto and that Patheon’s failure or omission to

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do so will not be considered negligence for the purposes of excluding or limiting a claim under this indemnity.

9.2 Patheon Indemnification Obligations. Patheon shall indemnify Flexion, its Affiliates, and their respective directors, officers, employees, and agents (the “Flexion Indemnified Parties”), and defend and save each of them harmless, from and against any and all (a) Third Party Losses incurred by any of them resulting from, or relating to, any claim of personal injury or property damage to the extent that the injury or damage is in connection with, arising from, or occurring as a result of (i) the breach or inaccuracy of any representation or warranty made by Patheon in this Agreement, (ii) any negligence or willful misconduct by Patheon or any of its Affiliates; and (iii) any product liability claim made by any Person with respect to any Product Manufactured by Patheon to the extent any such liability is based on or caused by a Patheon Nonconformance; (b) Third Party Losses incurred by any of them in connection with, arising from, or occurring as a result of a claim that any Existing Patheon Intellectual Property or Patheon Improvement used by Patheon in its Manufacture of the Product infringes or misappropriates the patent, trademark, or other intellectual property rights of such Person; except, in each case, for which Flexion has an obligation to indemnify the Patheon Indemnified Parties pursuant to Section 9.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses and provided, however, that Patheon will not be required to indemnify the Flexion Indemnified Parties with respect to any such Loss hereunder to the extent the same is caused by any breach of contract, negligent act or omission, or intentional misconduct by Flexion Indemnified Parties.

9.3 Indemnification Procedure.

(a) Notice of Claim. The indemnified Party (the “Indemnified Party”) shall give the indemnifying Party (the “Indemnifying Party”) prompt written notice (an “Indemnification Claim Notice”) of any Loss, action, or discovery of facts upon which such Indemnified Party intends to base a request for indemnification under Section 9.1 or 9.2 (a “Claim”), but in no event shall the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses upon which it intends to seek indemnification.

(b) Control of Defense. At its option, the Indemnifying Party may assume the defense of any Claims by giving written notice to the Indemnified Party within [...***...] days after the Indemnifying Party’s receipt of an Indemnification Claim Notice; provided that the assumption of the defense of a Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party’s Claim. Upon assuming the defense of a Claim, the Indemnifying Party may appoint as lead counsel in the defense of such Claim any legal counsel selected by the Indemnifying Party. In the event the

Indemnifying Party assumes the defense of a Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnified Party in connection with the Claim. Subject to clause (c) below, if the Indemnifying Party assumes the defense of a Claim, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense, or settlement of such Claim. In the event that it is ultimately determined that the Indemnifying Party is not obliged to indemnify, defend, or hold harmless an Indemnified Party from and against any Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the Indemnifying Party in its defense of such Claim.

(c) Right to Participate in Defense. Without limiting Section 9.3(b), any Indemnified Party shall be entitled to participate in, but not control, the defense of a Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing, (ii) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 9.3(b) (in which case the Indemnified Party shall control the defense), or (iii) the interests of the Indemnified Party and the Indemnifying Party with respect to such Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules, or equitable principles.

(d) Settlement. With respect to any Losses (i) relating solely to the payment of money damages in connection with a Claim, (ii) that will not result in the Indemnified Party becoming subject to injunctive or other relief or otherwise adversely affect the business or reputation of the Indemnified Party in any manner, and (iii) as to which the Indemnifying Party has acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement, or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Claims, where the Indemnifying Party has assumed the defense of the Claim in accordance with Section 9.3(b), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement, or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld or delayed. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, agree to any settlement or acquiesce to any judgment with respect to a Claim that obligates the Indemnified Party to pay any amount subject to indemnification by the Indemnifying Party or causes the Indemnified Party to admit to any civil or criminal liability.

(e) Cooperation. If the Indemnifying Party chooses to defend or prosecute any Claim, the Indemnified Party shall cooperate in the defense or

prosecution thereof and shall, at the Indemnifying Party's expense, furnish such records, information, and testimony, provide such witnesses, and attend such conferences, discovery proceedings, hearings, trials, and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its time and reasonable out-of-pocket expenses in connection therewith.

(f) Expenses. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Claim shall be reimbursed on a monthly basis in arrears by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obliged to indemnify the Indemnified Party.

9.4 Insurance. During the Term and for [...***...] thereafter, each Party shall procure and maintain at its own expense from a qualified and licensed insurer liability insurance or indemnity policies, in an amount not less than \$[...***...] in the aggregate with respect to public and products liability, subject to such deductible or self-retention limits as either Party in its business discretion may elect. Such policies shall insure against liability on the part of each Party and any of its Affiliates, as their interests may appear, due to injury, disability, or death of any person or persons, or injury to property, arising from the distribution of the Products. Each Party will either (a) include the other Party and its officers and employees and consultants as additional insureds on such policies, or (b) ensure that such policy contains an indemnity to principal clause. Promptly following the execution of this Agreement, each Party shall provide to the other a certificate of insurance (i) summarizing the insurance coverage and (ii) identifying any exclusions. Each Party shall promptly notify the other of any material adverse alterations to the terms of this policy or decreases in the amounts for which insurance is provided.

9.5 Limitation on Damages

(a) Maximum Liability. Except with respect to (i) [...***...] of Patheon or (ii) for damages incurred by Flexion arising from, or occurring as a result of a claim by a Third Party that any [...***...] used by Patheon in its Manufacture of the Product [...***...] or (iii) breaches of [...***...], Patheon's maximum liability to Flexion under this Agreement for any reason whatsoever, including, without limitation, any liability arising under Sections 2.7, 2.8, 3.10, 3.12 or 9.2 hereof or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement in

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each calendar year (liability cap pro-rated for part calendar years) will not exceed [...***...]% of the revenues received by Patheon pursuant to this Agreement in the [...***...] period prior to the month in which the underlying event occurred that gave rise to the liability (e.g. the date of the incident or manufacture).

(b) NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR (I) ANY (DIRECT OR INDIRECT) LOSS OF PROFITS, OF PRODUCTION, OF ANTICIPATED SAVINGS, OF BUSINESS, OF GOODWILL OR OF USE OF THE PRODUCT OR COSTS OF ANY SUBSTITUTE SERVICES OR (II) ANY OTHER LIABILITY, DAMAGE, COST OR EXPENSE OF ANY KIND INCURRED BY THE OTHER PARTY OF AN INDIRECT OR CONSEQUENTIAL NATURE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF THE DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS PARAGRAPH IS INTENDED TO LIMIT OR RESTRICT DAMAGES AVAILABLE FOR [...***...].

(c) The limitations set forth in Sections 9.5(a) and 9.5(b) shall not act to exclude or limit either Party's liability for (i) personal injury or death caused by the negligence of that Party, or for (ii) fraudulent misrepresentation.

(d) Sole & Exclusive Remedies. Notwithstanding anything in this Article IX to the contrary:

(i) Except as described in Section 9.5(c) above and except for Patheon's indemnification obligations set forth in Section 9.2, Patheon's sole liability and Flexion's sole and exclusive remedy whether in contract, tort, equity or otherwise for Non-Conforming Product based on or caused by a Patheon Nonconformance shall be the rights and remedies set forth in Section 2.8, 3.10 and 3.12 of this Agreement and in Section 8.2(a)(iii) of this Agreement.

(ii) Patheon's sole liability and Flexion's sole and exclusive remedy whether in contract, tort, equity or otherwise for Patheon's failure to Manufacture the full quantity of Product specified in a Purchase Order by the Agreed Delivery Date shall be the rights and remedies set forth in Section 2.7 and Section 8.2(a)(iii) of this Agreement.

9.6 Product Liability Claims. As soon as it becomes aware, each Party will give the other prompt written notice of any defect or alleged defect in a Product, any injury alleged to have occurred as a result of the use or application of the Product, and any circumstances that may give rise to litigation or recall of a Product or regulatory action that may affect the sale or Manufacture of a Product, specifying, to the extent the Party has such information, the time, place, and circumstances thereof and the names and addresses of the persons involved. Each Party will also furnish promptly to the other copies of all papers received in respect of any claim, action, or suit arising out of such alleged defect, injury, or regulatory action.

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9.7 Allocation of Risk. This Agreement (including, without limitation, this ARTICLE IX) is reasonable and creates a reasonable allocation of risk for the relative profits the Parties each expect to derive from the Products.

ARTICLE X. MISCELLANEOUS

10.1 Notices. Notwithstanding that advance notification of any notices or other communications may be given by electronic mail transmission, all notices or other communications that shall or may be given pursuant to this Agreement shall be in writing (including by confirmed receipt electronic mail) and shall be deemed to be effective (a) when delivered if sent by registered or certified mail, return receipt requested, or (b) on the next business day, if sent by overnight courier, (c) when sent if sent by electronic mail provided that receipt is confirmed, in each case to the Parties at the following addresses (or at such other addresses as shall be specified by like notice) with postage or delivery charges prepaid:

If to Flexion:

Flexion Therapeutics, Inc.
Attn: Michael Clayman, MD
Telephone: [...***...]
Email: [...***...]

With a copy to: Legal

If to Patheon:

Attention:

Patheon UK Limited
Executive Director & General Manager
Kingfisher Drive, Covingham
Swindon, Wiltshire SN3 5BZ
England
Email: [...***...]

with copy to

Legal Director.

10.2 Force Majeure. Neither Party shall be liable for delay in delivery, performance or nonperformance, in whole or in part, nor shall the other Party have the right to terminate this Agreement except as otherwise specifically provided in this Section 10.2 where such delay in delivery, performance or nonperformance results from acts beyond the reasonable control and without the fault or negligence of such Party including, but not limited to, the following conditions: fires, floods, storms, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, or acts, omissions, or delays in acting by any governmental authority; provided that the Party affected by such a condition shall, within five (5) days of its occurrence, give notice to the other Party stating the nature of the condition, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no

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longer duration than is reasonably required, and the nonperforming Party shall use its commercially reasonable efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for [...***...] days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the non-affected Party may terminate this Agreement immediately by written notice to the affected Party.

10.3 Independent Contractor. The Parties to this Agreement are independent contractors. Nothing contained in this Agreement shall be construed to place the Parties in the relationship of employer and employee, partners, principal, and agent or a joint venture. Neither Party shall have the power to bind or obligate the other Party nor shall either Party hold itself out as having such authority.

10.4 Waiver. Save where expressly stated in Sections 2.8 and 8.2(a)(iii), no waiver by either Party of any provision or breach of this Agreement shall constitute a waiver by such Party of any other provision or breach, and no such waiver shall be effective unless made in writing and signed by an authorized representative of the Party against whom waiver is sought. No course of conduct or dealing between the Parties will act as a modification or waiver of any provision of this Agreement. Either Party's consent to or approval of any act of the other Party shall not be deemed to render unnecessary the obtaining of that Party's consent to or approval of any subsequent act by the other Party.

10.5 Entire Agreement. This Agreement (together with all Exhibits and Schedules hereto, which are hereby incorporated by reference), the Quality Agreement, and the Technical Transfer Agreement constitute the final, complete, and exclusive agreement between the Parties relating to the subject matter hereof and supersede all prior conversations, understandings, promises, and agreements relating to the subject matter hereof, including without limitation that (i) certain Confidentiality Agreement dated September 22, 2014 between Flexion and Patheon and the Letter Agreement, and (ii) that certain Patheon Partner External User Account/Access Form, Client Agreement and Authorization signed by Flexion on June 5, 2015.

Neither Party has relied upon any communications, representations, terms or promises, verbal or written, not set forth herein. No terms, provisions or conditions of any purchase order or other business form or written authorization used by Flexion or Patheon will have any effect on the rights, duties, or obligations of the Parties under or otherwise modify this Agreement, regardless of any failure of Flexion or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both Parties.

10.5A Assignment; Change of Control. This Agreement may not be assigned by Patheon without the prior written consent of Flexion. Notwithstanding the foregoing, either Party may assign this Agreement to an Affiliate or to an acquirer or successor in interest in connection with a Change of Control of such Party without the prior written consent of the other Party, provided that such Party provides the other Party with written notice of any such assignment. This Agreement shall be binding upon and inure to the benefit of Flexion and Patheon and their respective successors, heirs, executors, administrators, and permitted assigns. "Change of Control" means the closing of (a) a merger, consolidation or similar transaction providing for the acquisition of the direct or indirect ownership of more than fifty percent (50%) of a Party's

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shares or similar equity interests or voting power of the outstanding voting securities or that represents the power to direct the management and policies of such Party (including any acquisition arising through the offering of any shares of Patheon or any of its Affiliates on any securities or stock exchange), or (b) the sale of all or substantially all of a Party's assets related to the subject matter of the Agreement.

10.6 Amendment; Modification. This Agreement may not be amended, modified, altered, or supplemented except by a writing signed by both Parties. No modification of any nature to this Agreement and no representation, agreement, arrangement, or other communication shall be binding on the Parties unless such is expressly contained in writing and executed by the Parties as an amendment to this Agreement. This Agreement may not be amended in any respect by any purchase order, invoice, acknowledgment, or other similar printed document issued by either Party.

10.7 Governing Law

(a) The laws of [...***...], whether procedural or substantive (but excluding application of any choice of law provisions contained therein) shall apply to all matters pertaining only to (a) title to and ownership of Materials, Equipment or the Facility, and its appurtenances including, without limitation, all rights therein and the creation, exercise and extinction of such rights, obligations and liabilities or (b) employment law matters. In relation to such matters, both Parties shall submit to the exclusive jurisdiction of the [...***...] Courts. For the avoidance of doubt, the Parties agree that nothing in this Agreement shall (i) grant Flexion any property ownership rights in the Facility or (ii) shall constitute a lease to the Facility.

(b) In all other respects, this Agreement shall be construed under and governed by the laws of [...***...] without regard to the application of principles of conflicts of law. In relation to such matters, both Parties shall submit to the exclusive jurisdiction of [...***...].

(c) Any preliminary issue over which of sub-section 10.7(a) or (b) applies to a particular claim or dispute shall be determined in accordance with provisions of 10.7(a).

(d) The Parties expressly exclude the application of the United Nations Convention on Contracts for the International Sale of Goods, if applicable.

10.8 Compliance with Applicable Laws. Each Party and its Affiliates, and their respective representatives, shall comply with all applicable laws, rules and regulations in the performance of their obligations under this Agreement. Without limiting the foregoing, each Party and its Affiliates, and their respective representatives, shall comply with export control laws and regulations of the country of Manufacture and of the United States. Neither Party nor its Affiliates (or representatives) shall, directly or indirectly, without prior U.S. government authorization, export, re-export, or transfer the Product to any country subject to a U.S. trade embargo, to any resident or national of any country subject to a

U.S. trade embargo, or to any person or entity listed on the “Entity List” or “Denied Persons List” maintained by the U.S. Department of Commerce or the list of “Specifically Designated Nationals and Blocked Persons” maintained by the U.S. Department of Treasury. In so far as the same applies to a Party or its Affiliates, each Party and its Affiliates and respective representatives shall comply with the requirements of the Foreign Corrupt Practices Act of 1977 (15 U.S.C. § 78dd-1, et seq.).

10.9 Dispute Resolution.

(a) The Parties recognize that disputes may arise from time to time during the Term of this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes arising under this Agreement in an expedient manner by mutual cooperation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 10.9 if and when a dispute arises under this Agreement.

(b) Unless otherwise specifically recited in the Agreement, disputes between the Parties under this Agreement will be first referred to the Project Manager of each Party as soon as reasonably possible after such dispute has arisen. If the Project Managers are unable to resolve such a dispute within fifteen (15) days of being requested by a Party to resolve such dispute, either Party may, by written notice to the other, have such dispute referred to the Steering Committee. If the Steering Committee is unable to resolve such dispute within thirty (30) days of being requested by a Party to resolve such dispute, each Party shall have the right, pursuant to written notice, to refer such dispute to the [...***...] of each Party for attempted resolution by negotiations within thirty (30) days after such written notice is received. If the [...***...] are unable to resolve such dispute within thirty (30) days of being requested by a Party to resolve such dispute, each Party shall have the right to pursue any remedies available to it at law or in equity.

10.10 Securities Authorities and Stock Exchange Filings; Press Releases; Use of Trademarks.

(a) The Parties shall coordinate in advance with each other in connection with (i) a Party’s decision to file this Agreement with any securities authority or with any stock exchange on which securities issued by a Party or its Affiliate are traded, or (ii) any other disclosure of information pertaining to this Agreement as otherwise required by the rules and regulations of the Securities and Exchange Commission or any other securities authority or stock exchange on which securities issued by a Party or its Affiliates are traded, and, in each such instance, (a) the filing Party will provide the other Party at least ten (10) business days to review a draft redacted version of this Agreement, and (b) both Parties shall work together in good faith to agree on the disclosure to be made, having due and proper regard to their legal obligations; provided that the filing Party subject to such rules and regulations shall ultimately retain control over what information to disclose to any securities authority or stock exchange. Each filing Party shall use reasonable efforts to seek confidential treatment for terms proposed to be redacted; provided that the Parties shall use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligations, neither Party (nor any of its Affiliates) shall be obligated to consult

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with or obtain approval from the other Party with respect to any filings to any securities authority or stock exchange.

(b) Except for the filings described in Section 10.10(a) above, the Parties agree not to disclose in any press release or other public statement any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party. Neither Party shall (a) issue a press release or make any other public statement that references this Agreement or (b) use the other Party's or the other Party's Affiliates' names or trademarks for publicity or advertising purposes, except with the prior written consent of the other Party. Each Party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures to the Securities and Exchange Commission or any other governmental or regulatory agencies, including requests for confidential treatment of Proprietary Information of either Party included in any such disclosure.

10.11 Severability. If any provision of this Agreement is found by a proper authority to be unenforceable, that provision to the extent it is found to be unenforceable or invalid shall be severed and the remainder of the provision and this Agreement will continue in full force and effect. The Parties shall use their best efforts to agree upon a valid and enforceable provision as a substitute for any invalid or unenforceable provision, taking in to account the Parties' original intent of this Agreement.

10.12 Construction. Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms "hereof," "herein," "hereby," and derivative or similar words refer to this entire Agreement; (d) the terms "Article," "Section," "Exhibit," "Schedule," or "clause" refer to the specified Article, Section, Exhibit, Schedule, or clause of this Agreement; (e) "or" is disjunctive but not necessarily exclusive; and (f) the term "including" or "includes" means "including without limitation" or "includes without limitation." Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless business days are specified. The captions and headings of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties, and no rule of strict construction shall be applied against either Party hereto.

10.13 Third Party Beneficiaries. This Agreement is not intended to confer upon any non-party rights or remedies hereunder, except as may be received or created as part of a valid assignment.

10.14 Further Assurances. Each of the Parties agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such additional assignments, agreements, documents, and instruments, that may be necessary or as the other Party hereto may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

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10.15 Counterparts. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original. Electronic or Facsimile signatures shall be treated as original signatures.

10.16 [...***...]

[The remainder of this page is left blank intentionally.]

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first written above.

PATHEON UK LIMITED:

FLEXION THERAPEUTICS, INC.:

By: /s/ A.M. Botterill

By: /s/ Michael D. Clayman, M.D.

Name: A.M. Botterill

Name: Michael D. Clayman, M.D.

Title: Exec. Dir. & Gen. Manager

Title: CEO

[...***...]

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Schedule 2.9

[...***...]

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Schedule 1.60

[...***...]

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Schedule 1.62

[...***...]

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Schedule 1.82

[...***...]

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Schedule 2.1(a)

I. [...***...]

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Schedule 6.4(a)

[...***...]

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Schedule 8.4(a)

[...***...]

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TECHNICAL TRANSFER AND SERVICE AGREEMENT

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [*], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

TECHNICAL TRANSFER AND SERVICE AGREEMENT

This **TECHNICAL TRANSFER AND SERVICE AGREEMENT** (this “Agreement”), dated as of July 31, 2015 (the “Effective Date”), is made by and between Flexion Therapeutics, Inc., a Delaware corporation having its principal place of business at 10 Mall Road, Suite 301, Burlington, Massachusetts, United States (“Flexion”), and Patheon UK Limited, a company incorporated in England and Wales having its principal place of business at Kingfisher Drive, Covingham, Swindon, SN35BZ, United Kingdom (“Patheon”). Flexion and Patheon are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

RECITALS

WHEREAS, Flexion has a commercial interest in the Manufacture (as defined herein) and commercialization of FX006 drug product, an extended-release formulation of triamcinolone acetonide (TCA) which is manufactured using Flexion’s Manufacturing Process (the “Product”);

WHEREAS, concurrently herewith, the Parties are executing a manufacturing and supply agreement (the “Manufacturing and Supply Agreement”) pursuant to which Patheon would be a manufacturer and supplier of the Product; and

WHEREAS, in anticipation of the Manufacturing and Supply Agreement and the goods and services that Patheon will supply thereunder, the Parties desire to enter into a binding agreement pursuant to which Patheon would undertake certain technical transfer and construction services in order to validate and scale up portions of Flexion’s technology package and prepare Patheon’s facilities for the Manufacture of the Product;

NOW, THEREFORE, in consideration of the foregoing, the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

ARTICLE 1 DEFINITIONS

The following terms will have the meanings set forth below. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular. Any term not defined hereunder shall have the meaning ascribed to such term in the Manufacturing and Supply Agreement.

1.1 “Act” means the United States Federal Food, Drug and Cosmetic Act, as amended.

1.2 “Additional Services” means any services requested and approved by Flexion that supplement Patheon’s regular performance of the Services as described in Schedule 2.1(a) of the Manufacturing and Supply Agreement.

1.3 “Affiliate(s)” means, with respect to any Person, any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. For the purposes of this Section 1.3 only, a Person will be regarded as in control of another Person if such Person owns, or directly or indirectly controls, more than 50% of the voting securities (or comparable equity interests) or other ownership interests of the other Person, or if such Person directly or indirectly possesses the power to direct or cause the direction of the management or policies of the other Person, whether through the ownership of voting securities, by contract, or any other means whatsoever.

1.4 “Agreement” has the meaning set forth in the preamble hereto.

1.5 “API” means the active pharmaceutical ingredient triamcinolone acetonide, micronized.

1.6 “Applicable Law” means applicable United States, Canadian, English and other foreign federal, state, and local laws, orders, rules, regulations, guidelines, standards, customs and ordinances, including, without limitation, those (to the extent they are applicable) of the FDA, Health Canada, the Medicines and Healthcare Products Regulatory Agency in the United Kingdom and other comparable foreign Regulatory Authorities, including the Food Drug and Cosmetic Act.

1.7 “Base Fee” means the monthly fee paid by Flexion in consideration for the Services, as more specifically set forth in Schedule 2.1(a) of the Manufacturing and Supply Agreement. For the avoidance of doubt, Base Fees do not include Capital Expenditures, Product Fees (as defined in the Manufacturing and Supply Agreement), Material Costs (as defined in the Manufacturing and Supply Agreement), or charges for Bill Back Items or Additional Services.

1.8 “Bill Back Items” means items and services set forth in Schedule 2.1(a) of the Manufacturing and Supply Agreement that are used or necessary in connection with the Manufacture of the Products and which result in a nominal cost to Flexion.

1.9 “Capital Expenditures” has the meaning set forth in Section 2.2.

1.10 “Certificate of Analysis” has the meaning set forth in Section 1.8a of the Manufacturing and Supply Agreement.

1.11 “Change of Control” has the meaning set forth in Section 9.6.

1.12 “Claim” has the meaning set forth in Section 7.3(a).

1.13 “Completion of the Tech Transfer” has the meaning set forth in Section 8.2.

1.14 “Control” or “Controlled” means ownership or the right by a Party to assign or grant a license or sublicense under intellectual property rights to the other Party of the scope set forth herein, without breaching the terms of any agreement with a Third Party.

1.15 “Discretionary Manufacturing Changes” has the meaning set forth in Exhibit 2.1-F.

1.16 “Effective Date” has the meaning set forth in the Preamble.

1.17 “EMA” means the European Medicines Agency.

1.18 “Equipment” means any equipment used in the Manufacture of the Product as more fully set forth in Section 2.9 of the Manufacturing and Supply Agreement.

1.19 “Exploit” means to make, have made, import, use, sell, offer for sale, receive or otherwise dispose of the Product or process, including the research, development (including the conduct of clinical trials), registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, export, transport, distribution, promotion, or marketing of the Product or process.

1.20 “Facility” means the facility of Patheon located at Kingfisher Drive, Swindon, Wiltshire SN3 5BZ, United Kingdom.

1.21 “FDA” means the United States Food and Drug Administration and any successor organization thereto and all agencies under its direct control.

1.22 “Flexion” has the meaning set forth in the Preamble.

1.23 “Flexion Indemnified Parties” has the meaning set forth in Section 7.2.

1.24 “Flexion Manufacturing Equipment” has the meaning set forth in Exhibit 2.1-F.

1.25 “Flexion’s Manufacturing Process” means the proprietary process owned or Controlled by Flexion for Manufacturing the Product as disclosed by Flexion to Patheon, and each intermediate of the Product, as established as of the Effective Date, including, without limitation, as set forth in the investigational new drug application filed with the FDA (“IND”) and, when applicable, as set forth in the NDA as may be filed with, and approved by, the FDA.

1.26 “Flexion On Site Representative” has the meaning set forth in Section 0(a).

1.27 “GMP” means the current good manufacturing practices applicable from time to time to the Manufacturing of the Product, or any intermediate of the Product, pursuant to Applicable Law, including those promulgated under the Act at 21 C.F.R. (chapters 210 and 211), and those promulgated under EC Directive 2003/94/EC, together with the latest FDA and EMA guidance documents pertaining to manufacturing and quality control practices, all as updated, amended and revised from time to time.

1.28 “Indemnification Claim Notice” has the meaning set forth in Section 7.3(a).

1.29 “Indemnified Party” has the meaning set forth in Section 7.3(a).

1.30 “Indemnifying Party” has the meaning set forth in Section 7.3(a).

1.31 “Key Technical Assumptions” has the meaning set forth in Exhibit 2.1-D.

1.32 “Loss” means any claims, lawsuits, losses, damages, liabilities, penalties, costs, and expenses (including reasonable attorneys’ fees and disbursements).

1.33 “Maintenance” means the maintenance of Equipment and Facilities in satisfactory operating condition, including the performance of systematic inspection and service of Equipment pursuant to the applicable Standard Operating Procedures of Patheon, as reviewed and agreed to by Flexion (the “Equipment Standard Operating Procedures”), or the manufacturer’s terms of operation and recommended procedures.

1.34 “Make Good Costs” has the meaning set forth in Section 8.11(c).

1.35 “Manufacture” and “Manufacturing Services” means the manufacturing, processing, formulating, sterilization, filling, packaging, labelling, storage, handling, and quality control testing of Materials or the Product as more particularly set out in Schedule 2.1(a) of the Manufacturing and Supply Agreement.

1.36 “Manufacturing and Supply Agreement” has the meaning set forth in the Recitals.

1.37 “Manufacturing Suite” means the manufacturing suite at the Facility capable of Manufacturing the Product pursuant to Flexion’s Manufacturing Process, whose footprint is attached as Exhibit 2.1-A, together with the areas identified in the plan attached as Exhibit 2.1-A as the areas for the bulk powder Manufacture and bulk vial filling and, pursuant to the terms of Section 2.10 of the Manufacturing and Supply Agreement, the Phase I Filling Space. The footprint of the Manufacturing Suite and the engineering approach shall be revised by the Parties in order to adapt the Manufacturing Suite to Flexion’s Manufacturing Process, as set forth in Section 2.1 hereto. Such footprint is diagrammatic in nature and is intended to generally depict the location and approximate size of current and future spaces allocated to Flexion. Such footprint may be amended to be specifically adapted to the Manufacture of the Product, and the Parties shall agree upon the definitive footprint, taking into account parameters such as the exact design of the space, space classifications, code requirements, equipment, materials, personnel, waste stream process flows, equipment sizing and utility requirements. For purposes of clarity, prior to the Phase III Manufacturing Suite Clearance Date (as defined in Section 2.10 of the Manufacturing and Supply Agreement), the definition of Manufacturing Suite shall include the Phase I Filling Space.

1.38 “Materials” means all API, excipients and processing aids, and processing, filling and packaging components, used in connection with the Manufacture of the Product and listed in Schedule 1.62 of the Manufacturing and Supply Agreement, as amended prior to Product launch, based on the Parties’ most recent usage experience rate, and to reflect changes to the Specifications.

1.39 “NDA” means the new drug application for a product, including the Product, requesting permission to place a drug on the market in accordance with 21 C.F.R. Part 314, and all supplements filed pursuant to the requirements of the FDA, including all documents, data, and other information filed concerning such product that are necessary for FDA approval to market such product in the Territory.

- 1.40 “NDC” means “national drug code,” a unique three-segment number, which is a universal product identifier for human drugs.
- 1.41 “Party” or “Parties” has the meaning set forth in the Preamble.
- 1.42 “Patheon” has the meaning set forth in the Preamble.
- 1.43 “Patheon Indemnified Parties” has the meaning set forth in Section 7.1.
- 1.44 “Patheon Manufacturing Equipment” has the meaning set forth in Exhibit 2.1-F.
- 1.45 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, or other similar entity or organization, including a government or political subdivision, department, or agency of a government.
- 1.46 Not used.
- 1.47 “Product” has the meaning set forth in the Recitals hereto, in finished, unpackaged form, according to the Specifications.
- 1.48 “Project Manager” has the meaning set forth in Section 2.7(c).
- 1.49 “Proprietary Information” has the meaning given in the Manufacturing and Supply Agreement.
- 1.50 “Quality Agreement” has the meaning set forth in Section 3.1 of the Manufacturing and Supply Agreement.
- 1.51 “Regulatory Approval” means any and all approvals (including pricing and reimbursement approvals), licenses, registrations, or authorizations of any Regulatory Authority necessary to Exploit the Product in any country in the Territory, including any (a) approval of a Product, Marketing Authorization and supplements and amendments thereto; (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labelling approval; and (d) technical, medical, and scientific licenses.
- 1.52 “Regulatory Authority” means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities regulating or otherwise exercising authority with respect to the Exploitation of the Product in the Territory.
- 1.53 “Remediation Period” has the meaning set forth in Section 8.5.
- 1.54 “Required Manufacturing Changes” has the meaning set forth in Exhibit 2.1-F.
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1.55 “Services” means the (a) Manufacturing Services performed by Patheon pursuant to the Manufacturing and Supply Agreement; and (b) the Transfer Services performed by Patheon under this Agreement.

1.56 “Specifications” means the specifications for each presentation of Product (*i.e.*, the dosage forms in Schedule 1.82 of the Manufacturing and Supply Agreement) given by Flexion to Patheon relating to the specifications of the Materials; the manufacturing specifications, directions and processes; the storage requirements; all environmental, health and safety information for the Product including material safety data sheets and the finished Product specifications, specifications for bulk and primary packaging and shipping requirements for the Product, as amended, modified, or supplemented from time to time.

1.57 “Steering Committee” has the meaning set forth in Section 2.7(e).

1.58 “Taxes” means all forms of taxation and statutory, governmental, state, federal, provincial, local, government or municipal charges, duties, imposts, contributions, levies, withholding or liabilities wherever chargeable and whether of the United Kingdom or any other jurisdiction (including for the avoidance of doubt, national insurance contributions in the United Kingdom) and any penalty, fine, surcharge, interest, charge, charges or costs thereto.

1.58 “Term” has the meaning set forth in Section 8.1.

1.60 “Territory” means [...***...] and other territories agreed by the Parties pursuant to Section 2.2(h) of the Manufacturing and Supply Agreement from time to time.

1.61 “Third Party” means a Person who is neither a Party nor an Affiliate of a Party.

1.62 “Third Party Losses” means Losses incurred as a result of claims brought by Third Parties.

1.63 “Timeline” has the meaning set forth in Section 2.1.

1.64 “Transfer Services” means the services rendered under this Agreement, as described in Section 2.1 and in the Exhibits attached to this Agreement, based on the Key Technical Assumptions stated therein.

1.65 “VAT” has the meaning set forth in Section 9.15(c).

ARTICLE 2

TRANSFER SERVICES

2.1 Description of Transfer Services. Patheon will (a) provide engineering and construction services, directly or using third parties (pursuant to Section 9.8 hereto), to construct the Manufacturing Suite in accordance with the engineering approach and the footprints set forth in Exhibit 2.1-A of this Agreement, as it may be amended by mutual written agreement of the Parties, and the projected capital requirements set forth in Exhibit 2.1-B, (b) procure and/or validate the Equipment necessary to Manufacture the Product in accordance with Exhibit 2.1-F and perform the Transfer Services set forth in Exhibit 2.1-C, and (c) provide other services set forth in Exhibit 2.1-D in order to validate and implement Flexion's Manufacturing Process for the Product in compliance with the Quality Agreement, GMP, all other Applicable Law and the Specifications and register the Facility to Manufacture the Product (collectively, the "Transfer Services"). Patheon will perform the Transfer Services, (i) to facilitate the Regulatory Approval of the Manufacturing Suite as the manufacturing, testing, and packaging sites for the Product, (ii) so that the Product is Manufactured and tested using Flexion's Manufacturing Process including testing and releasing (pursuant to the terms of the Quality Agreement) all Materials according to the Specifications and test methods, including the Specifications set forth in the NDA when approved. Patheon will use its commercially reasonable efforts to complete the Transfer Services in a timely fashion in accordance with the schedule set forth in Exhibit 2.1-E (the "Timeline"). The Parties will cooperate with one another in the performance of this Agreement in good faith.

2.2 Payments for Transfer Services. The Parties acknowledge and agree that Patheon's consideration for the Transfer Services performed hereunder is (a) the payment of the Base Fees, as set forth in Schedule 2.1(a) of the Manufacturing and Supply Agreement, (b) the payments associated with the Equipment, Manufacturing Suite construction and related process and support and validation services, each in accordance with the capital requirements set forth in Exhibit 2.1-B (together, the "Capital Expenditures"); (c) charges for Bill Back Items; and (d) charges for Additional Services. All payments from Flexion to Patheon hereunder shall be in British Pounds (GBP) and will be due and payable in accordance with the invoicing procedures set forth in ARTICLE IV of the Manufacturing and Supply Agreement. All invoices from Patheon to Flexion for Capital Expenditures shall include all (if any) applicable invoices from vendors for the supply, transportation, installation, and commissioning of the Equipment that pertain to the Transfer Services invoiced by Patheon. Flexion acknowledges that the amounts of Capital Expenditures are estimates and are subject to review once manufacturing details and process specification requirements have been confirmed, any necessary machine trials performed and upon receipt of formal quotations from the equipment suppliers; provided however that, in no event shall the Capital Expenditures exceed the amount set forth in Exhibit 2.1-B by more than [...***...] percent ([...***...]%) unless otherwise mutually agreed by the Parties in writing.

2.3 Modifications. The Parties may modify and agree upon the definitive engineering approach, footprint of the Manufacturing Suite, or the Timeline, taking into account parameters such as the exact design of the space, space classifications, code requirements, Equipment, materials, personnel, waste stream process flows, equipment sizing and utility requirements. Any such modifications shall be discussed by the Parties and agreed to in writing including as to any consequential fees and costs or savings relating thereto, duly executed by the Parties.

2.4 Flexion's Responsibilities.

(a) To assist Patheon in its performance of the Transfer Services under this Agreement, Flexion shall (i) at its expense provide Patheon in a timely fashion with relevant information, documentation, and data relating to (1) Flexion's Manufacturing Process, (2) the Equipment necessary to Manufacture the Product in accordance with Flexion's Manufacturing Process, and (3) Product safety and information, documentation, and data, including any applicable NDA numbers, NDC codes, "CMC" sections of NDAs, validation protocols, validation reports, method validation protocols, method validation reports, and other documents necessary or reasonably requested by Patheon for Patheon to Manufacture the Product, provide the Transfer Services or otherwise necessary for Patheon's performance hereunder, and (ii) provide Flexion-Supplied Materials pursuant to Section 2.10. If requested by Patheon to provide support or information, Flexion shall use commercially reasonable efforts to provide such reasonable and necessary support or information in order to enable Patheon to perform the Transfer Services under this Agreement as soon as reasonably possible and in any event within [...***...] business days of Patheon's request (or will provide an explanation of the legitimate reason for any delay and a projected date by which such support or information will be provided). In the event Flexion is to review or approve any information, documentation, data, or samples prepared or supplied by or on behalf of Patheon, it will complete such review and approval process as soon as reasonably possible and in any event within [...***...] business days of Patheon's request.

(b) It is understood and acknowledged by the Parties that Flexion will retain ownership of the IND and NDA to the Product, and any supplements thereto, and is responsible for the NDA submission documents and all correspondence with the FDA and other competent Regulatory Authority concerning the Product, other than submission documents and correspondence associated with GMP inspections of the Facility; provided, however, that Section 2.9 of this Agreement and Sections 3.6 and 5.1 of the Manufacturing and Supply Agreement will govern the ownership of the intellectual property rights described or disclosed in such NDA and supplements.

(c) Flexion shall have the sole responsibility for the filing of all documents with all applicable Regulatory Authorities, and to take any other actions that may be required for the receipt of Regulatory Approval for the development or commercial manufacture of the Product (other than the licences, registrations and Regulatory Authority approvals to be obtained by Patheon pursuant to Section 3.3(b) of the Manufacturing and Supply Agreement). Flexion will, at its expense and in cooperation with Patheon, use commercially reasonable efforts to diligently and proactively pursue Regulatory Approval for Patheon's Manufacture of the Product at the Facility in a timely fashion in accordance with the Timeline. Without limiting such obligation, Flexion shall be responsible for filing the NDA submission documents, drug listing the Product, and completing correspondence with the FDA concerning the Product. All documentation and data provided by Patheon in support of the NDA filing shall be accurate and true and will reflect the current processes and procedures in place at Patheon. Flexion shall provide Patheon with a copy of any Regulatory Approval relevant to this Agreement on request including any Regulatory Approval required for the storage, receipt or distribution of the Product by Flexion or its designee.

(d) Where documents or data generated by Patheon in relation to the Transfer Services are to be filed by Flexion with any Regulatory Authority and such filing includes data or information pertaining to a Patheon Regulatory Obligation within the meaning of Section 3.15 of the Manufacturing and Supply Agreement, prior to filing any such documents and data with the Regulatory Authority, Flexion shall provide Patheon with a copy of the documents incorporating such data so as to give Patheon the opportunity to review the accuracy of such documents as it relates to the Patheon Regulatory Obligation in accordance with the review and comment procedures set forth in Section 3.15 of the Manufacturing and Supply Agreement (including the process for resolution of inaccuracies set forth in Section 3.15(c) thereto). Notwithstanding anything in Section 3.15 of the Manufacturing and Supply Agreement to the contrary: (i) at least [...***...] calendar days prior to filing with the Regulatory Authority any documentation which is or is equivalent to the Quality document portion (Drug Product section) of the U.S. Investigational New Drug application, the EU Clinical Trial application and Investigational Medicinal Product Dossier, the Common Technical Document module 3 (Drug Product section) of the US New Drug Application, U.S. Biological License Application, or the EU Marketing Authorization Application, as the case may be, Flexion shall provide Patheon with a copy of the Initial Draft (as defined in the Manufacturing and Supply Agreement) of such portion so as to permit Patheon to verify that the Initial Draft accurately describes the development and validation work Patheon has performed and the manufacturing and control processes that Patheon will perform pursuant to this Agreement; (ii) Patheon shall provide comments regarding such Initial Draft no later than [...***...] days prior to the required filing date with the applicable Regulatory Authority (including notifying Flexion of any identified inaccuracies); and (iii) Flexion shall deliver a copy of the final version of the filing promptly after the required filing date.

2.5 Patheon's Responsibilities. Patheon will, at its expense, in consideration for the payments and reimbursements set forth in Section 2.2, provide the Transfer Services and use its commercially reasonable efforts to complete the Transfer Services in a timely fashion in accordance with the Timeline. Patheon will provide to Flexion all data and documentation necessary or reasonably useful to support Flexion's submissions to the FDA, or any responses to questions raised by the FDA with respect to those Transfer Services, that are necessary or reasonably useful for Regulatory Approval of the Facility as the manufacturing, testing, and packaging site for the Product.

2.6 Equipment. Patheon, acting as Flexion's agent, shall purchase the Flexion Manufacturing Equipment on Flexion's behalf. Title to all Flexion Manufacturing Equipment will be held by Flexion. The Parties shall procure, supply, install, commission and validate the Equipment in compliance with (a) Exhibit 2.1-F; (b) the capital requirements set forth in Exhibit 2.1-B and (c) the "Qualification and Validation" process set forth in Exhibit 2.1-C. Patheon is authorized to use the Flexion Manufacturing Equipment pursuant to Exhibit 2.1-F solely for the purposes of performing the Transfer Services and for the Manufacturing Services as set forth in the Manufacturing and Supply Agreement.

2.7 Flexion On Site Representatives; Reporting of Results; Project Managers; Steering Committee.

(a) Flexion shall have the right at all times throughout the Term to have [...***...] representatives (or other number as reasonably requested by Flexion after discussion by the members of the Steering Committee) (each, a "Flexion On Site Representative") present in that

portion of the Facility that is being constructed or used to Manufacture the Product or store Materials, to observe the procedures and processes used to Manufacture the Product or to perform the activities associated with the transfer of Flexion's Technology hereunder. The Flexion On Site Representatives shall have full access to the Manufacturing Suite and to the non-financial records that relate to the Product, and all records pertaining to any Materials and to Third Party invoices specifically invoiced by Patheon to Flexion as a Capital Expenditure or Bill Back Item. For the avoidance of doubt, the term "non-financial records" as used in this Agreement does not include the Reports (defined in Section 3.11 of the Manufacturing and Supply Agreement). Patheon shall provide reasonable (semi-permanent) on-site accommodations at the Facility for the Flexion On Site Representatives (e.g., office space). Flexion On Site Representatives shall be appropriately trained by Flexion (e.g. GMP training) and shall observe at all times Patheon's policies and procedures (as amended from time to time) as they pertain to the Facility, including policies relating to health and safety and compliance with GMP; provided that Flexion is given notice of such policies and given a reasonable period of time to review and implement such policies. Flexion will comply with all reasonable directions of Patheon in relation to the same. Patheon may refuse or limit in its sole discretion at any time admission to the Facility by any Flexion On Site Representative who fails to observe such policies or comply with such reasonable directions. For the avoidance of doubt, Flexion On Site Representatives shall have (i) no management authority over any Patheon employee and (ii) no authority to conclude contracts on behalf of Flexion.

(b) Patheon will respond to Flexion's inquiries regarding the status of the Transfer Services on an ongoing basis, and Patheon will endeavor to keep Flexion informed of interim results of the Transfer Services. Patheon will provide copies of all analytical, cleaning, and process validation protocols, data summaries, reports and all batch records, test methods, and specifications for Flexion's review, comment, and approval prior to implementation and execution. Once such protocols, data summaries, reports, records, methods, and specifications have been approved and executed, Patheon will provide copies to Flexion. Patheon will provide Flexion with information relating to the Equipment to be used in connection with the Manufacture of the Product, which Equipment will be subject to Flexion's review and approval (not to be unreasonably withheld or delayed). Within five (5) business days after Flexion's request, Patheon will provide to Flexion documentation that summarizes the implementation efforts of the Transfer Services at the Facility.

(c) Patheon and Flexion will each appoint a project manager (each, a "Project Manager" and, together, the "Project Managers"), who will meet as needed to resolve any issues or problems associated with the Transfer Services. Flexion's Project Manager may be one of the Flexion On Site Representatives. Flexion reserves the right to request replacement of any personnel assigned by Patheon to perform the Transfer Services hereunder. If Patheon disagrees with such request and the Parties cannot reach resolution on Flexion's request for replacement, such request will be discussed by the Steering Committee pursuant to the procedures set forth in Exhibit 2.7 hereto.

(d) Patheon shall ensure that sufficient numbers of adequately educated and experienced staff are retained at the Facility in order to provide the Transfer Services. Patheon shall perform the Transfer Services under the direction of key personnel of Patheon to a project for the duration of the project ("Key Personnel"). Key Personnel include the Project Manager,

Operational Manager, Quality Manager or other personnel reasonably agreed-to by the Parties. Patheon shall provide information on the qualifications and background of all proposed Key Personnel prior to such Key Personnel's commencement of activities under this Agreement on Patheon's behalf. Patheon will not remove Key Personnel without Flexion's prior written consent (not to be unreasonably withheld, conditioned or delayed) except in the event of such Key Personnel's promotion, resignation, incapacity or death, or termination for cause. Patheon will use commercially reasonable efforts to minimize turnover in Key Personnel, and will provide [...***...] business days' notice to Flexion, whenever practical, of any changes to the Key Personnel, at which point, both Parties shall discuss and reasonable agree on a suitable replacement.

(e) The Parties desire to establish a steering committee (the "Steering Committee") as described in Exhibit 2.7.

2.8 Dispute Resolution.

(a) The Parties recognize that disputes may arise from time to time during the term of this Agreement that relate to whether either Party has fulfilled its obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes arising under this Agreement in an expedient manner by mutual cooperation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 2.8 if and when a dispute arises under this Agreement.

(b) Unless otherwise specifically recited in the Agreement, disputes between the Parties under this Agreement will be first referred to the Project Manager of each Party as soon as reasonably possible after such dispute has arisen. If the Project Managers are unable to resolve such a dispute within [...***...] days of being requested by a Party to resolve such dispute, either Party may, by written notice to the other, have such dispute referred to the Steering Committee. If the Steering Committee is unable to resolve such a dispute within [...***...] day of being requested by a Party to resolve such dispute, either Party may, by written notice to the other, have such dispute referred to the [...***...] of each Party for attempted resolution by negotiations within [...***...] days after such notice received.

2.9 Ownership. The Parties' intellectual property ownership rights relating to the subject matter of this Agreement shall be governed by ARTICLE V of the Manufacturing and Supply Agreement.

2.10 Materials. Patheon will purchase all Patheon-Supplied Materials (as defined in the Manufacturing and Supply Agreement) for the Transfer Services as set forth in Schedule 1.62 of the Manufacturing and Supply Agreement. Flexion shall purchase all Flexion-Supplied Materials (as defined in the Manufacturing and Supply Agreement) for the Transfer Services and ship such Flexion-Supplied Materials to Patheon in accordance with this Section 2.10 (except as otherwise mutually agreed to by the Parties in writing, in which case such Materials shall be considered Bill Back Items hereunder). All shipments from Flexion to Patheon will be made DDP (Incoterms 2010) the Facility unless otherwise agreed. All shipments of Flexion-Supplied Materials, if required, will be accompanied by Certificate(s) of Analysis from the Material manufacturer or Flexion, confirming its compliance with the Material's specifications. Flexion

will obtain the proper release of the Flexion-Supplied Materials from the applicable customs agency and Regulatory Authority. Flexion or Flexion's designated broker will be the "Importer of Record" for Flexion-Supplied Materials imported to the Facility. Flexion-Supplied Materials will be held by Patheon on behalf of Flexion as set forth in this Agreement. Title to Flexion-supplied Materials will at all times remain the property of Flexion or a Flexion Affiliate. Any Flexion-Supplied Materials received by Patheon will only be used by Patheon to perform the Transfer Services or associated activities necessary to perform the Transfer Services (e.g., media fills or validation runs).

2.11 Bill Back Items. Bill Back Items will be charged to Flexion at Patheon's cost plus a [...***...] handling fee. Patheon shall invoice Flexion monthly for any Bill Back Items used in connection with the Transfer Services during the preceding month in accordance with ARTICLE IV of the Manufacturing and Supply Agreement. Patheon may only invoice Bill Back Items that have been quoted to and approved in writing by Flexion's Project Manager, or otherwise mutually agreed to by the parties in advance.

2.11A Additional Services. If Flexion is interested in having Patheon perform Additional Services, Flexion will provide Patheon with a written request containing sufficient detail to enable Patheon to provide Flexion with a quote and proposal to provide such Additional Services. Patheon may only invoice for Additional Services that have been quoted to and approved in writing by Flexion's Project Manager and that have been agreed in writing by the Parties in a Change of Scope Agreement. Patheon shall invoice Flexion monthly for any Additional Services performed by Patheon during the preceding month in accordance with ARTICLE IV of the Manufacturing and Supply Agreement.

2.12 Storage. Patheon will provide storage capacity to support storage of the required quantity of Materials necessary for Transfer Services which will be governed by Section 2.2(e) of the Manufacturing and Supply Agreement.

2.13 Shipping. Except to the extent set forth otherwise in this Agreement, any shipment from Patheon to Flexion, whether of Product, Materials or otherwise, shall be made pursuant to Section 2.3(e) of the Manufacturing and Supply Agreement.

2.14 Changes in Applicable Law. Should during the Term of this Agreement, a change or changes in Applicable Law lead to Patheon (a) providing services not originally contemplated by Patheon, or (b) incurring increased costs in order to comply with said change or changes, any such services or costs (to the extent pertaining to the Product or related to Flexion's Manufacturing Process or the Flexion Manufacturing Equipment) shall constitute an Additional Service subject to mutual written agreement of the Parties; provided that, if such services or costs relate generically to the entire Facility then such costs to Flexion shall be prorated as applicable.

2.15 Base Fees. Patheon will invoice Flexion monthly in advance for the Base Fees, and such Base Fees will be due and payable, in accordance with the provisions and invoicing procedures set forth in ARTICLE IV of the Manufacturing and Supply Agreement.

ARTICLE 3
CONFIDENTIALITY

3.1 Confidentiality Obligations. The Parties agree that the terms of ARTICLE VII of the Manufacturing and Supply Agreement shall govern the confidentiality obligations of the Parties and are incorporated herein by this reference.

ARTICLE 4
FLEXION'S REPRESENTATIONS,
WARRANTIES, AND COVENANTS

4.1 Commercially Reasonable Efforts. Except where specifically stated to the contrary in this Agreement otherwise, Flexion will use its commercially reasonable efforts to perform Flexion's obligations hereunder.

4.2 Additional Representations, Warranties, and Covenants of Flexion. Flexion warrants, represents, and covenants that as of the Effective Date the warranties, representations and covenants set out in Sections 6.4(a) of the Manufacturing and Supply Agreement shall apply to the performance of the Transfer Services.

ARTICLE 5
PATHEON'S REPRESENTATIONS,
WARRANTIES, AND COVENANTS

Patheon represents, warrants, and covenants to Flexion as follows:

5.1 Commercially Reasonable Efforts. Except where specifically stated to the contrary in this Agreement otherwise, Patheon will use its commercially reasonable efforts to perform the Transfer Services in accordance with the agreed upon Timeline. In the event Patheon is not able to meet the Timeline, Patheon will provide written notice to Flexion of such inability as soon as practical, but in any event within [...***...] of discovering such inability.

5.2 Qualified Personnel and Transfer Services. Patheon will engage and employ professionally qualified personnel to perform the Transfer Services contemplated hereunder. Patheon represents and warrants that there is no claim, suit, proceeding, or other investigation issued on Patheon, or to the knowledge of Patheon (after due inquiry), pending or threatened against Patheon, which is likely to prevent or materially adversely affect the rights and interests of Flexion hereunder or keep Patheon from performing its obligations hereunder.

5.3 Additional Representations, Warranties, and Covenants of Patheon. Patheon warrants, represents, and covenants that:

(a) (i) it has facilities, personnel, experience, and expertise sufficient in quality and quantity to perform the obligations hereunder, (ii) it shall so perform in conformity with GMPs

where applicable, and (iii) its management shall establish, and Patheon shall observe and comply with, appropriate quality assurance, quality controls, and review procedures for implementation of the Transfer Services;

(b) it has at the Effective Date and shall during the Term observe and comply with, at (subject to Section 2.14) its sole cost and expense, all Applicable Laws now in force or that may hereafter be in force, including federal, state, and local laws, orders, regulations, rules, customs, and ordinances now in force or that may hereafter be in force pertaining to Patheon's performance of the Transfer Services and the Facility and including, without limitation, (i) labor laws, orders, regulations, rules, customs, and ordinances and (ii) those of the FDA pertaining to Patheon's performance of the Transfer Services and the Facility, and any laws, orders, regulations, rules, or ordinances issued in addition to, as a supplement to or as a replacement of Applicable Laws.

(c) none of it, its Affiliates, nor any Person under its direction or control has ever been, nor will it engage suppliers which have to its actual knowledge, after due inquiry, been, (i) debarred or convicted of a crime for which a person can be debarred, under Section 335(a) or 335(b) of the Act, or any equivalent Applicable Law of the country of Manufacture, (ii) threatened to be debarred under the Act or any equivalent Applicable Law of the country of Manufacture or (iii) indicted for a crime or otherwise (to its actual knowledge after due inquiry) engaged in conduct for which a person can be debarred under the FDA or any equivalent Applicable Law of the country of Manufacture, and Patheon agrees that it will, within [...***...], notify Flexion in the event it receives notification of any such debarment, conviction, threat or indictment. Should Patheon become aware of any actual or suspected noncompliance with the foregoing, Patheon will notify Flexion in writing of such issue within [...***...]. For the purpose of this Section 5.3, suppliers and subcontractors engaged by Patheon to undertake the Manufacture of the Product shall be deemed to be under Patheon's direction or control;

(d) none of it, its Affiliates, nor any Person under its direction or control is currently excluded from a federal or state health care program under Sections 1128 or 1156 of the Social Security Act, 42 U.S.C. §§ 1320a-7, 1320c-5 or any equivalent Applicable Law of the country of Manufacture, as may be amended or supplemented;

(e) none of it, its Affiliates, nor any Person under its direction or control is otherwise currently excluded from contracting with the U.S. federal government or the government of the country of Manufacture;

(f) none of it, its Affiliates, nor any Person under its direction or control is otherwise currently excluded, suspended, or debarred from any U.S. or foreign governmental program;

(g) it shall immediately notify Flexion if, at any time during the Term, Patheon, its Affiliates, or any Person under its direction or control is convicted of an offense that would subject it or Flexion to exclusion, suspension, or debarment from any U.S. or foreign governmental program; and

(h) it will not enter into any agreement or arrangement with any other Person that would prevent its ability to perform its obligations hereunder.

5.4 Legal Compliance. Section 6.6 of the Manufacturing and Supply Agreement shall apply to this Agreement and any violation thereof by Patheon or its employees, agents, or contractors in the performance of this Agreement shall constitute a material default for the purpose of Section 8.5 of this Agreement.

5.6 Disclaimer. THE FOREGOING EXPRESS WARRANTIES AND THOSE IN ARTICLE 4 and ARTICLE 6 ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT, AND ALL OTHER WARRANTIES ARE HEREBY DISCLAIMED AND EXCLUDED BY EACH PARTY.

ARTICLE 6

GENERAL REPRESENTATION AND WARRANTIES

Each Party represents, warrants, and covenants to the other as follows:

6.1 Power and Authorization. Such Party (a) is duly formed and in good standing under the laws of the jurisdiction of its formation, (b) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (c) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.

6.2 Enforceability. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other similar laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity. Except for the FDA's approval of Patheon's manufacturing, testing, and packaging for the Product from the Manufacturing Suite, all necessary consents, approvals, and authorizations of all Regulatory Authorities, other governmental authorities, and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

6.3 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not and will not conflict with or violate any requirement of Applicable Law or any provision of the articles of incorporation, bylaws, limited partnership agreement, or other constituent document of such Party and (b) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

6.4 Compliance with Applicable Law. Each Party and its Affiliates, and their respective representatives, shall comply with all Applicable Laws in the performance of their obligations under this Agreement. Without limiting the foregoing, each Party and its Affiliates, and their respective representatives, shall comply with export control laws and regulations of the

country of Manufacture and of the United States. Neither Party nor its Affiliates (or representatives) shall, directly or indirectly, without prior U.S. government authorization, export, re-export, or transfer the Product to any country subject to a U.S. trade embargo, to any resident or national of any country subject to a U.S. trade embargo, or to any person or entity listed on the “Entity List” or “Denied Persons List” maintained by the U.S. Department of Commerce or the list of “Specifically Designated Nationals and Blocked Persons” maintained by the U.S. Department of Treasury. In so far as the same applies to a Party or its Affiliates, each Party and its Affiliates and respective representatives shall comply with the requirements of the Foreign Corrupt Practices Act of 1977 (15 U.S.C. § 78dd-1, et seq.).

ARTICLE 7

INDEMNIFICATION

7.1 Indemnification by Flexion. Flexion will indemnify Patheon, its Affiliates, and their respective directors, officers, employees, and agents (the “Patheon Indemnified Parties”), and defend and save each of them harmless from and against any and all (i) Third Party Loss incurred by any of them in connection with, arising from, or occurring as a result of (a) any claim of personal injury or property damage to the extent that the injury or damage is the result of or arises other than from a breach of this Agreement by Patheon, (b) a claim that the Transfer Services performed by Patheon hereunder, in accordance with the terms and conditions of this Agreement, infringes or misappropriates a patent or any other intellectual property rights, if it is a claim related to the use of Flexion Manufacturing Equipment, Existing Flexion Intellectual Property (as defined in the Manufacturing and Supply Agreement), Flexion Improvements (as defined in the Manufacturing and Supply Agreement) or the Manufacturing Process or the Product, (c) any negligence or willful misconduct by Flexion or any of its Affiliates, or (d) any breach by Flexion of any of its obligations or any inaccuracy of any of Flexion’s warranties under this Agreement, or (ii) any Loss incurred by any of them as a direct result of and to the extent of the negligence or willful misconduct of the Flexion On Site Representatives at the Facility, except, in each case, for those Losses for which Patheon has an obligation to indemnify the Flexion Indemnified Parties pursuant to Section 7.2 below, as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses; and provided, however, that Flexion will not be required to indemnify the Patheon Indemnified Parties with respect to any such Loss hereunder to the extent the same is caused by any breach of contract, negligent act or omission, or intentional misconduct by Patheon or any of its Affiliates. For the avoidance of doubt, the parties acknowledge that Patheon has not and will not conduct any freedom to operate searches in relation to the Product and/or Flexion’s Manufacturing Process nor reviewed any third party patents in relation thereto and that Patheon’s failure or omission to do so will not be considered negligence for the purposes of excluding or limiting a claim under this indemnity.

7.2 Indemnification by Patheon. Patheon will indemnify Flexion, its Affiliates, and their respective directors, officers, employees, and agents (the “Flexion Indemnified Parties”), and defend and save each of them harmless from and against any and all Third Party Loss incurred by any of them in connection with, arising from, or occurring as a result of (a) any claim of personal injury or property damage to the extent that the injury or damage is the result of a failure by Patheon to perform the Transfer Services in accordance with the terms of this Agreement; (b) a claim that any Existing Patheon Intellectual Property (as defined in the

Manufacturing and Supply Agreement) or other intellectual property of Patheon employed by Patheon in providing the Transfer Services infringes or misappropriates a United States patent or any other intellectual property rights except to the extent such claim is based on the use of Existing Flexion Intellectual Property, Flexion Improvements, the Manufacturing Process or the Product in accordance with the terms and conditions of this Agreement, (c) any claim of personal injury or property damage to the extent that the injury or damage is the result of any negligence or willful misconduct by Patheon or any of its Affiliates, or (d) any claim of personal injury or property damage to the extent that the injury or damage is the result of any breach by Patheon of any of its obligations or any inaccuracy of any of Patheon's warranties under this Agreement; except, in each case, for those Losses for which Flexion has an obligation to indemnify the Patheon Indemnified Parties pursuant to Section 7.1 above, as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses; and provided, however, that Patheon will not be required to indemnify the Flexion Indemnified Parties with respect to any such Loss hereunder to the extent the same is caused by any breach of contract, negligent act or omission, or intentional misconduct by Flexion or any of its Affiliates.

7.3 Indemnification Procedures.

(a) Notice of Claim. The indemnified Party (the "Indemnified Party") shall give the indemnifying Party (the "Indemnifying Party") prompt written notice (an "Indemnification Claim Notice") of any Loss, action, or discovery of facts upon which such Indemnified Party intends to base a request for indemnification under Section 7.1 or 7.2 (a "Claim"), but in no event shall the Indemnifying Party be liable for any Loss that results from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the Claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Loss upon which it intends to seek indemnification.

(b) Control of Defense. At its option, the Indemnifying Party may assume the defense of any Claims by giving written notice to the Indemnified Party within [...***...] days after the Indemnifying Party's receipt of an Indemnification Claim Notice; provided that the assumption of the defense of a Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's Claim. Upon assuming the defense of a Claim, the Indemnifying Party may appoint as lead counsel in the defense of such Claim any legal counsel selected by the Indemnifying Party. In the event the Indemnifying Party assumes the defense of a Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnified Party in connection with the Claim. Subject to clause (c) below, if the Indemnifying Party assumes the defense of a Claim, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense, or settlement of such Claim. In the event that it is ultimately determined that the Indemnifying Party is not obliged to indemnify, defend, or hold harmless an Indemnified Party from and against any Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all

costs and expenses (including reasonable attorneys' fees and costs of suit) and any Loss incurred by the Indemnifying Party in its defense of such Claim.

(c) Right to Participate in Defense. Without limiting Section 7.3(b), any Indemnified Party shall be entitled to participate in, but not control, the defense of a Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing, (ii) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 7.3(b) (in which case the Indemnified Party shall control the defense), or (iii) the interests of the Indemnified Party and the Indemnifying Party with respect to such Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules, or equitable principles.

(d) Settlement. With respect to any Loss relating solely to the payment of money damages in connection with a Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business or reputation of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement, or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Claims, where the Indemnifying Party has assumed the defense of the Claim in accordance with Section 7.3(b), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement, or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, agree to any settlement or acquiesce to any judgment with respect to a Claim that obligates the Indemnified Party to pay any amount subject to indemnification by the Indemnifying Party or causes the Indemnified Party to admit to any civil or criminal liability.

(e) Cooperation. If the Indemnifying Party chooses to defend or prosecute any Claim, the Indemnified Party shall cooperate in the defense or prosecution thereof and shall, at the Indemnifying Party's expense, furnish such records, information, and testimony, provide such witnesses, and attend such conferences, discovery proceedings, hearings, trials, and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of records and information that are reasonably relevant to such Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable time and out-of-pocket expenses in connection therewith.

(f) Expenses. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Claim shall be reimbursed on a monthly basis in arrears by the Indemnifying Party, without prejudice to the Indemnifying Party's right to, contest the

Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obliged to indemnify the Indemnified Party.

7.4 Limitation of Liability.

(a) SUBJECT TO SECTION 7.4(b) BELOW, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR (I) ANY (DIRECT OR INDIRECT) LOSS OF PROFITS, OF PRODUCTION, OF ANTICIPATED SAVINGS, OF BUSINESS, OF GOODWILL OR OF USE OF THE PRODUCT OR COSTS OF ANY SUBSTITUTE SERVICES OR (II) FOR ANY OTHER LIABILITY, DAMAGE, COST OR EXPENSE OF ANY KIND INCURRED BY THE OTHER PARTY OF AN INDIRECT OR CONSEQUENTIAL NATURE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF THE DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS PARAGRAPH IS INTENDED TO LIMIT OR RESTRICT THE DAMAGES AVAILABLE FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 3.

(b) Nothing in this Agreement is intended to limit either Party's liability for: (i) death or personal injury caused by its negligence; or (ii) fraud or fraudulent misrepresentation.

(c) If any part of the Transfer Services provided or procured by Patheon is not materially performed in accordance with the terms of this Agreement, then Flexion's sole remedy whether in contract, tort, equity or otherwise (in addition to those expressly set forth in ARTICLE 8) will be for Patheon to repeat that part of the Transfer Service at Patheon's cost (provided that where the Transfer Services to be repeated requires Flexion-Supplied Materials, Flexion will provide such Flexion-Supplied Materials and Patheon shall reimburse Flexion for the actual costs for such Flexion-Supplied Materials, including associated shipment costs); provided that, (i) Patheon shall only be liable to reimburse the costs of any Flexion-Supplied Materials and associated shipment costs [...***...], and (ii) Patheon's aggregate liability in each calendar year (liability cap to be pro-rated for partial calendar years) to reimburse the costs of any Flexion-Supplied Materials shall not exceed [...***...]% of the [...***...] received by Patheon in the [...***...] period prior to the month in which the underlying event occurred that gave rise to the liability (e.g. the date of the incident or manufacture) up to a maximum of £[...***...]. Patheon shall not be liable to reimburse the cost of any Flexion-Supplied Materials under any other circumstances.

7.5 Insurance. During the Term and for [...***...] thereafter, each Party shall procure and maintain at its own expense from a qualified and licensed insurer liability insurance or indemnity policies, in an amount not less than \$[...***...] in the aggregate with respect to public and products liability, subject to such deductible or self-retention limits as either Party in its business discretion may elect. Such policies shall insure against liability on the part of each Party and any of its Affiliates, as their interests may appear, due to injury, disability, or death of any person or persons, or injury to property, arising from the distribution of the Products. Each Party will either (a) include the other Party and its officers, employees and consultants as additional insureds on such policies, or (b) ensure that such policy contains an indemnity to principal clause. Promptly following the execution of this Agreement, each Party shall provide to the other a certificate of insurance (i) summarizing the insurance coverage and (ii) identifying

any exclusions. Each Party shall promptly notify the other of any material adverse alterations to the terms of this policy or decreases in the amounts for which insurance is provided.

ARTICLE 8

TERM AND TERMINATION

8.1 Term. This Agreement will remain in full force and effect unless and until it expires or is terminated in accordance with the provisions of this ARTICLE 8 (the “Term”).

8.2 Expiration. This Agreement will expire upon completion of the Transfer Services as described herein or until the Parties agree that the Transfer Services have been completed (the “Completion of the Tech Transfer”).

8.3 Termination by Flexion. Flexion may terminate this Agreement in its entirety (a) prior to the FDA Approval Date by giving Patheon ninety (90) days’ written notice for convenience, in which case, Section 8.11(f) shall apply, or (b) by giving Patheon thirty (30) days written notice if Patheon (due primarily to its acts or omissions) fails to complete Manufacturing Suite construction by the date stated in the Timeline and due solely to such failure, Patheon has not Manufactured registration batches in the Manufacturing Suite by [...***...].

8.4 Termination by Mutual Agreement. This Agreement may be terminated at any time upon mutual written agreement between the Parties.

8.5 Termination for Default. Each Party will have the right to terminate this Agreement at any time upon written notice to the other Party, if such other Party (a) breaches any of the representations, warranties, covenants, or agreements set forth in this Agreement or (b) otherwise defaults in the performance of any of its duties or obligations under this Agreement, which in either case has a material effect on the other Party, and which breach or default is not cured within ninety (90) days after written notice is given to the breaching Party specifying the breach or default (“Remediation Period”). The aggrieved Party’s right to terminate this Agreement for a particular breach under this Section 8.5 may only be exercised for a period of one hundred and twenty (120) days following the expiry of the Remediation Period (where the breach has not been remedied) and, if the termination right is not exercised during this period, then the aggrieved Party will be deemed to have waived its right to terminate this Agreement for such breach.

8.6 Bankruptcy; Insolvency. To the extent permitted by law, each Party will have the right to terminate this Agreement immediately upon notice to the other Party, if the other Party shall file in any court or agency, pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for arrangement or for the appointment of a receiver or trustee of the other Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

8.7 Cross Termination. Should either Flexion or Patheon exercise its right to terminate this Agreement or the Manufacturing and Supply Agreement in its entirety (but not in the event of an expiration of this Agreement as set forth in Section 8.2) prior to the FDA Approval Date, then the Manufacturing and Supply Agreement, this Agreement and the Quality Agreement will concurrently and automatically terminate.

8.8 No Release. Neither the termination nor expiration of this Agreement will release or operate to discharge either Party from any liability or obligation that may have accrued prior to such termination or expiration, including any obligation to pay to the other Party any amounts accrued under this Agreement with respect to the period prior to the effective date of such expiration or termination. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof will not limit remedies that may otherwise be available in law or equity.

8.9 Obligations. Notwithstanding the giving of any notice of termination pursuant to this ARTICLE 8, each Party will continue to fulfill its obligations under this Agreement at all times until the effective date of any such termination or expiration.

8.10 Survival. The expiration or termination of this Agreement shall be without prejudice to any rights or obligations of the Parties that may have accrued prior to such termination, and the provisions of Sections 2.2 (as it may relate to any unpaid amounts due and owing), 2.6 (as it may relate to the use to which Patheon may put the Flexion Manufacturing Equipment), 2.8, 2.9 and ARTICLE 1, ARTICLE 3, ARTICLE 7, ARTICLE 8, and ARTICLE 9 shall survive the expiration or termination of this Agreement.

8.11 Rights and Duties Upon Termination.

(a) Upon termination of this Agreement, Patheon will, as promptly as practicable, (i) cease work on the Transfer Services, and (ii) make available for collection by Flexion, [...***...] (Incoterms 2010) the Facility, all Materials and results and information resulting from the Transfer Services (whether in written or electronic form) that are then in Patheon's or its subcontractors' possession and that are the property of Flexion in accordance with Section 2.9 of this Agreement, including all Flexion Proprietary Information. Flexion shall return to Patheon all Patheon Proprietary Information.

(b) Upon termination of this Agreement, Flexion will (i) pay all earned but unpaid fees and charges for the Transfer Services, including Material Costs, Capital Expenditures, Bill Back Items, Additional Services, Base Fees (through the month of such termination) to reflect Transfer Services performed as of the date of such termination by Patheon; and (ii) pay all due and outstanding invoices in accordance with ARTICLE IV of the Manufacturing and Supply Agreement, including those for Bill Back Items or Additional Services performed as of the date of such expiration and termination; provided that, the Parties agree that if any fees or charges are duplicated under Section 8.3 of the Manufacturing and Supply Agreement, Flexion shall only be obligated to make such payment once.

(c) Upon termination of this Agreement, Flexion will pay to Patheon all and any removal and Make Good Costs associated with the removal of the Flexion Manufacturing

Equipment from the Facility as agreed to in good faith by the Parties in writing. “Make Good Costs” means the reasonable costs required to repair the Facility and return it to a clean, safe and useable area based on the repair of damage caused by the installation or removal of Flexion Manufacturing Equipment.

(d) Upon termination of this Agreement prior to termination of the Manufacturing and Supply Agreement, Flexion will, as promptly as practicable, pay to Patheon the Manufacturing Services Termination Costs pursuant to the provisions of Sections 8.3(f) and 8.3(g) of the Manufacturing and Supply Agreement to the extent applicable to this Agreement or the Transfer Services.

(e) Upon termination of this Agreement, in the event that Patheon will not be Manufacturing the Product for Flexion pursuant to the Manufacturing and Supply Agreement, Flexion shall remove all Flexion Manufacturing Equipment and Materials from the Facility within [...***...] days of said termination under all sections other than Section 8.5 and within [...***...] days [...***...] of a termination by Flexion pursuant to Section 8.5 that is not reasonably disputed by Patheon, failing which Flexion will pay a fee equivalent to the aggregate monthly Base Fee for each month or part month the Flexion Manufacturing Equipment or Materials remain at the Facility post-termination.

(f) Upon termination of this Agreement by Flexion pursuant to Section 8.3(a), in addition to any other obligation of Flexion under Section 8.11, Flexion shall also pay Patheon compensation of £1,300,000 (one million, three hundred thousand British Pounds). The Parties confirm that this sum represents a genuine pre-estimate of Patheon’s loss in such circumstances.

ARTICLE 9

MISCELLANEOUS

9.1 Notices. Notwithstanding that advance notification of any notices or other communications may be given by electronic mail transmission, all notices or other communications that shall or may be given pursuant to this Agreement shall be in writing (including by confirmed receipt electronic mail) and shall be deemed to be effective (a) when delivered if sent by registered or certified mail, return receipt requested, or (b) on the next business day, if sent by overnight courier, (c) when sent if sent by electronic mail provided that receipt is confirmed, in each case to the Parties at the following addresses (or at such other addresses as shall be specified by like notice) with postage or delivery charges prepaid.

If to Flexion:

Flexion Therapeutics, Inc.
Attn: Michael Clayman, MD
Telephone: [...***...]
Email: [...***...]

With a copy to: Legal

If to Patheon:

Attention:

Executive Director & General Manager
Patheon UK Limited
Kingfisher Drive, Covingham
Swindon, Wiltshire SN3 5BZ
England
Email: [...***...]

with copy to

Legal Director.

9.2 Force Majeure. Neither Party shall be liable for delay in delivery, performance or nonperformance, in whole or in part, nor shall the other Party have the right to terminate this Agreement except as otherwise specifically provided in this Section 9.2 where such delay in delivery, performance or nonperformance results from acts beyond the reasonable control and without the fault or negligence of such Party including, but not limited to, the following conditions: fires, floods, storms, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, or acts, omissions, or delays in acting by any governmental authority; provided that the Party affected by such a condition shall, within five (5) days of its occurrence, give notice to the other Party stating the nature of the condition, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required, and the nonperforming Party shall use its commercially reasonable efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for [...***...] days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the non-affected Party may terminate this Agreement immediately by written notice to the affected Party.

9.3 Independent Contractor. The Parties to this Agreement are independent contractors. Nothing contained in this Agreement will be construed to place the Parties in the relationship of employer and employee, partners, principal, and agent or a joint venture. Neither Party will have the power to bind or obligate the other Party nor will either Party hold itself out as having such authority.

9.4 Waiver. Save where expressly stated to the contrary in this Agreement, no waiver by either Party of any provision or breach of this Agreement will constitute a waiver by such Party of any other provision or breach, and no such waiver will be effective unless made in writing and signed by an authorized representative of the Party against whom waiver is sought. No course of conduct or dealing between the Parties will act as a modification or waiver of any provision of this Agreement. Either Party's consent to or approval of any act of the other Party will not be deemed to render unnecessary the obtaining of that Party's consent to or approval of any subsequent act by the other Party.

9.5 Entire Agreement. This Agreement (together with all Exhibits hereto, which are hereby incorporated by reference), the Manufacturing and Supply Agreement and the Quality Agreement, constitute the final, complete, and exclusive agreement between the Parties relating to the subject matter hereof and supersede all prior conversations, understandings, promises, and agreements relating to the subject matter hereof, including without limitation that (i) certain Confidentiality Agreement dated September 22, 2014 between Flexion and Patheon and the Letter Agreement between the Parties dated 1 May 2015, and (ii) that certain Patheon Partner External User Account/Access Form, Client Agreement and Authorization signed by Flexion on June 5, 2015. Neither Party has relied upon any communication, representation, term, or promise, verbal or written, not set forth herein.

9.6 Assignment; Change of Control.

This Agreement may not be assigned by Patheon without the prior written consent of Flexion. Notwithstanding the foregoing, either Party may assign this Agreement to an Affiliate or to an acquirer or successor in interest in connection with a Change of Control of such Party without the prior written consent of the other Party, provided that such Party provides the other Party with written notice of any such assignment. This Agreement shall be binding upon and inure to the benefit of Flexion and Patheon and their respective successors, heirs, executors, administrators, and permitted assigns. “Change of Control” means the closing of (a) a merger, consolidation or similar transaction providing for the acquisition of the direct or indirect ownership of more than fifty percent (50%) of a Party’s shares or similar equity interests or voting power of the outstanding voting securities or that represents the power to direct the management and policies of such Party (including any acquisition arising through the offering of any shares of Patheon or any of its Affiliates on any securities or stock exchange), or (b) the sale of all or substantially all of a Party’s assets related to the subject matter of the Agreement.

9.7 Amendment; Modification. This Agreement may not be amended, modified, altered, or supplemented except by a writing signed by both Parties. No modification of any nature to this Agreement and no representation, agreement, arrangement, or other communication will be binding on the Parties unless such is expressly contained in writing and executed by the Parties as an amendment to this Agreement. This Agreement may not be amended in any respect by any purchase order, invoice, acknowledgment, or other similar printed document issued by either Party.

9.8 Subcontractors. Prior to subcontracting any of Patheon’s obligations hereunder, Patheon will notify Flexion (1) in advance of engaging a proposed subcontractor that directly relates to the Manufacture of the Product and will obtain Flexion’s prior written approval of each such subcontractor, and (2) within six (6) months of all other subcontractors so engaged. The terms of any subcontract will be in writing and will not be materially inconsistent with this Agreement or the Manufacturing and Supply Agreement, including Section 3.14 of the Manufacturing and Supply Agreement. No subcontracting will release Patheon from its responsibility for its obligations under this Agreement. Patheon will be responsible for the work and activities of each subcontractor as they relate to performance of Patheon’s obligations under this Agreement, including compliance with the terms of this Agreement.

9.9 Governing Law.

(a) The laws of [...***...], whether procedural or substantive (but excluding application of any choice of law provisions contained therein) shall apply to all matters pertaining only to (a) title to and ownership of Materials, Equipment or the Facility, and its appurtenances including, without limitation, all rights therein and the creation, exercise and extinction of such rights, obligations and liabilities or (b) employment law matters. In relation to such matters, both Parties shall submit to the exclusive jurisdiction of the [...***...] Courts. For the avoidance of doubt, the Parties agree that nothing in this Agreement shall (i) grant Flexion any property ownership rights in the Facility or (ii) shall constitute a lease to the Facility.

(b) In all other respects, this Agreement shall be construed under and governed by the laws of [...***...] without regard to the application of principles of conflicts of law. In relation to such matters, both Parties shall submit to the exclusive jurisdiction of the [...***...].

(c) Any preliminary issue over which of sub-section 9.9(a) or (b) applies to a particular claim or dispute shall be determined in accordance with provisions of 9.9(a).

(d) The Parties expressly exclude the application of the United Nations Convention on Contracts for the International Sale of Goods, if applicable.

9.10 Severability. If any provision of this Agreement is found by a proper authority to be unenforceable, that provision to the extent it is found to be unenforceable or invalid will be severed and the remainder of the provision and this Agreement will continue in full force and effect. The Parties shall use their best efforts to agree upon a valid and enforceable provision as a substitute for any invalid or unenforceable provision, taking in to account the Parties' original intent of this Agreement.

9.11 Construction. Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms "hereof," "herein," "hereby," and derivative or similar words refer to this entire Agreement; (d) the terms "Article," "Section," "Exhibit," or "clause" refer to the specified Article, Section, Exhibit, or clause of this Agreement; (e) "or" is disjunctive but not necessarily exclusive; and (f) the term "including" or "includes" means "including without limitation" or "includes without limitation." Whenever this Agreement refers to a number of days, such number will refer to calendar days unless business days are specified. The captions and headings of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement will be deemed to be the language mutually chosen by the Parties, and no rule of strict construction will be applied against either Party hereto.

9.12 Third Party Beneficiaries. This Agreement is not intended to confer upon any non-party any right or remedy hereunder, except as may be received or created as part of a valid assignment.

9.13 Further Assurances. Each of the Parties agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such additional assignments, agreements, documents, and instruments, that may be necessary or as the other Party hereto may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

9.14 Counterparts. This Agreement may be signed in counterparts, each and every one of which will be deemed an original. Facsimile or PDF signatures will be treated as original signatures.

9.15 Taxes.

(a) Subject to (b) and (c) below, Patheon will bear all Taxes however designated as a result of the provision of the Transfer Services under this Agreement.

(b) Flexion acknowledges that it will be responsible for all Taxes that arise in respect of the following:

(i) The acquisition of the Flexion-Supplied Materials.

(ii) The acquisition of the Flexion Manufacturing Equipment.

(c) Any payment due under this Agreement for the provision of Transfer Services to Flexion by Patheon is exclusive of value added or equivalent tax in any other jurisdiction, including any related interest and penalties (hereinafter all referred to as "VAT"). If any VAT is payable on a Transfer Service supplied by Patheon to Flexion under this Agreement, this VAT will be added to the invoice amount and will be for the account of (and reimbursable to Patheon by) Flexion. Where applicable, Patheon will use its reasonable commercial efforts to ensure that its invoices to Flexion are issued in such a way that these invoices meet the requirements for deduction of input VAT by Flexion, to the extent permitted by law to do so.

(d) Flexion acknowledges that all amounts due in respect of any fees payable by Flexion under this Agreement shall be paid in full without any set-off, counterclaim, deduction or withholding in respect of any Tax liabilities.

The remainder of this page is left blank intentionally.

IN WITNESS WHEREOF, this Technical Transfer and Service Agreement has been executed by the Parties hereto as of the day and year first written above.

PATHEON UK LIMITED:

FLEXION THERAPEUTICS, INC.:

By: /s/ A.M. Botterill

By: /s/ Michael D. Clayman, M.D.

Name: A.M. Botterill

Name: Michael D. Clayman, M.D.

Title: Exec. Dir. & Gen. Manager

Title: CEO

Signature Page of Technical Transfer and Service Agreement

Exhibit 2.1-A

[...***...]

Exhibit 2.1-B

[...***...]

Exhibit 2.1-C

[...***...]

Exhibit 2.1-D

[...***...]

Exhibit 2.1-E

[...***...]

Exhibit 2.1-F

[...***...]

Exhibit 2.7

Steering Committee

1. Generally. The purpose of the Steering Committee shall be to oversee the Technical Transfer and Service Agreement, the Manufacturing and Supply Agreement and the Quality Agreement (the “Agreements”) and to facilitate communications between the Parties with respect thereto. The Steering Committee shall have the responsibilities and authority allocated to it in this Exhibit 2.7. The Steering Committee shall have the obligation to exercise its authority consistent with the respective purpose for the Steering Committee as stated herein and any such decisions shall be made in good faith.
 2. Formation and Purpose. Promptly following the Effective Date, the Parties shall confer and then create a Steering Committee. The Steering Committee shall have authority, subject to Paragraph 5, to oversee the priorities and budgets (not less than on a quarterly basis), to oversee manufacturing and controls for the Products, to review and approve all associated regulatory filings and correspondence under the Agreements (including reviewing and approving itemized budgets with respect to the foregoing), to approve the projects and plans of any subcommittee it establishes consistent with this authority and to review any concerns either Party may have concerning key employees employed by the Parties to provide the Transfer Services under the Technical Transfer Agreement and the Services under the Manufacturing and Supply Agreement.
 3. General Steering Committee Membership and Procedure.
 - (a) Membership. Each Party shall designate an equal number of representatives (not to exceed three (3) for each Party) to the Steering Committee with appropriate expertise to serve as members of the Steering Committee. The Steering Committee representatives must all be employees of such Party or an Affiliate of such Party, with the caveat that each Party may designate for the Steering Committee up to one (1) representative who is not an employee if: (i) such non-employee representative agrees in writing to be bound to the terms of this Agreement for the treatment and ownership of confidential information of the Parties, and (ii) the other Party consents to the designation of such non-employee representative, which consent shall not be unreasonably withheld. Each Party may replace its Steering Committee representatives at any time upon written notice to the other Party. The Steering Committee shall have a chairperson which shall be appointed by Flexion. The chairperson of the Steering Committee shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting of the Steering Committee, and preparing and issuing minutes of each meeting within fifteen (15) days thereafter.
 - (b) Meetings. The Steering Committee shall be constituted and the first meeting of the Steering Committee shall be held within sixty (60) days following the Effective Date, with the Steering Committee considering finalization and approval of workplans prepared by the Parties for inclusion and commencement under the Agreements. Otherwise, the Steering Committee shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less
-

frequently than once every six (6) months. Meetings of the Steering Committee may be held in person or by means of telecommunication (telephone, video, or web conferences). To the extent that the Steering Committee holds any meetings in person, the Parties will alternate in designating the location for such in-person meetings, with Flexion selecting the first meeting location for the Steering Committee. A reasonable number of additional representatives of a Party may attend meetings of the Steering Committee in a non-voting capacity. Each Party shall be responsible for all of its own expenses of participating in the Steering Committee.

- (c) Meeting Agendas. Each Party will disclose to the other proposed agenda items along with appropriate information at least three (3) business days in advance of each meeting of the Steering Committee; provided, that a Party may provide its agenda items to the other Party within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for the Steering Committee meeting.
- (d) Limitations of Steering Committee Powers. The Steering Committee shall have only such powers as are specifically delegated to it hereunder or from time to time as agreed to in writing by the mutual consent of the Parties and shall not be a substitute for the rights of the Parties. Without limiting the generality of the foregoing, the Steering Committee shall not have any power to amend the Agreements. Any amendment to the terms and conditions of this Agreement shall be implemented pursuant to Section 9.7 above. Additionally, no member of the Steering Committee shall be able to vote in the Steering Committee and thereby bind its respective Party on any material matter except as otherwise properly authorized, approved, or delegated by such Party in accord with Paragraph 5.

4 Restrictions. Neither Party shall exercise its right to finally resolve a dispute at the Steering Committee in accordance with this Paragraph 4 in a manner that (i) excuses such Party from any of its obligations specifically enumerated under this Agreement; (ii) expands the obligations of the other Party under this Agreement; (iii) negates any consent rights or other rights specifically allocated to the other Party under this Agreement; (iv) purports to resolve any dispute involving the breach or alleged breach of this Agreement; (v) resolves a matter if the provisions of this Agreement specify that mutual agreement is required for such matter; or (vi) would require the other Party to perform any act that is inconsistent with applicable law.

5 Authorization of Steering Committee Representatives. Each representative serving on the Steering Committee shall be responsible for ensuring that he or she acts only as duly authorized by its respective Party and obtains any advance approvals, delegations, or other authorizations from his or her respective Party in advance of making any Steering Committee votes.

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

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

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

Date: November 12, 2021

/s/ Michael D. Clayman, M.D.

Michael D. Clayman, M.D.

President and Chief Executive Officer

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

I, Frederick W. Driscoll, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

Date: November 12, 2021

/s/ Frederick W. Driscoll

Frederick W. Driscoll

Principal Financial and Accounting Officer

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 of Flexion Therapeutics, Inc. (the “Registrant”), and Frederick W. Driscoll, Chief Financial Officer of 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 our knowledge:

- (1) this Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the “Report”), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 12, 2021

/s/ Michael D. Clayman, M.D.

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

Date: November 12, 2021

/s/ Frederick W. Driscoll

Frederick W. Driscoll
Principal Financial and Accounting 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.

**Document and Entity
Information - shares**

**9 Months Ended
Sep. 30, 2021**

Nov. 01, 2021

[Cover \[Abstract\]](#)

Document Type	10-Q	
Amendment Flag	false	
Document Period End Date	Sep. 30, 2021	
Document Fiscal Year Focus	2021	
Document Fiscal Period Focus	Q3	
Entity Registrant Name	Flexion Therapeutics, Inc.	
Entity Central Index Key	0001419600	
Entity Current Reporting Status	Yes	
Entity Interactive Data Current	Yes	
Current Fiscal Year End Date	--12-31	
Entity Filer Category	Non-accelerated Filer	
Entity Common Stock, Shares Outstanding		50,321,366
Entity Shell Company	false	
Entity Small Business	true	
Entity Emerging Growth Company	false	
Title of 12(b) Security	Common stock, \$0.001 par value per share	
Trading Symbol	FLXN	
Security Exchange Name	NASDAQ	
Entity File Number	001-36287	
Entity Incorporation, State or Country Code	DE	
Entity Tax Identification Number	26-1388364	
Entity Address, Address Line One	10 Mall Road	
Entity Address, Address Line Two	Suite 301	
Entity Address, City or Town	Burlington	
Entity Address, State or Province	MA	
Entity Address, Postal Zip Code	01803	
City Area Code	781	
Local Phone Number	305-7777	
Document Quarterly Report	true	
Document Transition Report	false	

**Condensed Consolidated
Balance Sheets (Unaudited) -
USD (\$)
\$ in Thousands**

**Sep. 30, Dec. 31,
2021 2020**

Current assets

<u>Cash and cash equivalents</u>	\$	\$
	136,824	107,704
<u>Marketable securities</u>	5,229	67,576
<u>Accounts receivable, net</u>	29,375	30,025
<u>Inventories</u>	14,669	15,394
<u>Prepaid expenses and other current assets</u>	6,659	5,112
<u>Total current assets</u>	192,756	225,811
<u>Property and equipment, net</u>	19,480	19,538
<u>Right-of-use assets</u>	5,695	6,577
<u>Total assets</u>	217,931	251,926

Current liabilities

<u>Accounts payable</u>	7,492	6,928
<u>Accrued expenses and other current liabilities</u>	24,875	20,008
<u>Deferred revenue</u>	10,000	10,000
<u>Operating lease liabilities</u>	1,619	1,526
<u>Current portion of long-term debt</u>	0	16,806
<u>Total current liabilities</u>	43,986	55,268
<u>Long-term operating lease liability, net</u>	5,328	6,123
<u>Long-term debt, net</u>	80,087	44,114
<u>2024 convertible notes, net</u>	170,418	162,786
<u>Other long-term liabilities</u>	489	295
<u>Total liabilities</u>	300,308	268,586

Commitments and contingencies

<u>Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2021 and December 31, 2020 and 0 shares issued and outstanding at September 30, 2021 and December 31, 2020</u>	0	0
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Stockholders' deficit

<u>Common stock, \$0.001 par value; 100,000,000 shares authorized; 50,299,458 and 49,403,034 shares issued and outstanding, at September 30, 2021 and December 31, 2020, respectively</u>	50	49
<u>Additional paid-in capital</u>	780,954	765,607
<u>Accumulated other comprehensive loss</u>	0	(11)
<u>Accumulated deficit</u>	(863,381)	(782,305)
<u>Total stockholders' deficit</u>	(82,377)	(16,660)
<u>Total liabilities and stockholders' deficit</u>	\$	\$
	217,931	251,926

**Condensed Consolidated
Balance Sheets (Unaudited)
(Parenthetical) - \$ / shares**

Sep. 30, 2021 Dec. 31, 2020

Statement of Financial Position [Abstract]

<u>Preferred stock, par value</u>	\$ 0.001	\$ 0.001
<u>Preferred stock, shares authorized</u>	10,000,000	10,000,000
<u>Preferred stock, shares issued</u>	0	0
<u>Preferred stock, shares outstanding</u>	0	0
<u>Common stock, par value</u>	\$ 0.001	\$ 0.001
<u>Common stock, shares authorized</u>	100,000,000	100,000,000
<u>Common stock, shares issued</u>	50,299,458	50,299,458
<u>Common stock, shares outstanding</u>	49,403,034	49,403,034

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited) - USD (\$) shares in Thousands, \$ in Thousands	3 Months Ended		9 Months Ended	
	Sep. 30, 2021	Sep. 30, 2020	Sep. 30, 2021	Sep. 30, 2020
Revenues				
<u>Product revenue, net</u>	\$ 21,326	\$ 23,664	\$ 74,090	\$ 59,242
<u>Type of Revenue [Extensible List]</u>	Product [Member]	Product [Member]	Product [Member]	Product [Member]
Operating expenses				
<u>Cost of sales</u>	\$ 3,727	\$ 5,130	\$ 14,791	\$ 12,887
<u>Type of Cost, Good or Service [Extensible List]</u>	Product [Member]	Product [Member]	Product [Member]	Product [Member]
<u>Research and development</u>	\$ 14,771	\$ 10,092	\$ 41,487	\$ 43,733
<u>Selling, general and administrative</u>	26,986	27,312	81,993	81,341
<u>Total operating expenses</u>	45,484	42,534	138,271	137,961
<u>Loss from operations</u>	(24,158)	(18,870)	(64,181)	(78,719)
Other (expense) income				
<u>Interest income</u>	54	62	531	584
<u>Interest expense</u>	(5,787)	(5,125)	(16,156)	(14,848)
<u>Other expense</u>	(421)	(457)	(1,270)	(581)
<u>Total other (expense) income</u>	(6,154)	(5,520)	(16,895)	(14,845)
<u>Loss before income taxes</u>	(30,312)	(24,390)	(81,076)	(93,564)
<u>Income tax expense</u>		248		495
<u>Net loss</u>	\$ (30,312)	\$ (24,638)	\$ (81,076)	\$ (94,059)
<u>Net loss per common share, basic and diluted</u>	\$ (0.60)	\$ (0.50)	\$ (1.62)	\$ (2.16)
<u>Weighted average common shares outstanding, basic and diluted</u>	50,265	49,298	50,027	43,563
Other comprehensive income (loss):				
<u>Unrealized gains (losses) from available-for-sale securities, net of tax of \$0</u>	\$ 2	\$ (9)	\$ 11	\$ (68)
<u>Total other comprehensive income (loss)</u>	2	(9)	11	(68)
<u>Comprehensive loss</u>	\$ (30,310)	\$ (24,647)	\$ (81,065)	\$ (94,127)

**Condensed Consolidated
Statements of Operations
and Comprehensive Loss
(Unaudited) (Parenthetical) -
USD (\$)
\$ in Thousands**

3 Months Ended

9 Months Ended

Sep. 30, 2021 Sep. 30, 2020 Sep. 30, 2021 Sep. 30, 2020

[Income Statement \[Abstract\]](#)

<u>Unrealized gains from available-for-sale securities, tax</u>	\$ 0	\$ 0	\$ 0	\$ 0
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Condensed Consolidated Statements of Changes in Stockholders' Deficit (Unaudited) - USD (\$) \$ in Thousands	Total	Common Stock [Member]	Additional Paid-in- Capital [Member]	Accumulated Other Comprehensive (Loss) Income [Member]	Accumulated Deficit [Member]
<u>Balance at Dec. 31, 2019</u>	\$ (20,108)	\$ 38	\$ 648,391	\$ 62	\$ (668,599)
<u>Balance (in shares) at Dec. 31, 2019</u>		38,361,000			
<u>Issuance of common stock for equity awards, net of shares withheld for taxes</u>	9	\$ 1	8		
<u>Issuance of common stock for equity awards, net of shares withheld for taxes (in shares)</u>		201,000			
<u>Stock-based compensation expense</u>	4,651		4,651		
<u>Net loss</u>	(36,802)				(36,802)
<u>Other comprehensive income</u>	(56)			(56)	
<u>Balance at Mar. 31, 2020</u>	(52,306)	\$ 39	653,050	6	(705,401)
<u>Balance (in shares) at Mar. 31, 2020</u>		38,562,000			
<u>Balance at Dec. 31, 2019</u>	(20,108)	\$ 38	648,391	62	(668,599)
<u>Balance (in shares) at Dec. 31, 2019</u>		38,361,000			
<u>Net loss</u>	(94,059)				
<u>Other comprehensive income</u>	(68)				
<u>Balance at Sep. 30, 2020</u>	(3,095)	\$ 49	759,520	(6)	(762,658)
<u>Balance (in shares) at Sep. 30, 2020</u>		49,306,000			
<u>Balance at Mar. 31, 2020</u>	(52,306)	\$ 39	653,050	6	(705,401)
<u>Balance (in shares) at Mar. 31, 2020</u>		38,562,000			
<u>Issuance of common stock, net of issuance costs</u>	96,764	\$ 10	96,754		
<u>Issuance of common stock net of issuance costs (in shares)</u>		10,615,000			
<u>Issuance of common stock for equity awards, net of shares withheld for taxes</u>	1		1		
<u>Issuance of common stock for equity awards, net of shares withheld for taxes (in shares)</u>		11,000			
<u>Employee stock purchase plan</u>	891		891		
<u>Employee stock purchase plan (in shares)</u>		82,000			

<u>Stock-based compensation expense</u>	3,787		3,787		
<u>Net loss</u>	(32,619)				(32,619)
<u>Other comprehensive income</u>	(3)			(3)	
<u>Balance at Jun. 30, 2020</u>	16,515	\$ 49	754,483	3	(738,020)
<u>Balance (in shares) at Jun. 30, 2020</u>			49,270,000		
<u>Issuance of common stock for equity awards, net of shares withheld for taxes</u>	78	\$ 36	78		
<u>Stock-based compensation expense</u>	4,959		4,959		
<u>Net loss</u>	(24,638)				(24,638)
<u>Other comprehensive income</u>	(9)			(9)	
<u>Balance at Sep. 30, 2020</u>	(3,095)	\$ 49	759,520	(6)	(762,658)
<u>Balance (in shares) at Sep. 30, 2020</u>			49,306,000		
<u>Balance at Dec. 31, 2020</u>	(16,660)	\$ 49	765,607	(11)	(782,305)
<u>Balance (in shares) at Dec. 31, 2020</u>			49,403,000		
<u>Issuance of common stock, net of issuance costs</u>	1,700		1,700		
<u>Issuance of common stock net of issuance costs (in shares)</u>			134,000		
<u>Issuance of common stock for equity awards, net of shares withheld for taxes</u>	8	\$ 1	7		
<u>Issuance of common stock for equity awards, net of shares withheld for taxes (in shares)</u>			405,000		
<u>Stock-based compensation expense</u>	4,640		4,640		
<u>Net loss</u>	(28,556)				(28,556)
<u>Other comprehensive income</u>	1			1	
<u>Balance at Mar. 31, 2021</u>	(38,867)	\$ 50	771,954	(10)	(810,861)
<u>Balance (in shares) at Mar. 31, 2021</u>			49,942,000		
<u>Balance at Dec. 31, 2020</u>	(16,660)	\$ 49	765,607	(11)	(782,305)
<u>Balance (in shares) at Dec. 31, 2020</u>			49,403,000		
<u>Net loss</u>	(81,076)				
<u>Other comprehensive income</u>	11				
<u>Balance at Sep. 30, 2021</u>	(82,377)	\$ 50	780,954		(863,381)
<u>Balance (in shares) at Sep. 30, 2021</u>			50,299,000		
<u>Balance at Mar. 31, 2021</u>	(38,867)	\$ 50	771,954	(10)	(810,861)
<u>Balance (in shares) at Mar. 31, 2021</u>			49,942,000		

<u>Issuance of common stock for equity awards, net of shares withheld for taxes (in shares)</u>		46,000		
<u>Employee stock purchase plan</u>	921		921	
<u>Employee stock purchase plan (in shares)</u>		118,000		
<u>Stock-based compensation expense</u>	3,975		3,975	
<u>Net loss</u>	(22,208)			(22,208)
<u>Other comprehensive income</u>	8		8	
<u>Balance at Jun. 30, 2021</u>	(56,171)	\$ 50	776,850	(2)
<u>Balance (in shares) at Jun. 30, 2021</u>		50,106,000		
<u>Issuance of common stock for equity awards, net of shares withheld for taxes</u>	(92)	\$ 193	(92)	
<u>Stock-based compensation expense</u>	4,196		4,196	
<u>Net loss</u>	(30,312)			(30,312)
<u>Other comprehensive income</u>	2		2	
<u>Balance at Sep. 30, 2021</u>	\$ (82,377)	\$ 50	\$ 780,954	\$ (863,381)
<u>Balance (in shares) at Sep. 30, 2021</u>		50,299,000		

**Condensed Consolidated
Statements of Cash Flows
(Unaudited) - USD (\$)
\$ in Thousands**

**9 Months Ended
Sep. 30, 2021 Sep. 30, 2020**

Cash flows from operating activities

Net loss \$ (81,076) \$ (94,059)

Adjustments to reconcile net loss to cash used in operating activities

Depreciation 1,573 1,295

Amortization of right-of-use assets 1,315 1,224

Stock-based compensation expense 12,811 13,397

Provision for inventory 1,773 0

Non cash interest expense 540 518

Amortization (accretion) of premium (discount) on marketable securities 441 (18)

Loss on disposal of fixed assets 0 262

Loss on debt extinguishment 502

Amortization of debt discount and debt issuance costs 7,842 6,947

Premium paid on securities purchased (54) (534)

Changes in operating assets and liabilities:

Accounts receivable 650 9,216

Inventory (1,048) (1,063)

Prepaid expenses and other current assets (1,547) (496)

Accounts payable 980 (6,693)

Accrued expenses and other current liabilities 4,992 216

Deferred revenue 0 10,000

Lease liabilities (1,135) (1,031)

Net cash used in operating activities (51,441) (60,819)

Cash flows from investing activities

Purchases of property and equipment (1,737) (8,860)

Proceeds from sale of fixed assets 0 13

Purchases of marketable securities (5,175) (56,216)

Sale and redemption of marketable securities 67,146 54,398

Net cash provided by (used in) investing activities 60,234 (10,665)

Cash flows from financing activities

Proceeds from borrowings under term loan 55,000 15,000

Proceeds from revolving line of credit 20,000 20,000

Repayments of revolving line of credit 0 (15,000)

Proceeds From The Offering Of Common Stock 0 97,289

Proceeds from issuance of common stock (net of issuance costs) 1,700

Payments of public offering costs (125) (400)

Payments on notes payable (56,875)

Payment of debt issuance costs (210)

Proceeds from the exercise of stock options (net of shares withheld for taxes) (84) 88

Proceeds from employee stock purchase plan 921 891

Net cash provided by financing activities 20,327 117,868

<u>Net increase in cash and cash equivalents</u>	29,120	46,384
<u>Cash and cash equivalents at beginning of period</u>	107,704	82,253
<u>Cash and cash equivalents at end of period</u>	136,824	128,637
<u>Non-cash operating, investing and financing activities</u>		
<u>Right-of-use asset obtained in exchange for operating lease obligation</u>	433	
<u>Purchases of property and equipment in accounts payable and accrued expenses</u>	15	870
<u>Public offering costs in accounts payable and accrued expenses</u>	0	125
<u>Supplemental disclosures of cash flow information</u>		
<u>Cash paid for interest</u>	\$ 6,483	\$ 6,042

Overview and Nature of the Business

9 Months Ended
Sep. 30, 2021

[Organization, Consolidation and Presentation of](#)

[Financial Statements](#)

[\[Abstract\]](#)

[Overview and Nature of the Business](#)

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, the most common form of 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 two pipeline programs focused on the local treatment of musculoskeletal conditions: FX201, an investigational IA gene therapy product candidate in clinical development for the treatment of OA, and FX301, a locally administered peripheral nerve block product candidate in clinical development for the control of post-operative 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 will 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 as to when, if ever, the Company will generate sales of ZILRETTA that are significant enough to achieve profitability or if the development efforts supporting the Company’s pipeline, including future clinical trials, will be successful.

Proposed Acquisition by Pacira BioSciences, Inc.

On October 11, 2021, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Pacira BioSciences, Inc., a Delaware corporation (“Pacira”), and Oyster Acquisition Company Inc., a Delaware corporation and wholly owned subsidiary of Pacira (“Purchaser”). Pursuant to the Merger Agreement, on October 22, 2021, Purchaser commenced a tender offer (the “Offer”) to purchase each issued and outstanding share of the Company’s common stock (the “Shares”) at an offer price of (i) \$8.50 per Share in cash, net of applicable withholding taxes and without interest, plus (ii) one non-transferable contractual contingent value right per Share, which will represent the right to receive one or more contingent payments up to \$8.00 in the aggregate, in cash, net of applicable withholding taxes and without interest, upon the achievement of specified milestones on or prior to December 31, 2030.

Promptly following the completion of the Offer, upon the terms and subject to the conditions of the Merger Agreement, Purchaser will merge with and into the Company (the “Merger”), with the Company continuing as the surviving corporation and as a wholly owned subsidiary of Pacira. The Merger Agreement contemplates that the Merger will be effected pursuant to Section 251(h) of the Delaware General Corporation Law, which permits completion of the Merger

without a vote of the holders of common stock upon the acquisition by Purchaser of a majority of the aggregate voting power of common stock. As a result of the Merger, the Company will cease to be a publicly traded company.

The Merger Agreement contains customary representations and warranties. The Merger is expected to close before the end of the calendar year 2021, subject to the satisfaction or waiver of customary closing conditions, including, among others, that the number of Shares tendered in the Offer represent at least one Share more than 50% of the total number of Shares at the time of the expiration of the Offer. The Merger Agreement provides Pacira and the Company with certain termination rights and, under certain circumstances, may require the Company to pay Pacira a termination fee of \$18.0 million.

For additional information related to the Merger Agreement, refer to the Solicitation/ Recommendation Statement on Schedule 14D-9 filed by the Company with the Securities and Exchange Commission on October 22, 2021, together with the exhibits and annexes thereto and as amended or supplemented from time to time.

The Company recorded acquisition-related costs of approximately \$0.7 million for each of the three and nine months ended September 30, 2021, primarily for outside legal and external financial advisory fees associated with the pending acquisition by Pacira. These costs were recorded in general and administrative expense in the Company's condensed consolidated statements of operations and comprehensive loss in the respective reporting periods. Additional acquisition-related costs are expected to be incurred through the closing of the Merger.

Going Concern

The accompanying condensed consolidated financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the realization of assets and satisfaction of liabilities and commitments in the

normal course of business. The Company has incurred recurring losses and negative cash flows from operations. As of September 30, 2021, the Company had cash, cash equivalents, and marketable securities of approximately \$142.1 million.

The Company's operations have been and continue to be affected by the ongoing global pandemic of a novel strain of coronavirus ("COVID-19"). In March 2020, the World Health Organization declared COVID-19 a pandemic and recommended containment and mitigation measures worldwide. The COVID-19 pandemic has caused significant volatility and uncertainty, which could result in a prolonged economic downturn that has disrupted and is expected to continue to disrupt the Company's business. While there have been no material asset impairments recorded to date, any prolonged material future disruptions to the work of the Company's employees, suppliers, contract manufacturers, or vendors, or to the operations of physicians that administer ZILRETTA could negatively impact the Company's operations, availability of supplies, carrying value of assets, operating results, or cash flows.

The future viability of the Company is dependent on its ability to fund its operations through sales of ZILRETTA, and/or raising additional capital, such as through debt or equity offerings, as needed. The Company may not be able to obtain financing on acceptable terms, or at all. In particular, as a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility and disruptions, including declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any additional debt or equity financing more difficult, more costly, and more dilutive. 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/or reduce the scope of, or delay certain research and development activities, including the FX201 or FX301 programs, which could adversely affect its prospects.

In accordance with the amended and restated credit and security agreement described in Note 9, if the Company's liquidity decreases below \$100.0 million, the Company will need to comply with a minimum revenue covenant and all amounts received from customer collections will be applied to immediately reduce the Company's revolving credit facility. The minimum revenue covenant is set annually and is applied to the trailing six-months of net revenue and is determined based on the Company's approved forecast, as determined by the Lenders. The amended and restated credit and security agreement also has a material adverse event clause. If the minimum revenue covenant becomes applicable and the Company fails to comply with it, or a material adverse change as defined in the agreement occurs, the amounts due under the amended and restated credit and security agreement could be declared immediately due and payable, resulting in the Company immediately needing additional funds. As of September 30, 2021, the Company was in compliance with all financial covenants under the amended and restated credit and security agreement.

If the Company is unable to grow sales of ZILRETTA in future periods, it is possible that the Company may not maintain compliance with the revenue covenant, in the event it applies, in future periods, which would require the Company to repay its outstanding borrowings under the term loan and revolving credit facility. Given the recent decrease in revenue as compared to the Company's expectations, the Company expects that absent raising additional capital through financing or other transactions its cash balance is likely to decrease below \$100.0 million within the next twelve months, and the Company believes there is substantial risk that it would fail to meet the minimum revenue covenant at that time or shortly thereafter if demand for ZILRETTA does not increase in line with its expectations. If the Company is or expects to be subject to and unable to meet the minimum revenue covenant, the Company would plan to request a waiver from the lenders, although there can be no assurances that such a request would be granted or would not be conditioned on additional terms or concessions. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of one year after the date that the financial statements are issued.

Management's plans that would be intended to mitigate the conditions that raise substantial doubt about the Company's ability to continue as a going concern include reducing operating expenses through hiring and travel freezes, delaying, reducing, or ceasing all research and development activities outside of the ongoing clinical trials, reduction of certain external expenses, and elimination of non-essential operating expenses, requesting a waiver of the minimum revenue covenant from the lenders, and remaining opportunistic with respect to raising additional capital through financing or other transactions. However, as the Company is expecting to close the planned merger with Pacira prior to the end of 2021, none of the above actions have been taken or have been approved to be taken and therefore cannot be considered in management's going concern evaluation as a mitigating action.

The Company has concluded that without taking into consideration the planned Merger with Pacira, management's plans do not alleviate the substantial doubt about the Company's ability to continue as a going concern. As the planned Merger with Pacira has not occurred as of the issuance of these financial statements, it also cannot be considered within management's plans to alleviate the conditions raised around substantial doubt. As a result, in accordance with the requirements of ASC 205-40, management has concluded that it is required to disclose that substantial doubt exists about the Company's ability to continue as a going concern for one year from the date these financial statements are issued.

[Accounting Policies](#)

[\[Abstract\]](#)

[Summary of Significant
Accounting Policies](#)

2. **Summary of Significant Accounting Policies**

Basis of Presentation

The accompanying condensed consolidated financial statements as of September 30, 2021, and for the three and nine months ended September 30, 2021 and 2020, 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 that are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the SEC on March 10, 2021.

The information presented in the condensed consolidated financial statements and related notes as of September 30, 2021, and December 31, 2020, and for the three and nine months ended September 30, 2021 and 2020, is unaudited. The December 31, 2020, condensed consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, footnotes, and notes, required by GAAP for complete financial statements.

Interim results for the three and nine months ended September 30, 2021, are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2021, or any future period.

Recent Accounting Pronouncements

Accounting Standards Recently Issued

In August 2020, the FASB issued ASU No. 2020-06, ("ASU 2020-06"). The new standard simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. The new guidance reduced the number of accounting models for convertible preferred stock instruments and made certain disclosure amendments intended to improve the information provided to users. The guidance also amended the derivative guidance for the "own stock" scope exception, which exempts qualifying instruments from being accounted for as derivatives if certain criteria are met. Finally, the standard changed the way certain convertible instruments are treated when calculating earnings per share. The standard is effective for the Company for fiscal years, and the interim periods within those years, beginning after December 15, 2021, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2020-06 on the Company's condensed consolidated financial statements.

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 and nine months ended September 30, 2021 and the year ended December 31, 2020.

Revenue Recognition

On October 6, 2017, the U.S. Food and Drug Administration ("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 that 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.

Product Revenue, Net

The Company primarily sells ZILRETTA to specialty distributors and a specialty pharmacy, who then subsequently resell ZILRETTA to physicians, clinics, and certain medical centers or hospitals. The Company also contracts directly with healthcare providers and inter-

such as Group Purchasing Organizations (“GPOs”). In addition, 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 significant performance obligation. There are no other promises to deliver goods or services beyond what is specified in each accepted customer contract. The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payables 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 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 discussed 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 of variable consideration represent a range of possible outcomes that are probability-weighted in accordance with the expected value method in Topic 606, considering relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and historical customer buying and payment patterns. Overall, these reserves reflect the Company’s best estimates of the amount of consideration that the Company is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price 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 the period such variances become known.

Service Fees and Allowances

The Company compensates its customers and GPOs 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 services have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through September 30, 2021, 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 customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as with respect to expenses and other current liabilities, net, on the condensed consolidated balance sheets. The Company currently estimates product returns liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. Historically, the Company has received an immaterial amount of returns. In the third quarter of 2021, there was a significant increase in actual and expected product returns from specialty distributors of product that was never sold through to healthcare providers. This was due to the fact that the majority of product sold during the third quarter had between 3-4 months of expiry remaining. The vast majority of returns were related to product that was sold to the specialty distributors during the third quarter of 2021 and resulted in a \$2.0 million reduction in revenue in the third quarter of 2021. In addition, the Company increased its estimate of future returns relating to short-dated product, which resulted in an additional \$1.4 million reduction in revenue in the third quarter of 2021.

Chargebacks

Chargebacks for fees and discounts to qualified government healthcare providers represent the estimated obligations resulting from the Company’s commitments to sell products to qualified VA hospitals and 340b entities at prices lower than the list prices charged to customers who purchase the product from the Company. The 340b Drug Discount Program is a U.S. 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 government entity. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of 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 chargeback amounts 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 statement of operations when the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in trade payables.

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 the 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 that remains in the distribution channel inventories at the end of each reporting period.

Purchaser/Provider Discounts and Rebates

The Company offers rebates to eligible purchasers and healthcare providers that are variable based on volume of product purchased. Rebates are based on actual purchase levels during the rebate purchase period. In the third quarter of 2021, the Company implemented an off-invoice discount ("OID") program whereby providers receive the discounted price immediately upon purchase, rather than having to wait until the end of the quarter for a rebate payment. Specialty distributors and other customers charge the Company for the difference between what they pay for the product (list price) and the net selling price after taking into account the OID. Chargeback amounts are generally determined based on the difference of resale to the eligible 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 commercial chargebacks consist of credits that the Company issues for units sold to qualified healthcare providers but for which no chargeback has been submitted, and chargebacks that customers have claimed, but for which the Company has not yet issued a credit. The Company estimates these rebates and records such estimates in the period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included as a component of accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Other Incentives

Other incentives that the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which is intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by their insurance. 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 incur 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 that 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 nine months ended September 30, 2021 and 2020:

<i>(In thousands)</i>	Service Fees, Allowances and Chargebacks	Government Rebates and Other Incentives	Product Returns	Purchaser/ Provider Discounts and Rebates	Total
Balance as of December 31, 2020	\$ 1,733	\$ 530	\$ 628	\$ 1,832	\$ 4,723
Provision related to sales in the current quarter	2,188	383	151	2,703	5,425
Credits and payments made	(1,969)	(266)	(9)	(1,832)	(4,176)
Adjustments related to prior period sales	—	—	(111)	—	(111)
Balance as of March 31, 2021	1,952	647	659	2,703	5,961
Provision related to sales in the current quarter	2,682	424	179	3,100	6,385
Credits and payments made	(2,527)	(311)	(86)	(2,711)	(5,635)
Adjustments related to prior period sales	(10)	—	—	—	(10)
Balance as of June 30, 2021	\$ 2,097	\$ 760	\$ 752	\$ 3,092	\$ 6,699
Provision related to sales in the current quarter	2,538	290	3,130	3,245	9,203
Credits and payments made	(2,859)	(401)	(1,331)	(5,182)	(9,773)
Adjustments related to prior period sales	—	—	291	—	291
Balance as of September 30, 2021	\$ 1,776	\$ 649	\$ 2,842	\$ 1,155	\$ 6,422
Balance as of December 31, 2019	\$ 1,847	\$ 248	\$ 402	\$ 1,656	\$ 4,153
Provision related to sales in the current quarter	1,590	254	114	526	2,484
Credits and payments made	(1,852)	(199)	(10)	(1,656)	(3,717)
Adjustments related to prior period sales	—	95	—	—	95
Balance as of March 31, 2020	1,585	398	506	526	3,015
Provision related to sales in the current quarter	1,417	133	98	892	2,540
Credits and payments made	(1,172)	(262)	(1)	(528)	(1,963)
Adjustments related to prior period sales	—	90	—	2	92
Balance as of June 30, 2020	\$ 1,830	\$ 359	\$ 603	\$ 892	\$ 3,684
Provision related to sales in the current quarter	2,270	265	136	1,314	4,385

Credits and payments made	(2,585)	(198)	(21)	(894)	(3,
Adjustments related to prior period sales	—	40	—	2	
Balance as of September 30, 2020	\$ 1,515	\$ 466	\$ 718	\$ 1,314	\$ 4,

License Agreement – On March 30, 2020, the Company entered into an exclusive license agreement with Hong Kong Tainuo Pharmaceutical Co., Ltd. (“HK Tainuo”) and Jiangsu Tainuo Pharmaceutical Co. Ltd. (“Jiangsu Tainuo”), a subsidiary of China Shijiazhuang Pharmaceutical Co., Ltd. for the development and commercialization (other than manufacturing) of ZILRETTA in Greater China (consisting of mainland China, Hong Kong and Macau, and Taiwan). Under the terms of the agreement, HK Tainuo paid the Company an upfront payment of \$10.0 million, of which \$5.0 million was received as of June 30, 2020, and the remaining \$5.0 million was received as of September 30, 2020. The Company is also eligible to receive up to \$32.5 million in aggregate development, regulatory, and commercial sales milestone payments. All payments received from HK Tainuo are subject to applicable Hong Kong withholding taxes. HK Tainuo is responsible for the clinical development, product registration, and commercialization of ZILRETTA in Greater China, and Jiangsu Tainuo serves as the guarantor of HK Tainuo’s obligations and responsibilities under the agreement. The Company is solely responsible for the manufacture and supply of ZILRETTA in Greater China. Tainuo for all clinical and commercial activities. The terms related to product manufacturing and supply, including pricing and minimum purchase requirements agreed to in the license agreement, will be covered by a separate supply agreement, which has not yet been finalized. All amounts owed to the Company are nonrefundable and non-creditable once paid. Unless terminated earlier in accordance with its terms, the license agreement continues in effect in perpetuity or as long as HK Tainuo or Jiangsu Tainuo continue to sell ZILRETTA in Greater China. Either party may terminate the agreement prior to expiration in the event of a material breach if not cured within 60 days from the date of notice of such breach (30 days in the case of payment obligations), or either party files for bankruptcy. The Company also has the right to terminate the agreement if HK Tainuo, Jiangsu Tainuo, or any affiliate of each commences any action or proceeding that challenges the validity, enforceability, or scope of any Company patent in Greater China. Upon any such termination, the license granted to HK Tainuo will terminate and all know-how and patents will revert back to the Company. The Company concluded that the license and supply obligations were not distinct performance obligations, and therefore the transaction price will be recognized as revenue as the

Company’s supply obligation is fulfilled over the term of the supply agreement, which has not yet commenced. No revenue was recognized associated with this contract as of September 30, 2021. The proceeds associated with the upfront payment have been recorded in shareholders’ equity as deferred revenue on the Company’s condensed consolidated balance sheet as of September 30, 2021, as there is uncertainty around the timing of when the revenue will be recognized. The Company will re-evaluate the classification of deferred revenue when the supply agreement is finalized.

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 recognition and accrued expenses related to clinical development 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.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company’s business, results of operations, and financial condition, including sales, expenses, reserves and allowances, clinical trials, research and development expenses, and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national, and international customers and markets. The Company has made estimates of the impact of COVID-19 within its financial statements, and these estimates may be changes to those estimates in future periods.

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 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 reported 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 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 entered into 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. The rate 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 convertible senior notes and term loan described below) were also used as inputs to the analysis to determine the 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.*, taxes, insurance, etc.). Then the fixed contract consideration (including any related to non-components) must be allocated based on the relative fair values of 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, 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.

**Fair Value of Financial
Assets and Liabilities**

**9 Months Ended
Sep. 30, 2021**

Fair Value Disclosures

[Abstract]

**Fair Value of Financial Assets
and Liabilities**

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 September 30, 2021 and December 31, 2020, and indicate the level of the fair value hierarchy utilized to determine such fair value:

<i>(In thousands)</i>	Fair Value Measurements as of September 30, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 108,686	\$ —	\$ —	\$ 108,686
Marketable securities	—	5,229	—	5,229
	<u>\$ 108,686</u>	<u>\$ 5,229</u>	<u>\$ —</u>	<u>\$ 113,915</u>

<i>(In thousands)</i>	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 79,148	\$ 6,832	\$ —	\$ 85,980
Marketable securities	—	67,576	—	67,576
	<u>\$ 79,148</u>	<u>\$ 74,408</u>	<u>\$ —</u>	<u>\$ 153,556</u>

As of September 30, 2021 and December 31, 2020, the Company's cash equivalents that are invested in money market funds are valued using Level 1 inputs based on quoted prices for identical securities in active markets. The Company's marketable securities are valued using Level 2 inputs and primarily rely 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 2021 credit facility with Silicon Valley Bank as agent, MidCap Financial Trust, MidCap Funding XIII Trust (the "2021 term loan"), as well as a revolving credit facility. The amount outstanding on the 2021 term loan reported at its carrying value in the accompanying balance sheet as of September 30, 2021. The Company determined the fair value of the 2021 term loan using an income approach that utilizes a discounted cash flow analysis based on current market interest rates for debt with similar remaining years to maturity, adjusted for credit risk. The 2021 term loan was valued using Level 2 inputs as of September 30, 2021. The result of the calculation yielded a fair value that approximates its carrying value. The Company also concluded that the carrying value of the revolving credit facility approximates fair value because of the short-term maturity of this debt instrument.

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 fair value of the 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 debt instrument 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 fair value of the 2024 Convertible Notes, face value of \$201.3 million, was \$179.8 million at September 30, 2021.

Marketable Securities

9 Months Ended
Sep. 30, 2021

[Investments, Debt and
Equity Securities \[Abstract\]
Marketable Securities](#)

4. Marketable Securities

As of September 30, 2021 and December 31, 2020, the fair value of available-for-sale marketable securities by type of security was

<i>(In thousands)</i>	September 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 2,000	\$ —	\$ —	\$ 2,000
Corporate bonds	3,229	—	—	3,229
	<u>\$ 5,229</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,229</u>

<i>(In thousands)</i>	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 6,890	\$ —	\$ —	\$ 6,890
U.S. government obligations	9,997	1	—	9,998
Corporate bonds	50,700	2	(14)	50,688
	<u>\$ 67,587</u>	<u>\$ 3</u>	<u>\$ (14)</u>	<u>\$ 67,576</u>

As of September 30, 2021 and December 31, 2020, marketable securities consisted of \$5.2 million and \$67.6 million, respectively, investments that mature within 12 months. There were no investments with maturities greater than 12 months as of September 30, 2021 and December 31, 2020. The Company assesses its available-for-sale marketable securities for impairment on a quarterly basis in accordance with ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. There were no material impairments of the Company's available-for-sale marketable securities measured and carried at fair value during the three months ended September 30, 2021.

**Prepaid Expenses and Other
Current Assets**

**9 Months Ended
Sep. 30, 2021**

[Deferred Costs, Capitalized,
Prepaid, and Other Assets
Disclosure \[Abstract\]](#)

[Prepaid Expenses and Other
Current Assets](#)

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of September 30, 2021, and December 31, 2020:

	September 30, 2021	December 31, 2020
<i>(In thousands)</i>		
Prepaid expenses	\$ 6,065	\$ 4,346
Deposits	175	112
Interest receivable on marketable securities	18	246
Other	401	408
Total prepaid expenses and other current assets	<u>\$ 6,659</u>	<u>\$ 5,112</u>

Inventory

**9 Months Ended
Sep. 30, 2021**

[Inventory Disclosure](#)

[\[Abstract\]](#)

[Inventory](#)

6. Inventory

Inventory consisted of the following as of September 30, 2021, and December 31, 2020:

	September 30, 2021	December 31, 2020
<i>(In thousands)</i>		
Raw materials	\$ 2,831	\$ 4,287
Work in process	6,305	4,666
Finished goods	5,533	6,441
Total inventories	<u>\$ 14,669</u>	<u>\$ 15,394</u>

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. During the nine months ended September 30, 2021, the Company expensed \$5.2 million to cost of sales for unabsorbed manufacturing and overhead costs related to the operation of the United Kingdom facility at Patheon UK Limited. In addition, cost of sales for the three and nine months ended September 30, 2021, included charges of \$1.2 million and \$1.8 million, respectively, resulting from the write-down of short-dated ZILRETTA inventory that will not be sold prior to expiry.

**Property and Equipment,
Net**

**9 Months Ended
Sep. 30, 2021**

[Property, Plant and
Equipment \[Abstract\]](#)
[Property and Equipment, Net](#)

7. Property and Equipment, Net

Property and equipment, net, as of September 30, 2021, and December 31, 2020, consisted of the following:

<i>(In thousands)</i>	September 30, 2021	December 31, 2020
Computer and office equipment	\$ 1,215	\$ 1,203
Manufacturing equipment	12,656	12,297
Furniture and fixtures	609	609
Software	555	495
Leasehold improvements	1,177	1,157
Construction in progress	14,988	13,924
	<u>31,200</u>	<u>29,685</u>
Less: Accumulated depreciation	(11,720)	(10,147)
Total property and equipment, net	<u>\$ 19,480</u>	<u>\$ 19,538</u>

Depreciation for the three and nine months ended September 30, 2021, was approximately \$0.5 million and \$1.6 million, respectively, compared to \$0.5 and \$1.3 million, respectively, for the same periods in the prior year. No property and equipment was disposed of during the nine months ended September 30, 2021. The Company disposed of one piece of equipment during the nine months ended September 30, 2020, and recorded a loss on the disposal of \$0.3 million. As of September 30, 2021, construction in progress consisted primarily of equipment purchases related to the expansion of the Company's manufacturing capabilities at its contract manufacturer, Patheon U.K. Limited.

**Accrued Expenses and Other
Current Liabilities**

**9 Months Ended
Sep. 30, 2021**

[Payables and Accruals](#)

[\[Abstract\]](#)

[Accrued Expenses and Other
Current Liabilities](#)

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of September 30, 2021, and December 31, 2020:

	September 30, 2021	December 31, 2020
<i>(In thousands)</i>		
Research and development	\$ 2,972	\$ 1,856
Payroll and other employee-related expenses	10,189	10,674
Professional services fees	2,961	2,094
Accrued interest	2,943	1,464
Product revenue reserves	4,646	2,990
Other	1,164	930
Total accrued expenses and other current liabilities	<u>\$ 24,875</u>	<u>\$ 20,008</u>

[Debt Disclosure \[Abstract\]](#)[Debt](#)

9. Debt

*Amended and Restated Credit and Security Agreement**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, to borrow up to \$30.0 million in term loans (the “2015 term loan”). On August 2, 2019, the Company terminated the credit and security agreement and concurrently entered into an amended and restated credit and security agreement (the “Existing Credit Agreement”) with Silicon Valley Bank as agent, MidCap Financial Trust, Flexpoint MCLS Holdings, LLC, and the other lenders from time to time party thereto, providing for a term loan of \$40.0 million and a revolving credit facility of up to \$20.0 million, both of which mature on January 1, 2024. The Company concurrently borrowed the \$40.0 million term loan and used \$7.7 million of the proceeds to repay the remaining amount owed on the 2015 term loan.

On May 18, 2020, the Company borrowed \$15.0 million under a new term loan advance and immediately used the proceeds to repay an equal amount under the revolving credit facility, and the maximum principal amount of the revolving credit facility was reduced from \$20.0 million to \$5.0 million. The new term loan is subject to substantially the same terms, including interest rate, amortization, and maturity date, as the prior term loan under the credit facility.

On July 30, 2021, the Company entered into a second amendment (the “2021 Amended Credit Agreement”) to the Existing Credit Agreement with Silicon Valley Bank, as agent and lender, MidCap Financial Trust, MidCap Funding XIII Trust, and the other lenders from time to time party thereto (collectively, the “Lenders”), providing for a term loan facility of up to \$75.0 million, with \$55.0 million available at closing and an additional \$20.0 million (the “second tranche”) available upon positive Phase 1 clinical trial data in either of the Company’s two pipeline programs, FX201 and FX301, sufficient to initiate a Phase 2 clinical study, and a revolving credit facility of up to \$25.0 million, both of which mature on February 1, 2024, which may be extended to July 1, 2026, upon satisfaction of certain specified conditions set forth in the 2021 Amended Credit Agreement (the “Maturity Date”). The Company concurrently borrowed the \$55.0 million term loan (the “2021 term loan”), simultaneously used \$48.1 million of the proceeds to repay the outstanding term loan under the Existing Credit Agreement, and drew down \$20.0 million from the revolving

credit facility, bringing the total revolver balance to \$25.0 million. In connection with the repayment of the Existing Credit Agreement, the Company recorded a debt extinguishment loss of \$0.5 million primarily related to the write-off of the unamortized portion of the final payment, which was recorded as a component of interest expense on the statement of operations for the three and nine months ended September 30, 2021.

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 2021 Amended Credit Agreement. The Company also agreed not to encumber any of its intellectual property without the Lenders’ prior written consent.

The 2021 Amended Credit Agreement contains certain representations, warranties, and covenants, including a minimum revenue covenant that will be in effect at any time the Company’s liquidity (defined as cash, cash equivalents and marketable securities held with Silicon Valley Bank and certain accounts receivable as deemed eligible under the 2021 Amended Credit Agreement) is below \$100.0 million (if the second tranche is undrawn) or \$120.0 million

(if the second tranche is drawn). Additionally, if the Company's liquidity is below \$100.0 million, all amounts received from customer collections will be applied immediately to reduce the revolving credit facility. The minimum revenue covenant, if it applies in the future, is applied to the trailing six-months of net revenue and is determined based on the Company's approved forecast, as determined by the Lenders.

The amended and restated credit and security agreement also has a material adverse event clause. If the minimum revenue covenant becomes applicable and the Company fails to comply with it, or a material adverse change as defined in the agreement occurs, the amounts due under the amended and restated credit and security agreement could be declared immediately due and payable. As of September 30, 2021, the Company was compliant with all financial covenants.

Term loan borrowings under the 2021 credit facility accrue interest monthly at a floating interest rate equal to the greater of (i) prime rate plus 2.75% or (ii) 6.0% per annum. Following an interest-only period of 24 months (if the second tranche is undrawn), or 36 months (if the second tranche is drawn), principal is due in equal monthly installments through Maturity Date. Upon the Maturity Date, the Company will be obligated to pay a final payment equal to 4.75% 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 September 30, 2021, the carrying value of the 2021 term loan was approximately \$55.1 million, all of which is presented as long-term debt in the Company's condensed consolidated balance sheet as of September 30, 2021. In connection with the planned merger with Pacira, the Company evaluated the terms of the 2021 Amended Credit Agreement and determined the agreement will require acceleration of payments upon a change of control.

The Company may prepay the term loan at any time by paying the outstanding principal balance, a final payment equal to 4.75% of the term loan amount, all accrued interest, and a prepayment fee of 3% of the outstanding term loan amount if repaid in the first year, 2% of the outstanding term loan amount if repaid in the second year, and 1% of the outstanding term loan amount if repaid in the third year of the loan; no prepayment fee is required thereafter.

As of September 30, 2021, annual principal and interest payments due under the term loan were as follows:

Year	Aggregate Minimum Payments (in thousands)
2021	568
2022	3,346
2023	10,907
2024	20,710
2025	19,587
Thereafter	13,523
Total	\$ 68,641
Less interest	(11,029)
Less unamortized portion of final payment	(2,525)
Total	<u>\$ 55,087</u>

Revolving Credit Facility

Borrowings under the 2021 Amended Credit Agreement revolving credit facility accrue interest monthly at a floating interest rate equal to the greater of (i) the Prime Rate plus 1.75% or (ii) 5.00%. In addition to paying interest on any amounts borrowed under the revolving credit facility, the Company may owe an unused revolving line facility fee equal to 0.25% per annum of the average unused portion of the revolving line, multiplied by the difference between the total amount available to be borrowed (the "Revolving Commitment Amount") and the greater of the average outstanding revolver balance and 25% of the Revolving Commitment Amount.

The Company may retire the revolving credit facility early, at any time, by paying the outstanding principal balance, all accrued interest, and a termination fee equal to 2% of the Revolving Commitment Amount if repaid in the first year, and 1% of the Revolving Commitment Amount if repaid in the second year; with no termination fee thereafter.

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 was 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 September 30, 2021, 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 and nine months ended September 30, 2021, was \$4.1 million and \$12.2 million, including \$2.4 million and \$7.2 million, related to amortization of the debt discount.

The table below summarizes the carrying value of the 2024 Convertible Notes as of September 30, 2021:

	<i>(in thousands)</i>
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	38,104
Carrying value 2024 Convertible Notes	<u>\$ 170,418</u>

Stock-Based Compensation

9 Months Ended
Sep. 30, 2021

[Share-based Payment
Arrangement \[Abstract\]
Stock-Based Compensation](#)

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. Expected volatility is based on historical volatility of the Company's common stock. 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 and nine months ended September 30, 2021 and 2020, were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Risk-free interest rates	0.96 - 1.12%	0.47%	0.96 - 1.28%	0.47 - 1.79%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Expected term (in years)	6.0	6.0	6.0	6.0
Expected volatility	71.8 - 71.9%	72.5%	71.8 - 72.4%	65.4 - 72.5%

The following table summarizes stock option activity for the nine months ended September 30, 2021:

	Shares Issuable Under Options	Weighted Average Exercise Price Per Share
<i>(In thousands, except per share amounts)</i>		
Outstanding as of December 31, 2020	4,592	\$ 17.77
Granted	587	8.30
Exercised	(43)	3.40
Cancelled	(837)	18.81
Outstanding as of September 30, 2021	4,299	\$ 16.42
Options vested and expected to vest at September 30, 2021	4,299	\$ 16.42
Options exercisable at September 30, 2021	3,302	\$ 17.91

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 42,682 shares of the Company's common stock, with an aggregate intrinsic value of approximately \$386,138, were exercised during the nine months ended September 30, 2021.

At September 30, 2021 and 2020, there were options for the purchase of 4,299,337 and 4,753,623 shares of the Company's common stock outstanding, respectively, with a weighted average remaining contractual term of 6.0 years and 6.5 years, respectively, and with a weighted average exercise price of \$16.42 and \$17.74 per share, respectively.

The weighted average grant date fair value of options granted during the nine months ended September 30, 2021 and 2020, was \$5.28 and \$8.86 per share, respectively.

Restricted Stock Units

During the nine months ended September 30, 2021, the Company awarded 1,169,320 restricted stock units ("RSUs") to employees at a weighted average grant date fair value of \$10.79 per share. The majority of 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.

Included in the 2021 RSU awards was a grant of 106,100 RSUs to the Company's chief executive officer. These RSUs have two performance conditions relating to achieving a certain revenue threshold for the year ending December 31, 2021, as well as progressing at least one of the Company's current pipeline assets. The number of shares ultimately eligible for vesting under the RSU award will depend upon the degree to which the performance conditions are achieved. The maximum number of shares that are eligible for vesting under the award is 159,150, which would be earned based on 150% achievement of the performance conditions. The portion of the RSUs eligible for vesting will vest in four substantially equal installments starting in 2022 upon confirmation of such performance metrics being achieved and thereafter on January 1 of the subsequent three years so that all of such shares will have vested on January 1, 2025, subject to the employee's continued employment with, or services to, the Company on each vesting date. As of September 30, 2021, the Company concluded that it was not probable that either performance condition would be met. Therefore, no expense has been recognized on these awards during the three and nine months ended September 30, 2021.

The following table summarizes the RSU activity for the nine months ended September 30, 2021:

<i>(In thousands, except per share amounts)</i>	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested balance as of December 31, 2020	2,193	\$ 14.15
Granted	1,169	10.79
Vested/Released	(626)	14.57
Cancelled	(490)	13.42
Nonvested Balance as of September 30, 2021	<u>2,246</u>	<u>\$ 12.45</u>

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 and nine months ended September 30, 2021 and 2020, as follows:

<i>(In thousands)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 1,166	\$ 1,403	\$ 3,469	\$ 4,692
Selling, general and administrative	3,030	3,556	9,342	8,705
Total	<u>\$ 4,196</u>	<u>\$ 4,959</u>	<u>\$ 12,811</u>	<u>\$ 13,397</u>

As of September 30, 2021, unrecognized stock-based compensation expense for stock options outstanding was approximately \$6.7 million, which is expected to be recognized over a weighted average period of 2.5 years. As of September 30, 2021, unrecognized stock-based compensation expense for RSUs outstanding was \$21.9 million, which is expected to be recognized over a weighted average period of 2.3 years.

Net Loss per Share

**9 Months Ended
Sep. 30, 2021**

[Earnings Per Share](#)

[\[Abstract\]](#)

[Net Loss per Share](#)

11. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three and nine months ended September 30, 2021 and 2020:

<i>(In thousands, except per share amounts)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	\$ (30,312)	\$ (24,638)	\$ (81,076)	\$ (94,059)
Net loss:	<u>\$ (30,312)</u>	<u>\$ (24,638)</u>	<u>\$ (81,076)</u>	<u>\$ (94,059)</u>
Denominator:				
Weighted average common shares outstanding, basic and diluted	<u>50,265</u>	<u>49,298</u>	<u>50,027</u>	<u>43,563</u>
Net loss per share, basic and diluted	<u>\$ (0.60)</u>	<u>\$ (0.50)</u>	<u>\$ (1.62)</u>	<u>\$ (2.16)</u>

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:

<i>(In thousands)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Shares issuable upon conversion of the				
2024 Convertible Notes	7,515	7,515	7,515	7,515
Stock options	4,676	4,986	4,579	4,946
Restricted stock units	2,301	2,058	2,350	1,485
Total	<u>14,492</u>	<u>14,559</u>	<u>14,444</u>	<u>13,946</u>

[Commitments and
Contingencies Disclosure](#)

[\[Abstract\]](#)

[Commitments and
Contingencies](#)

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”), for an initial term of 42 months. In June 2019, the Company amended the Lease to add additional square feet of office space and extend the term of the Lease through April 30, 2025 (the “Amended Lease”). As a result of the Amended Lease, the total rentable floor area is 41,873 square feet. Starting in August 2019, the Company’s minimum monthly lease payment is approximately \$108,000, which increases over the term of the Amended Lease. In addition to the base rent for the office space, the Company is responsible for its share of operating expenses and real estate taxes.

The lease cost for the Amended Lease (including the expense relating to the original Lease) for the three and nine months ended September 30, 2021, amounted to \$0.5 million and \$1.4 million for each of the three and nine months ended September 30, 2021 and 2020, respectively, and was included in operating expenses. As of September 30, 2021, the remaining lease term on the Amended Lease was 3.6 years, which includes the 18-month extension resulting from the amendment signed in June 2019.

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. The lease cost for the Woburn lease amounted to \$58,000 and \$150,000 for the three and nine months ended September 30, 2021 respectively, as compared to \$46,000 and \$139,000, respectively, for the same periods in the prior year, and was included in operating expenses.

In June 2021, the Company amended the Woburn lease to extend the term of the lease through February 29, 2024. Starting in March 2022, the Company’s minimum monthly lease payment will be approximately \$20,400, which increases over the term of the amended lease. The Company accounted for the amended lease as a modification that is not a separate contract from the original lease, as the amended lease does not contain any additional rights, and recorded an incremental right-of-use asset and lease liability of \$0.4 million, which represents the present value of the lease payments over the remaining lease term of 2.7 years, discounted at 8.4%. As of September 30, 2021, the remaining lease term on the Woburn lease, as amended, was 2.4 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 a 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.

In June 2019, the Company and Patheon amended the Manufacturing Agreement and the Technical Transfer Agreement. The amendment primarily modifies the compensation structure, which is comprised of base fees and per product fees the Company pays to Patheon and does not result in any additional rights of use. The Company accounted for the amendment as a lease modification that is not a separate contract from the original lease. As part of the modification, the Company reassessed whether the contract is or contains a lease and determined that there is an operating lease component for the use of dedicated manufacturing suites. The remainder of the consideration is allocated to the service component. The Company also reassessed the lease liability by calculating the present value of the remaining lease payments as of the modification date, discounted at 6.1%. The modification resulted in an increase to each of the lease liability and right of use asset of \$0.5 million.

In April 2020, the Company entered into a side letter amending the Manufacturing Agreement with Patheon pursuant to which the parties agreed that the Company would continue to pay the monthly base fee for maintaining the manufacturing suites, but minimum purchase obligations would be cancelled for 2020 as the Company temporarily suspended manufacturing activities for ZILRETTA due to COVID-19. The amendment did not change the amount of fixed consideration owed to Patheon over the life of the contract, nor did it grant the Company any additional rights of use. As such, there was no change in the accounting for the embedded lease as a result of this amendment. The Company restarted manufacturing activities at Patheon in the fourth quarter of 2020.

As of September 30, 2021, the remaining lease term on the Patheon lease was 6.1 years. The lease cost for the three and nine months ended September 30, 2021, amounted to \$61,000 and \$185,000, respectively, compared to \$58,000 and \$171,000, respectively, for the same periods in the prior year, and is included in inventory as part of manufacturing overhead.

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

<i>(In thousands)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Operating lease cost				
Operating lease cost included in operating expenses	\$ 525	\$ 513	\$ 1,552	\$ 1,540
Operating lease cost included in inventory	61	58	185	171
Total operating lease cost	586	571	1,737	1,711
Operating cash flows from operating leases	855	699	2,450	2,256

Maturities of lease liability due under these lease agreements as of September 30, 2021, were as follows:

Year	Operating Lease Obligations <i>(In thousands)</i>
2021	515
2022	2,087
2023	2,142
2024	1,975
2025	809
Thereafter	422
Present value of imputed interest	(2,115)
Total	\$ 5,835

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 was extended. The initial term of the agreement was five years, commencing in July 2016. In May 2021, the Company entered into an amendment to the Supply Agreement that became effective on June 30, 2021. The total term of the Supply Agreement, as amended, is eight 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.

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, the Company made an upfront payment to GeneQuine of \$2.0 million. The upfront fee was attributed to the intellectual property acquired and recognized as research and development expense in December 2017 as the FX201 rights had not been commercially approved and had no alternative future use. In 2018, the Company paid GeneQuine \$750,000 for initiating a GLP toxicology study of FX201. In addition, the Company paid GeneQuine \$750,000 in November 2019 following the FDA acceptance of the Investigational New Drug (“IND”) application for FX201. The next milestone of \$2.5 million was achieved in March 2020, when the first patient was treated in the Phase 1 clinical trial. The Company may also be required to make additional milestone payments during the development of FX201, including up to \$4.5 million for the initiation of a Phase 2 proof of concept (“PoC”) clinical trial and, following successful PoC, up to an additional \$51.5 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. Milestone payments earned prior to regulatory approval of FX201 are 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 its estimated life. As of September 30, 2021, no other milestones under the arrangement were probable of being 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. In addition, in February 2020 the Company entered into a manufacturing agreement with another vendor for clinical trial supply of FX201 through Phase 3 clinical trials.

FX301-Related Agreements

In September 2019, the Company entered into a definitive agreement with Xenon Pharmaceuticals, Inc. (“Xenon”) that provides the Company with the global rights to develop and commercialize XEN402, Xenon’s NaV1.7 inhibitor known as funapide, formulated for extended release with a novel, Flexion proprietary thermosensitive hydrogel under the Company’s preclinical program known as FX301. The transaction was accounted for as an asset acquisition, as it did not qualify as a business combination. As part of the asset purchase transaction, the Company made an upfront payment to Xenon of \$3.0 million. The upfront fee was attributed to the intellectual property acquired and was recognized as research and development expense in September 2019 as the FX301 product candidate had not been commercially approved and had no alternative future use. The next milestone of \$0.5 million was achieved following the commencement of the GLP toxicology study. This milestone was recognized as research and development expense in the first quarter of 2020. The Company also paid \$1.0 million when the IND was cleared by FDA in February 2021 and \$2.0 million upon the initiation of the Phase 1b clinical trial in March 2021. These milestones were recognized as research and development expenses in the first quarter of 2021. The Company may also be required to make additional milestone payments during the development of FX301, including up to \$5.0 million through initiation of a Phase 2 PoC clinical trial and, following successful PoC, up to

\$40.8 million in development and global regulatory approval milestone payments and up to an additional \$75.0 million in sales-related milestone payments. Future milestone payments earned prior to regulatory approval of FX301 would be recognized as research and development expense in the period when the milestone events become probable of being achieved. Future milestones earned subsequent to regulatory approval would be recognized as an intangible asset and amortized to expense over the estimated life of FX301. As of September 30, 2021, no other milestones under the arrangement were probable of being achieved. As part of the transaction, the Company became the direct licensee of certain underlying Xenon patents and other proprietary rights related to XEN402 for human applications. The Xenon agreement grants the Company an exclusive, royalty-bearing, world-wide right and license (with a right to sublicense) for human applications under its patents directly related to XEN402, with a similar royalty-free license to other Xenon proprietary rights directly related to XEN402. The agreement with Xenon includes a tiered royalty ranging from mid-single digits to low double digits that is based on aggregate annual net sales of FX301 and requires the Company to use reasonable efforts to develop FX301 according to timelines set out in the agreement.

Legal Proceedings

Between October 22, 2021, and November 10, 2021, eleven complaints were filed in federal court by purported stockholders of Flexion regarding the Merger. The first complaint was filed on October 22, 2021, in the United States District Court for the Southern District of New York and is captioned *Elaine Wang v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-08693. The second complaint was filed on October 28, 2021, in the United States District Court for the Southern District of New York and is captioned *Marc Waterman v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-08804 (S.D.N.Y. filed October 28, 2021). The third complaint was filed on October 28, 2021, in the United States District Court for the Southern District of New York and is captioned *Melinda Turkington v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-08817. The fourth complaint was filed on November 1, 2021, in the United States District Court for the Southern District of New York and is captioned *Barbara Hart v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-08919. The fifth complaint was filed on November 1, 2021, in the United States District Court for the Southern

District of New York and is captioned *Lee Beary v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-08925. The sixth complaint was filed on November 2, 2021, in the United States District Court for the Southern District of New York and is captioned *Katherine Finger v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-09032. The seventh complaint was filed on November 2, 2021, in the United States District Court for the Eastern District of New York and is captioned *David Gruver v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-06106. The eighth complaint was filed on November 3, 2021, in the United States District Court for the Southern District of New York and is captioned *Theodore Meshover v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-09043. The ninth complaint was filed on November 4, 2021, in the United States District Court for the District of Delaware and is captioned *Sam Carlisle v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-01572-UNA. The tenth complaint was filed on November 4, 2021, in the United States District Court for the Eastern District of Pennsylvania and is captioned *Alex Ciccotelli v. Flexion Therapeutics, Inc., et al.*, Case No. 2:21-cv-04885. The eleventh complaint was filed on November 10, 2021, in the United States District Court for the District of Delaware and is captioned *James Murray v. Flexion Therapeutics, Inc., et al.*, Case No. 1:21-cv-01590-UNA (collectively, the “Complaints”). The Complaints name as defendants Flexion and each member of Flexion’s board of directors (the “Flexion Defendants”). The *Waterman* complaint additionally names as defendants Pacira and Purchaser (the “Pacira Defendants”). The plaintiffs generally contend that the Solicitation/Recommendation Statement on Schedule 14D-9, filed on October 22, 2021, has omitted or misrepresented material information regarding the Merger. The *Hart* complaint additionally alleges that Flexion engaged in an insufficient sales process and that members of Flexion’s board of directors and Flexion’s management had conflicts of interest with Flexion’s stockholders. The Complaints allege violations of Section 14(d) and/or Section 14(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) against all Flexion Defendants and assert violations of Section 20(a) of the Exchange Act against the members of Flexion’s board of directors. The *Waterman* complaint additionally alleges violations of Section 14(d), Section 14(e), and Section 20(a) of the Exchange Act against the Pacira Defendants. The Complaints collectively seek, among other relief, (i) injunctive relief preventing the consummation of the transactions contemplated by the Merger Agreement; (ii) rescission and/or rescissory damages in the event the transactions contemplated by the Merger Agreement are consummated; (iii) other damages purportedly incurred on account of defendants’ alleged misstatements or omissions; (iv) disclosure of certain information requested by the plaintiffs; (v) declaratory relief stating defendants violated the Exchange Act; and (vi) an award of plaintiffs’ expenses and attorneys’ fees. The Flexion Defendants have been served with the *Wang* complaint and the *Hart* complaint, but have not been served with any of the other Complaints. On November 12, 2021, the Company filed a Schedule 14D-9/A containing certain supplemental disclosures in order to moot the claims alleged in the

Complaints. The Flexion Defendants' deadline to respond to the *Wang* complaint is December 27, 2021, and the Flexion Defendants' deadline to respond to the *Hart* complaint is January 3, 2022.

Each of the Flexion Defendants and the Pacira Defendants intend to vigorously defend these actions. The Company believes that the Complaints are without merit and has not recorded an expense related to the outcome of these litigations because it is not yet possible to determine if a potential loss is probable nor reasonably estimable.

At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings.

Summary of Significant Accounting Policies (Policies)

[Accounting Policies](#)

[\[Abstract\]](#)

[Proposed Acquisition](#)

9 Months Ended

Sep. 30, 2021

Proposed Acquisition by Pacira BioSciences, Inc.

On October 11, 2021, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Pacira BioSciences, Inc., a Delaware corporation (“Pacira”), and Oyster Acquisition Company Inc., a Delaware corporation and wholly owned subsidiary of Pacira (“Purchaser”). Pursuant to the Merger Agreement, on October 22, 2021, Purchaser commenced a tender offer (the “Offer”) to purchase all of the issued and outstanding share of the Company’s common stock (the “Shares”) at an offer price of (i) \$8.50 per Share in cash, net of applicable withholding taxes and without interest, plus (ii) one non-transferable contractual contingent value right per Share, which will represent the right to receive one or more contingent payments up to \$8.00 in the aggregate, in cash, net of applicable withholding taxes and without interest, upon the achievement of specified milestones on or prior to December 31, 2030.

Promptly following the completion of the Offer, upon the terms and subject to the conditions of the Merger Agreement, Purchaser will acquire all of the Shares with and into the Company (the “Merger”), with the Company continuing as the surviving corporation and as a wholly owned subsidiary of Pacira. The Merger Agreement contemplates that the Merger will be effected pursuant to Section 251(h) of the Delaware General Corporation Law, which permits completion of the Merger without a vote of the holders of common stock upon the acquisition by Purchaser of a majority of the aggregate voting power of common stock. As a result of the Merger, the Company will cease to be a publicly traded company.

The Merger Agreement contains customary representations and warranties. The Merger is expected to close before the end of the calendar year 2021, subject to the satisfaction or waiver of customary closing conditions, including, among others, that the number of Shares tendered in the Offer represent at least one Share more than 50% of the total number of Shares at the time of the expiration of the Offer. The Merger Agreement provides Pacira and the Company with certain termination rights and, under certain circumstances, may require the Company to pay Pacira a termination fee of \$18.0 million.

For additional information related to the Merger Agreement, refer to the Solicitation/Recommendation Statement on Schedule 14D-9 filed with the Company with the Securities and Exchange Commission on October 22, 2021, together with the exhibits and annexes thereto and any amendments or supplements from time to time.

The Company recorded acquisition-related costs of approximately \$0.7 million for each of the three and nine months ended September 30, 2021, primarily for outside legal and external financial advisory fees associated with the pending acquisition by Pacira. These costs were recorded in general and administrative expense in the Company’s condensed consolidated statements of operations and comprehensive income for the respective reporting periods. Additional acquisition-related costs are expected to be incurred through the closing of the Merger.

[Going Concern](#)

Going Concern

The accompanying condensed consolidated financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. As of September 30, 2021, the Company had cash, cash equivalents, and marketable securities of approximately \$142.1 million.

The Company’s operations have been and continue to be affected by the ongoing global pandemic of a novel strain of coronavirus (“COVID-19”). In March 2020, the World Health Organization declared COVID-19 a pandemic and recommended containment and mitigation measures worldwide. The COVID-19 pandemic has caused significant volatility and uncertainty, which could result in a prolonged economic downturn that has disrupted and is expected to continue to disrupt the Company’s business. While there have been no material impairments recorded to date, any prolonged material future disruptions to the work of the Company’s employees, suppliers, contractors, manufacturers, or vendors, or to the operations of physicians that administer ZILRETTA could negatively impact the Company’s operations, availability of supplies, carrying value of assets, operating results, or cash flows.

The future viability of the Company is dependent on its ability to fund its operations through sales of ZILRETTA, and/or raising additional capital, such as through debt or equity offerings, as needed. The Company may not be able to obtain financing on acceptable terms, particularly, as a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility and disruptions, including declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any additional equity financing more difficult, more costly, and more dilutive. 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/or reduce the scope of, or delay certain research and development activities, including the FX201 or FX301 programs, which could adversely affect its prospects.

In accordance with the amended and restated credit and security agreement described in Note 9, if the Company’s liquidity decreases to less than \$100.0 million, the Company will need to comply with a minimum revenue covenant and all amounts received from customer collections will be applied to immediately reduce the Company’s revolving credit facility. The minimum revenue covenant is set annually and is applied to the trailing six-months of net revenue and is determined based on the Company’s approved forecast, as determined by the Lenders. The amended and restated credit and security agreement also has a material adverse event clause. If the minimum revenue covenant becomes applicable and the Company fails to comply with it, or a material adverse change as defined in the agreement occurs, the amounts due under the amended and restated credit and security agreement could be declared immediately due and payable, resulting in the Company immediately needing to

additional funds. As of September 30, 2021, the Company was in compliance with all financial covenants under the amended and restated credit and security agreement.

If the Company is unable to grow sales of ZILRETTA in future periods, it is possible that the Company may not maintain compliance with the minimum revenue covenant, in the event it applies, in future periods, which would require the Company to repay its outstanding borrowings under the term loan and revolving credit facility. Given the recent decrease in revenue as compared to the Company's expectations, the Company expects that absent raising additional capital through financing or other transactions its cash balance is likely to decrease below \$10 million within the next twelve months, and the Company believes there is substantial risk that it would fail to meet the minimum revenue covenant at that time or shortly thereafter if demand for ZILRETTA does not increase in line with its expectations. If the Company is or expects to be subject to and unable to meet the minimum revenue covenant, the Company would plan to request a waiver from the lenders, although there can be no assurances that such a request would be granted or would not be conditioned on additional terms or concessions. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of one year after the date that the financial statements are issued.

Management's plans that would be intended to mitigate the conditions that raise substantial doubt about the Company's ability to continue as a going concern include reducing operating expenses through hiring and travel freezes, delaying, reducing, or ceasing all research and development activities outside of the ongoing clinical trials, reduction of certain external expenses, and elimination of non-essential expenses, requesting a waiver of the minimum revenue covenant from the lenders, and remaining opportunistic with respect to raising additional capital through financing or other transactions. However, as the Company is expecting to close the planned merger with Pacira to the end of 2021, none of the above actions have been taken or have been approved to be taken and therefore cannot be considered management's going concern evaluation as a mitigating action.

The Company has concluded that without taking into consideration the planned Merger with Pacira, management's plans do not alleviate the substantial doubt about the Company's ability to continue as a going concern. As the planned Merger with Pacira has not occurred as of the issuance of these financial statements, it also cannot be considered within management's plans to alleviate the conditions raised above to alleviate substantial doubt. As a result, in accordance with the requirements of ASC 205-40, management has concluded that it is required to disclose that substantial doubt exists about the Company's ability to continue as a going concern for one year from the date these financial statements are issued.

[Basis of Presentation](#)

Basis of Presentation

The accompanying condensed consolidated financial statements as of September 30, 2021, and for the three and nine months ended September 30, 2021 and 2020, 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 that are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the SEC on March 10, 2021.

The information presented in the condensed consolidated financial statements and related notes as of September 30, 2021, and December 31, 2020, and for the three and nine months ended September 30, 2021 and 2020, is unaudited. The December 31, 2020, condensed consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, footnotes, notes, required by GAAP for complete financial statements.

Interim results for the three and nine months ended September 30, 2021, are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2021, or any future period.

[Recent Accounting Pronouncements](#)

Recent Accounting Pronouncements

Accounting Standards Recently Issued

In August 2020, the FASB issued ASU No. 2020-06, ("ASU 2020-06"). The new standard simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. The new guidance reduced the number of accounting models for convertible preferred stock instruments and made certain disclosure amendments intended to improve the information provided to users. The guidance also amended the derivative guidance for the "own stock" scope exception, which exempts qualifying instruments from being accounted for as derivatives if certain criteria are met. Finally, the standard changed the way certain convertible instruments are treated in calculating earnings per share. The standard is effective for the Company for fiscal years, and the interim periods within those years, beginning after December 15, 2021, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2020-06 on the Company's condensed consolidated financial statements.

[Consolidation](#)

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 and nine months ended September 30, 2021, and the year ended December 31, 2020.

[Revenue Recognition](#)

Revenue Recognition

On October 6, 2017, the U.S. Food and Drug Administration (“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 that 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.

Product Revenue, Net

The Company primarily sells ZILRETTA to specialty distributors and a specialty pharmacy, who then subsequently resell ZILRETTA to physicians, clinics, and certain medical centers or hospitals. The Company also contracts directly with healthcare providers and institutions such as Group Purchasing Organizations (“GPOs”). In addition, the Company enters into arrangements with government payers that result in 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 significant performance obligation. There are no other promises to deliver goods or services beyond what is specified in each accepted customer contract. The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payables 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 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 discussed 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 represent the expected consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method in Topic 606, taking into account relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and historical customer buying and payment patterns. Overall, these reserves reflect the Company’s best estimates of the amount of consideration that the Company is entitled to based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price 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 the period such variances become known.

Service Fees and Allowances

The Company compensates its customers and GPOs 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 services have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through September 30, 2021, and 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 with the related expenses and other current liabilities, net, on the condensed consolidated balance sheets. The Company currently estimates product returns as liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. Historically, the Company has received an immaterial amount of returns. In the third quarter of 2021, there was a significant increase in actual and expected product returns from specialty distributors of product that was never sold through to healthcare providers. This was due to the fact that the majority of product sold during the third quarter had between 3-4 months of expiry remaining. The vast majority of the product returned related to product that was sold to the specialty distributors during the third quarter of 2021 and resulted in a \$2.0 million reduction

in the third quarter of 2021. In addition, the Company increased its estimate of future returns relating to short-dated product, which an additional \$1.4 million reduction in revenue in the third quarter of 2021.

Chargebacks

Chargebacks for fees and discounts to qualified government healthcare providers represent the estimated obligations resulting from commitments to sell products to qualified VA hospitals and 340b entities at prices lower than the list prices charged to customers who purchase the product from the Company. The 340b Drug Discount Program is a U.S. 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 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 chargeback amounts 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 that 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 amounts 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 that remains in the distribution channel inventories at the end of each reporting period.

Purchaser/Provider Discounts and Rebates

The Company offers rebates to eligible purchasers and healthcare providers that are variable based on volume of product purchased and are based on actual purchase levels during the rebate purchase period. In the third quarter of 2021, the Company implemented an off-invoice discount ("OID") program whereby providers receive the discounted price immediately upon purchase, rather than having to wait until the end of the quarter for a rebate payment. Specialty distributors and other customers charge the Company for the difference between what they pay for the product (list price) and the net selling price after taking into account the OID. Chargeback amounts are generally determined at the time of resale to the eligible 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 commercial chargebacks consist of credits that the Company expects to issue for units sold to qualified healthcare providers but for which no chargeback has been submitted, and chargebacks that customers have claimed, but for which the Company has not yet issued a credit. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Other Incentives

Other incentives that the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which is intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by their insurance. 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 incur 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 that 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 nine months ended September 30, 2021 and 2020:

<i>(In thousands)</i>	Service Fees, Allowances and Chargebacks	Government Rebates and Other Incentives	Product Returns	Purchaser/ Provider Discounts and Rebates	Total
Balance as of December 31, 2020	\$ 1,733	\$ 530	\$ 628	\$ 1,832	\$ 4,723
Provision related to sales in the current quarter	2,188	383	151	2,703	5,425
Credits and payments made	(1,969)	(266)	(9)	(1,832)	(4,176)
Adjustments related to prior period sales	—	—	(111)	—	(111)
Balance as of March 31, 2021	1,952	647	659	2,703	5,961
Provision related to sales in the current quarter	2,682	424	179	3,100	6,385

Credits and payments made	(2,527)	(311)	(86)	(2,711)	(5,
Adjustments related to prior period sales	(10)	—	—	—	—
Balance as of June 30, 2021	\$ 2,097	\$ 760	\$ 752	\$ 3,092	\$ 6,
Provision related to sales in the current quarter	2,538	290	3,130	3,245	9,
Credits and payments made	(2,859)	(401)	(1,331)	(5,182)	(9,
Adjustments related to prior period sales	—	—	291	—	—
Balance as of September 30, 2021	\$ 1,776	\$ 649	\$ 2,842	\$ 1,155	\$ 6,
Balance as of December 31, 2019	\$ 1,847	\$ 248	\$ 402	\$ 1,656	\$ 4,
Provision related to sales in the current quarter	1,590	254	114	526	2,
Credits and payments made	(1,852)	(199)	(10)	(1,656)	(3,
Adjustments related to prior period sales	—	95	—	—	—
Balance as of March 31, 2020	1,585	398	506	526	3,
Provision related to sales in the current quarter	1,417	133	98	892	2,
Credits and payments made	(1,172)	(262)	(1)	(528)	(1,
Adjustments related to prior period sales	—	90	—	2	—
Balance as of June 30, 2020	\$ 1,830	\$ 359	\$ 603	\$ 892	\$ 3,
Provision related to sales in the current quarter	2,270	265	136	1,314	3,
Credits and payments made	(2,585)	(198)	(21)	(894)	(3,
Adjustments related to prior period sales	—	40	—	2	—
Balance as of September 30, 2020	\$ 1,515	\$ 466	\$ 718	\$ 1,314	\$ 4,

License Agreement – On March 30, 2020, the Company entered into an exclusive license agreement with Hong Kong Tainuo Pharm (“HK Tainuo”) and Jiangsu Tainuo Pharmaceutical Co. Ltd. (“Jiangsu Tainuo”), a subsidiary of China Shijiazhuang Pharmaceutical for the development and commercialization (other than manufacturing) of ZILRETTA in Greater China (consisting of mainland China, Hong Kong and Macau, and Taiwan). Under the terms of the agreement, HK Tainuo paid the Company an upfront payment of \$10.0 million, of which \$5.0 million was received as of June 30, 2020, and the remaining \$5.0 million was received as of September 30, 2020. The Company is also eligible to receive up to \$32.5 million in aggregate development, regulatory, and commercial sales milestone payments. All payments received from HK Tainuo are subject to applicable Hong Kong withholding taxes. HK Tainuo is responsible for the clinical development, product registration, and commercialization of ZILRETTA in Greater China, and Jiangsu Tainuo serves as the guarantor of HK Tainuo’s obligations and responsibilities under the agreement. The Company is solely responsible for the manufacture and supply of ZILRETTA in Greater China. HK Tainuo for all clinical and commercial activities. The terms related to product manufacturing and supply, including pricing and minimum purchase requirements agreed to in the license agreement, will be covered by a separate supply agreement, which has not yet been finalized. All amounts owed to the Company are nonrefundable and non-creditable once paid. Unless terminated earlier in accordance with its terms, the license agreement continues in effect in perpetuity or as long as HK Tainuo or Jiangsu Tainuo continue to sell ZILRETTA in Greater China. Either party may terminate the agreement prior to expiration in the event of a material breach if not cured within 60 days from the date of notice of such breach (30 days in the case of payment obligations), or either party files for bankruptcy. The Company also has the right to terminate the agreement if HK Tainuo, Jiangsu Tainuo, or any affiliate of each commences any action or proceeding that challenges the validity, enforceability, or scope of any Company patent in Greater China. Upon any such termination, the license granted to HK Tainuo will terminate and all know-how and patents will revert back to the Company. The Company concluded that the license and supply obligations were not distinct performance obligations, and therefore the transaction price will be recognized as revenue as the

Company’s supply obligation is fulfilled over the term of the supply agreement, which has not yet commenced. No revenue was recognized associated with this contract as of September 30, 2021. The proceeds associated with the upfront payment have been recorded in share-based deferred revenue on the Company’s condensed consolidated balance sheet as of September 30, 2021, as there is uncertainty around the timing of when the revenue will be recognized. The Company will re-evaluate the classification of deferred revenue when the supply agreement is finalized.

[Use of Estimates](#)

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 used in these condensed consolidated financial statements include estimates related to revenue recognition and accrued expenses related to research and clinical development 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.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company’s business, results of operations, and financial condition, including sales, expenses, reserves and allowances, clinical trials, research and development expenses, and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national, and international customers and markets. The Company has made estimates of the impact of COVID-19 within its financial statements, and these estimates may be changes to those estimates in future periods.

[Property and Equipment](#)

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 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 yet in service.

[Foreign Currencies](#)

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 reported in the consolidated statements of operations.

[Leases](#)

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 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 entered into 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 amount 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. The yield 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 convertible senior notes and term loan described below) were also used as inputs to the analysis to calculate the 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.*, taxes, insurance, etc.). Then the fixed contract consideration (including any related to non-components) must be allocated based on the relative fair value of 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 component. In contrast, the Company has elected not to apply the practical expedient for its lease of manufacturing space at Patheon, 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.

**Summary of Significant
Accounting Policies (Tables)**

**9 Months Ended
Sep. 30, 2021**

[Accounting Policies](#)

[\[Abstract\]](#)

[Summary of Product Revenue](#)

[Allowance And Reserve](#)

[Categories](#)

The following table summarizes activity in each of the product revenue allowance and reserve categories for the nine months ended September 30, 2021 and 2020:

<i>(In thousands)</i>	Service Fees, Allowances and Chargebacks	Government Rebates and Other Incentives	Product Returns	Purchaser/ Provider Discounts and Rebates	Total
Balance as of December 31, 2020	\$ 1,733	\$ 530	\$ 628	\$ 1,832	\$ 4,723
Provision related to sales in the current quarter	2,188	383	151	2,703	5,345
Credits and payments made	(1,969)	(266)	(9)	(1,832)	(4,076)
Adjustments related to prior period sales	—	—	(111)	—	(111)
Balance as of March 31, 2021	1,952	647	659	2,703	5,961
Provision related to sales in the current quarter	2,682	424	179	3,100	6,385
Credits and payments made	(2,527)	(311)	(86)	(2,711)	(5,635)
Adjustments related to prior period sales	(10)	—	—	—	(10)
Balance as of June 30, 2021	\$ 2,097	\$ 760	\$ 752	\$ 3,092	\$ 6,601
Provision related to sales in the current quarter	2,538	290	3,130	3,245	9,203
Credits and payments made	(2,859)	(401)	(1,331)	(5,182)	(9,773)
Adjustments related to prior period sales	—	—	291	—	291
Balance as of September 30, 2021	\$ 1,776	\$ 649	\$ 2,842	\$ 1,155	\$ 6,422
Balance as of December 31, 2019	\$ 1,847	\$ 248	\$ 402	\$ 1,656	\$ 4,153
Provision related to sales in the current quarter	1,590	254	114	526	2,484
Credits and payments made	(1,852)	(199)	(10)	(1,656)	(3,717)
Adjustments related to prior period sales	—	95	—	—	95
Balance as of March 31, 2020	1,585	398	506	526	3,015
Provision related to sales in the current quarter	1,417	133	98	892	2,540
Credits and payments made	(1,172)	(262)	(1)	(528)	(1,963)
Adjustments related to prior period sales	—	90	—	2	92
Balance as of June 30, 2020	\$ 1,830	\$ 359	\$ 603	\$ 892	\$ 3,684
Provision related to sales in the current quarter	2,270	265	136	1,314	4,385
Credits and payments made	(2,585)	(198)	(21)	(894)	(4,098)
Adjustments related to prior period sales	—	40	—	2	42
Balance as of September 30, 2020	\$ 1,515	\$ 466	\$ 718	\$ 1,314	\$ 3,813

[Property Plant and Equipment](#)
[Estimated Useful Lives](#)

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization expense is recognized using 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

**Fair Value of Financial
Assets and Liabilities
(Tables)**

**9 Months Ended
Sep. 30, 2021**

[Fair Value Disclosures](#)

[\[Abstract\]](#)

[Schedule of Assets Measured
at Fair Value on Recurring
Basis](#)

The following tables present information about the Company's assets that are measured at fair value on a recurring basis as of September 30, 2021 and December 31, 2020, and indicate the level of the fair value hierarchy utilized to determine such fair value:

<i>(In thousands)</i>	Fair Value Measurements as of September 30, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 108,686	\$ —	\$ —	\$ 108,686
Marketable securities	—	5,229	—	5,229
	<u>\$ 108,686</u>	<u>\$ 5,229</u>	<u>\$ —</u>	<u>\$ 113,915</u>

<i>(In thousands)</i>	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 79,148	\$ 6,832	\$ —	\$ 85,980
Marketable securities	—	67,576	—	67,576
	<u>\$ 79,148</u>	<u>\$ 74,408</u>	<u>\$ —</u>	<u>\$ 153,556</u>

**Marketable Securities
(Tables)**

**9 Months Ended
Sep. 30, 2021**

**[Investments, Debt and
Equity Securities \[Abstract\]
Summary of Fair Value of
Available-for-Sale Marketable
Securities by Type of Security](#)**

As of September 30, 2021 and December 31, 2020, the fair value of available-for-sale marketable securities by type of security was

	September 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<i>(In thousands)</i>				
Commercial paper	\$ 2,000	\$ —	\$ —	\$ 2,000
Corporate bonds	3,229	—	—	3,229
	<u>\$ 5,229</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,229</u>

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<i>(In thousands)</i>				
Commercial paper	\$ 6,890	\$ —	\$ —	\$ 6,890
U.S. government obligations	9,997	1	—	9,998
Corporate bonds	50,700	2	(14)	50,688
	<u>\$ 67,587</u>	<u>\$ 3</u>	<u>\$ (14)</u>	<u>\$ 67,576</u>

**Prepaid Expenses and Other
Current Assets (Tables)**

**9 Months Ended
Sep. 30, 2021**

[Deferred Costs, Capitalized,
Prepaid, and Other Assets
Disclosure \[Abstract\]](#)

[Prepaid Expenses and Other
Current Assets](#)

Prepaid expenses and other current assets consisted of the following as of September 30, 2021, and December 31, 2020:

	September 30, 2021	December 31, 2020
<i>(In thousands)</i>		
Prepaid expenses	\$ 6,065	\$ 4,346
Deposits	175	112
Interest receivable on marketable securities	18	246
Other	401	408
Total prepaid expenses and other current assets	<u>\$ 6,659</u>	<u>\$ 5,112</u>

Inventory (Tables)

**9 Months Ended
Sep. 30, 2021**

[Inventory Disclosure \[Abstract\]](#)
[Schedule of Inventory](#)

Inventory consisted of the following as of September 30, 2021, and December 31, 2020:

	September 30, 2021	December 31, 2020
<i>(In thousands)</i>		
Raw materials	\$ 2,831	\$ 4,287
Work in process	6,305	4,666
Finished goods	5,533	6,441
Total inventories	<u>\$ 14,669</u>	<u>\$ 15,394</u>

**Property and Equipment,
Net (Tables)**

**9 Months Ended
Sep. 30, 2021**

Property, Plant and Equipment
[Abstract]
Components of Property and
Equipment

Property and equipment, net, as of September 30, 2021, and December 31, 2020, consisted of the following:

<i>(In thousands)</i>	September 30, 2021	December 31, 2020
Computer and office equipment	\$ 1,215	\$ 1,203
Manufacturing equipment	12,656	12,297
Furniture and fixtures	609	609
Software	555	495
Leasehold improvements	1,177	1,157
Construction in progress	14,988	13,924
	<u>31,200</u>	<u>29,685</u>
Less: Accumulated depreciation	(11,720)	(10,147)
Total property and equipment, net	<u>\$ 19,480</u>	<u>\$ 19,538</u>

**Accrued Expenses and Other
Current Liabilities (Tables)**

**9 Months Ended
Sep. 30, 2021**

Payables and Accruals

[Abstract]

**Schedule of Accrued Expenses
and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following as of September 30, 2021, and December 31, 2020:

	September 30, 2021	December 31, 2020
<i>(In thousands)</i>		
Research and development	\$ 2,972	\$ 1,856
Payroll and other employee-related expenses	10,189	10,674
Professional services fees	2,961	2,094
Accrued interest	2,943	1,464
Product revenue reserves	4,646	2,990
Other	1,164	930
Total accrued expenses and other current liabilities	<u>\$ 24,875</u>	<u>\$ 20,008</u>

Debt (Tables)

9 Months Ended
Sep. 30, 2021

[Debt Disclosure \[Abstract\]](#)
[Schedule of Annual Principal and Interest Payments Due Under Term Loan](#)

As of September 30, 2021, annual principal and interest payments due under the term loan were as follows:

Year	Aggregate Minimum Payments (in thousands)
2021	568
2022	3,346
2023	10,907
2024	20,710
2025	19,587
Thereafter	13,523
Total	\$ 68,641
Less interest	(11,029)
Less unamortized portion of final payment	(2,525)
Total	<u>\$ 55,087</u>

[Summary of Carrying Value of Convertible Notes](#)

The table below summarizes the carrying value of the 2024 Convertible Notes as of September 30, 2021:

	(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	<u>38,104</u>
Carrying value 2024 Convertible Notes	<u>\$ 170,418</u>

**Stock-Based Compensation
(Tables)**

**9 Months Ended
Sep. 30, 2021**

**Share-based Payment
Arrangement [Abstract]**

Schedule of Relevant Data

The relevant data used to determine the value of the stock option grants for the three and nine months ended September 30, 2021 and 2020, were as follows:

**Used to Estimate Fair Value of
Stock Option Grants**

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Risk-free interest rates	0.96 - 1.12%	0.47%	0.96 - 1.28%	0.47 - 1.79%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Expected term (in years)	6.0	6.0	6.0	6.0
Expected volatility	71.8 - 71.9%	72.5%	71.8 - 72.4%	65.4 - 72.5%

**Summary of Stock Option
Activity**

The following table summarizes stock option activity for the nine months ended September 30, 2021:

	Shares Issuable Under Options	Weighted Average Exercise Price
		Per Share
<i>(In thousands, except per share amounts)</i>		
Outstanding as of December 31, 2020	4,592	\$ 17.77
Granted	587	8.30
Exercised	(43)	3.40
Cancelled	(837)	18.81
Outstanding as of September 30, 2021	4,299	\$ 16.42
Options vested and expected to vest at September 30, 2021	4,299	\$ 16.42
Options exercisable at September 30, 2021	3,302	\$ 17.91

Summary of of RSU Activity

The following table summarizes the RSU activity for the nine months ended September 30, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
		Share
<i>(In thousands, except per share amounts)</i>		
Nonvested balance as of December 31, 2020	2,193	\$ 14.15
Granted	1,169	10.79
Vested/Released	(626)	14.57
Cancelled	(490)	13.42
Nonvested Balance as of September 30, 2021	2,246	\$ 12.45

**Stock-Based Compensation
Expense Related to Stock
Options, and RSUs and Shares
Purchased Under Employee
Stock Purchase Plan**

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 and nine months ended September 30, 2021 and 2020, as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
<i>(In thousands)</i>				
Research and development	\$ 1,166	\$ 1,403	\$ 3,469	\$ 4,692
Selling, general and administrative	3,030	3,556	9,342	8,705
Total	\$ 4,196	\$ 4,959	\$ 12,811	\$ 13,397

Net Loss per Share (Tables)

9 Months Ended Sep. 30, 2021

[Earnings Per Share \[Abstract\]](#) [Schedule of Basic and Diluted](#) [Net Loss Per Share Attributable](#) [to Common Stockholders](#)

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three and nine months ended September 30, 2021 and 2020:

<i>(In thousands, except per share amounts)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	\$ (30,312)	\$ (24,638)	\$ (81,076)	\$ (94,059)
Net loss:	<u>\$ (30,312)</u>	<u>\$ (24,638)</u>	<u>\$ (81,076)</u>	<u>\$ (94,059)</u>
Denominator:				
Weighted average common shares outstanding, basic and diluted	<u>50,265</u>	<u>49,298</u>	<u>50,027</u>	<u>43,563</u>
Net loss per share, basic and diluted	<u>\$ (0.60)</u>	<u>\$ (0.50)</u>	<u>\$ (1.62)</u>	<u>\$ (2.16)</u>

[Schedule of Common Stock](#) [Equivalents Excluded from](#) [Calculation of Diluted Net Loss](#) [Per Share, as Including them](#) [Would have Anti-dilutive Effect](#)

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:

<i>(In thousands)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Shares issuable upon conversion of the				
2024 Convertible Notes	7,515	7,515	7,515	7,515
Stock options	4,676	4,986	4,579	4,946
Restricted stock units	2,301	2,058	2,350	1,485
Total	<u>14,492</u>	<u>14,559</u>	<u>14,444</u>	<u>13,946</u>

**Commitments and
Contingencies (Tables)**

**9 Months Ended
Sep. 30, 2021**

**Commitments and
Contingencies Disclosure**

[Abstract]

**Components of Lease Expense
and Related Cash Flows**

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

<i>(In thousands)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Operating lease cost				
Operating lease cost included in operating expenses	\$ 525	\$ 513	\$ 1,552	\$ 1,540
Operating lease cost included in inventory	61	58	185	171
Total operating lease cost	586	571	1,737	1,711
Operating cash flows from operating leases	855	699	2,450	2,256

**Schedule of Maturities of
Lease Liability Due Under
Lease Agreements**

Maturities of lease liability due under these lease agreements as of September 30, 2021, were as follows:

Year	Operating Lease Obligations <i>(In thousands)</i>
2021	515
2022	2,087
2023	2,142
2024	1,975
2025	809
Thereafter	422
Present value of imputed interest	(2,115)
Total	\$ 5,835

Overview and Nature of the Business - Additional Information (Detail) - USD (\$) \$ / shares in Units, \$ in Millions	3 Months Ended	9 Months Ended
	Oct. 11, 2021	Sep. 30, 2021 Sep. 30, 2021
<u>Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]</u>		
<u>Incorporation date</u>		Nov. 05, 2007
<u>Cash and cash equivalents and marketable securities</u>	\$ 142.1	\$ 142.1
<u>Liquidity</u>		100.0
<u>Cash balance</u>		100.0
<u>Pacira BioSciences, Inc [Member]</u>		
<u>Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]</u>		
<u>Acquisition-related costs</u>	\$ 0.7	\$ 0.7
<u>Pacira BioSciences, Inc [Member] Subsequent Event [Member]</u>		
<u>Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]</u>		
<u>Purchase of acquiree shares</u>	\$ 8.50	
<u>Percentage of share</u>	50.00%	
<u>Termination fee</u>	\$ 18.0	
<u>Pacira BioSciences, Inc [Member] Maximum [Member] Subsequent Event [Member]</u>		
<u>Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]</u>		
<u>Contingent payment</u>	\$ 8.00	

**Summary of Significant
Accounting Policies -
Additional Information
(Detail) - USD (\$)
\$ in Thousands**

Mar. 30, 2020

**3 6 9
Months Months Months
Ended Ended Ended
Sep. Jun. Sep.
30, 30, 30,
2020 2020 2021**

**Summary Of Significant
Accounting Policies [Line
Items]**

License agreement upfront
payment.

\$ 10,000

Revenue

\$ 0

Aggregate development,
regulatory and commercial
sales milestone payments

\$ 32,500

Collaborative agreements term
related to obligation and rights

terminate the agreement prior to expiration in the event of a material breach if not cured within 60 days from the date of notice of such breach (30 days in the case of payment obligations), or either party files for bankruptcy.

Collaborative arrangement
proceeds from upfront
payment received

\$ 5,000 \$ 5,000

Reduction of revenue sales
returns

2,000

Additional sales return
Maximum [Member]

\$ 1,400

**Summary Of Significant
Accounting Policies [Line
Items]**

Trade payment term

1 year

**Summary of Significant
Accounting Policies -
Summary of Product
Revenue Allowance And
Reserve Categories (Detail) -
USD (\$)
\$ in Thousands**

3 Months Ended

**Sep. 30, Jun. 30, Mar. 31, Sep. 30, Jun. 30, Mar. 31,
2021 2021 2021 2020 2020 2020**

Service Fees, Allowances and Chargebacks
[Member]

**Summary Of Significant Accounting
Policies [Line Items]**

<u>Beginning Balance</u>	\$ 2,097	\$ 1,952	\$ 1,733	\$ 1,830	\$ 1,585	\$ 1,847
<u>Provision related to sales in the current quarter</u>	2,538	2,682	2,188	2,270	1,417	1,590
<u>Credits and payments made</u>	(2,859)	(2,527)	(1,969)	(2,585)	(1,172)	(1,852)
<u>Adjustments related to prior period sales</u>		(10)				
<u>Ending Balance</u>	1,776	2,097	1,952	1,515	1,830	1,585

Government Rebates and Other Incentives
[Member]

**Summary Of Significant Accounting
Policies [Line Items]**

<u>Beginning Balance</u>	760	647	530	359	398	248
<u>Provision related to sales in the current quarter</u>	290	424	383	265	133	254
<u>Credits and payments made</u>	(401)	(311)	(266)	(198)	(262)	(199)
<u>Adjustments related to prior period sales</u>				40	90	95
<u>Ending Balance</u>	649	760	647	466	359	398

Product Returns [Member]

**Summary Of Significant Accounting
Policies [Line Items]**

<u>Beginning Balance</u>	752	659	628	603	506	402
<u>Provision related to sales in the current quarter</u>	3,130	179	151	136	98	114
<u>Credits and payments made</u>	(1,331)	(86)	(9)	(21)	(1)	(10)
<u>Adjustments related to prior period sales</u>	291		(111)			
<u>Ending Balance</u>	2,842	752	659	718	603	506

Purchaser/Provider Discounts and Rebates
[Member]

**Summary Of Significant Accounting
Policies [Line Items]**

<u>Beginning Balance</u>	3,092	2,703	1,832	892	526	1,656
<u>Provision related to sales in the current quarter</u>	3,245	3,100	2,703	1,314	892	526
<u>Credits and payments made</u>	(5,182)	(2,711)	(1,832)	(894)	(528)	(1,656)
<u>Adjustments related to prior period sales</u>				2	2	
<u>Ending Balance</u>	1,155	3,092	2,703	1,314	892	526

Product Revenue Allowance and Reserve
[Member]

Summary Of Significant Accounting Policies [Line Items]

<u>Beginning Balance</u>	6,701	5,961	4,723	3,684	3,015	4,153
<u>Provision related to sales in the current quarter</u>	9,203	6,385	5,425	3,985	2,540	2,484
<u>Credits and payments made</u>	(9,773)	(5,635)	(4,076)	(3,698)	(1,963)	(3,717)
<u>Adjustments related to prior period sales</u>	291	(10)	(111)	42	92	95
<u>Ending Balance</u>	\$ 6,422	\$ 6,701	\$ 5,961	\$ 4,013	\$ 3,684	\$ 3,015

**Summary of Significant
Accounting Policies -
Property Plant and
Equipment Estimated Useful
Lives (Detail)**

9 Months Ended

Sep. 30, 2021

Computers, Office Equipment, and Minor Computer Software [Member]

Property, Plant and Equipment [Line Items]

Estimated Useful Life (Years)

3 years

Computer Software [Member]

Property, Plant and Equipment [Line Items]

Estimated Useful Life (Years)

7 years

Manufacturing Equipment [Member] | Minimum [Member]

Property, Plant and Equipment [Line Items]

Estimated Useful Life (Years)

7 years

Manufacturing Equipment [Member] | Maximum [Member]

Property, Plant and Equipment [Line Items]

Estimated Useful Life (Years)

10 years

Furniture and Fixtures [Member]

Property, Plant and Equipment [Line Items]

Estimated Useful Life (Years)

5 years

**Fair Value of Financial
Assets and Liabilities -
Schedule of Assets Measured
at Fair Value on Recurring
Basis (Detail) - USD (\$)
\$ in Thousands**

**Sep. 30,
2021 Dec. 31,
2020**

Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis

[Line Items]

<u>Marketable securities</u>	\$ 5,229	\$ 67,576
------------------------------	----------	-----------

Fair Value Measurements, Recurring [Member]

Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis

[Line Items]

<u>Cash equivalents</u>	108,686	85,980
-------------------------	---------	--------

<u>Marketable securities</u>	5,229	67,576
------------------------------	-------	--------

<u>Assets, Total</u>	113,915	153,556
----------------------	---------	---------

Fair Value Measurements, Recurring [Member] | Level 1 [Member]

Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis

[Line Items]

<u>Cash equivalents</u>	108,686	79,148
-------------------------	---------	--------

<u>Marketable securities</u>	0	0
------------------------------	---	---

<u>Assets, Total</u>	108,686	79,148
----------------------	---------	--------

Fair Value Measurements, Recurring [Member] | Level 2 [Member]

Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis

[Line Items]

<u>Cash equivalents</u>	0	6,832
-------------------------	---	-------

<u>Marketable securities</u>	5,229	67,576
------------------------------	-------	--------

<u>Assets, Total</u>	5,229	74,408
----------------------	-------	--------

Fair Value Measurements, Recurring [Member] | Level 3 [Member]

Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis

[Line Items]

<u>Cash equivalents</u>	0	0
-------------------------	---	---

<u>Marketable securities</u>	0	0
------------------------------	---	---

<u>Assets, Total</u>	\$ 0	\$ 0
----------------------	------	------

**Fair Value of Financial
Assets and Liabilities -
Additional Information
(Detail) - 2024 Convertible
Notes [Member] - USD (\$)
\$ in Millions**

Sep. 30, 2021 May 02, 2017

Fair Value Balance Sheet Grouping Financial Statement Captions [Line Items]

<u>Fair value of liability</u>		\$ 136.7
<u>Unamortized debt discount</u>		\$ 64.5
<u>Debt instrument interest rate</u>	3.375%	3.375%
<u>Term loan, principal amount</u>		\$ 201.3
<u>Estimated fair value of Convertible Notes</u>	\$ 179.8	

**Marketable Securities -
Summary of Fair Value of
Available-for-Sale
Marketable Securities by
Type of Security (Detail) -
USD (\$)
\$ in Thousands**

Sep. 30, 2021 Dec. 31, 2020

Schedule of Available-for-sale Securities [Line Items]

<u>Amortized Cost</u>	\$ 5,229	\$ 67,587
<u>Gross Unrealized Gains</u>		3
<u>Gross Unrealized Losses</u>		(14)
<u>Fair Value</u>	5,229	67,576

Commercial Paper [Member]

Schedule of Available-for-sale Securities [Line Items]

<u>Amortized Cost</u>	2,000	6,890
<u>Fair Value</u>	2,000	6,890

Corporate Bonds [Member]

Schedule of Available-for-sale Securities [Line Items]

<u>Amortized Cost</u>	3,229	50,700
<u>Gross Unrealized Gains</u>		2
<u>Gross Unrealized Losses</u>		(14)
<u>Fair Value</u>	\$ 3,229	50,688

U.S. Government Obligations [Member]

Schedule of Available-for-sale Securities [Line Items]

<u>Amortized Cost</u>		9,997
<u>Gross Unrealized Gains</u>		1
<u>Fair Value</u>		\$ 9,998

**Marketable Securities -
Additional Information
(Detail) - USD (\$)
\$ in Thousands**

3 Months Ended 9 Months Ended

Sep. 30, 2021 Sep. 30, 2021 Dec. 31, 2020

Investments, Debt and Equity Securities [Abstract]

<u>Marketable securities</u>	\$ 5,229	\$ 5,229	\$ 67,576
<u>Long-term investment, marketable securities</u>	0	0	\$ 0
<u>Impairment for available-for-sale marketable securities</u>	\$ 0	\$ 0	

**Prepaid Expenses and Other
Current Assets - Prepaid
Expenses and Other Current
Assets (Detail) - USD (\$)
\$ in Thousands**

Sep. 30, 2021 Dec. 31, 2020

Deferred Costs, Capitalized, Prepaid, and Other Assets Disclosure [Abstract]

<u>Prepaid expenses</u>	\$ 6,065	\$ 4,346
<u>Deposits</u>	175	112
<u>Interest receivable on marketable securities</u>	18	246
<u>Other</u>	401	408
<u>Total prepaid expenses and other current assets</u>	\$ 6,659	\$ 5,112

**Inventory - Schedule of
Inventory (Detail) - USD (\$) Sep. 30, 2021 Dec. 31, 2020
\$ in Thousands**

Inventory Disclosure [Abstract]

<u>Raw materials</u>	\$ 2,831	\$ 4,287
<u>Work in process</u>	6,305	4,666
<u>Finished goods</u>	5,533	6,441
<u>Total inventories</u>	\$ 14,669	\$ 15,394

**Inventory - Additional
Information (Detail) - USD
(\$)
\$ in Thousands**

3 Months Ended	9 Months Ended	
Sep. 30, 2021	Sep. 30, 2021	Sep. 30, 2020

Inventory [Line Items]

Inventory finished goods shelf life

Provision for inventory

Product [Member] | United Kingdom Facility at Patheon UK Limited
[Member]

Inventory [Line Items]

Cost of sales expense for unabsorbed manufacturing and overhead
costs

	24 months	
\$ 1,200	\$ 1,773	\$ 0
	\$ 5,200	

**Property and Equipment,
Net - Components of
Property and Equipment
(Detail) - USD (\$)
\$ in Thousands**

Sep. 30, 2021 Dec. 31, 2020

Property, Plant and Equipment [Line Items]

<u>Property and equipment gross</u>	\$ 31,200	\$ 29,685
<u>Less: Accumulated depreciation</u>	(11,720)	(10,147)
<u>Total property and equipment, net</u>	19,480	19,538

Computer and Office Equipment [Member]

Property, Plant and Equipment [Line Items]

<u>Property and equipment gross</u>	1,215	1,203
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Manufacturing Equipment [Member]

Property, Plant and Equipment [Line Items]

<u>Property and equipment gross</u>	12,656	12,297
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Furniture and Fixtures [Member]

Property, Plant and Equipment [Line Items]

<u>Property and equipment gross</u>	609	609
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Leasehold Improvements [Member]

Property, Plant and Equipment [Line Items]

<u>Property and equipment gross</u>	1,177	1,157
-------------------------------------	-------	-------

Construction in Progress [Member]

Property, Plant and Equipment [Line Items]

<u>Property and equipment gross</u>	14,988	13,924
-------------------------------------	--------	--------

Software [Member]

Property, Plant and Equipment [Line Items]

<u>Property and equipment gross</u>	\$ 555	\$ 495
-------------------------------------	--------	--------

Property and Equipment, Net - Additional Information (Detail) \$ in Thousands	3 Months Ended		9 Months Ended	
	Sep. 30, 2021 USD (\$)	Sep. 30, 2020 USD (\$)	Sep. 30, 2021 USD (\$) Equipment	Sep. 30, 2020 USD (\$) Equipment
Property, Plant and Equipment [Abstract]				
Depreciation	\$ 500	\$ 500	\$ 1,573	\$ 1,295
Property and equipment disposals Equipment			0	1
Gains losses on disposals of property plant and equipment			\$ (300)	

**Accrued Expenses and Other
Current Liabilities -
Schedule of Accrued
Expenses and Other Current
Liabilities (Detail) - USD (\$)
\$ in Thousands**

Sep. 30, 2021 Dec. 31, 2020

Payables and Accruals [Abstract]

<u>Research and development</u>	\$ 2,972	\$ 1,856
<u>Payroll and other employee-related expenses</u>	10,189	10,674
<u>Professional services fees</u>	2,961	2,094
<u>Accrued interest</u>	2,943	1,464
<u>Product revenue reserves</u>	4,646	2,990
<u>Other</u>	1,164	930
<u>Total accrued expenses and other current liabilities</u>	\$ 24,875	\$ 20,008

Debt - Additional Information (Detail)	Jul. 30, 2021 USD (\$)	May 18, 2020 USD (\$)	May 02, 2017 USD (\$)	3 Months Ended	9 Months Ended	Jun. 30, 2021	Dec. 31, 2020 USD (\$)	Aug. 02, 2019 USD (\$)	Aug. 04, 2015 USD (\$)
				Sep. 30, 2021 USD (\$) \$/ shares	Sep. 30, 2021 TradingDay USD (\$) \$/ shares				
Debt Instrument [Line Items]									
Long-term debt, net				\$ 80,087,000	\$ 80,087,000		\$ 44,114,000		
Repayments of lines of credit				0	\$ 15,000,000				
Loss on debt extinguishment				502,000					
Minimum liquidity threshold				100,000,000.0					
Amount borrowed				\$ 55,000,000	\$ 15,000,000				
Interest on final payment				4.75%	4.75%				
Carrying value of term loan				\$ 55,100,000	\$ 55,100,000				
Current portion of long-term debt				\$ 0	0		\$ 16,806,000		
Debt issuance costs					\$ 210,000				
Repaid In Year One [Member]									
Debt Instrument [Line Items]									
Debt instrument interest rate				3.00%	3.00%				
Repaid In Year Two [Member]									
Debt Instrument [Line Items]									
Debt instrument interest rate				2.00%	2.00%				
Repaid In Year Three [Member]									
Debt Instrument [Line Items]									
Debt instrument interest rate				1.00%	1.00%				
Repaid In Year Three And Thereafter [Member]									
Debt Instrument [Line Items]									
Debt instrument interest rate				0.00%	0.00%				
2015 Term Loan [Member]									
Debt Instrument [Line Items]									
Carrying value of term loan				\$ 55,087,000	\$ 55,087,000				
Liability component of Convertible Notes recorded as long-term debt				68,641,000	\$ 68,641,000				
Mid Cap Financial Trust [Member] 2015 Term Loan [Member]									
Debt Instrument [Line Items]									
Term loan, maximum borrowings									\$ 30,000,000.0
Mid Cap Financial Trust [Member] 2019 Term Loan [Member]									
Debt Instrument [Line Items]									

Term loan, principal amount		\$	40,000,000.0
Debt instrument maturity date	Jan. 01, 2024		
Repayments of lines of credit	\$ 7,700,000		
Mid Cap Financial Trust			
[Member] 2019 Term Loan			
[Member] Revolving Credit Facility [Member]			
Debt Instrument [Line Items]			
Term loan, principal amount		\$	20,000,000.0
Silicon Valley Bank [Member]			
Debt Instrument [Line Items]			
Loss on debt extinguishment	\$		
	(500,000)	\$	(500,000)
Silicon Valley Bank [Member]			
 Second Tranche Undrawn 			
2021 Amended Credit Agreement [Member]			
Debt Instrument [Line Items]			
Company liquidity with banks	\$		100,000,000.0
Silicon Valley Bank [Member]			
 Second Tranche Drawn 			
2021 Amended Credit Agreement [Member]			
Debt Instrument [Line Items]			
Company liquidity with banks	120,000,000.0		
Silicon Valley Bank [Member]			
 Revolving Credit Facility [Member]			
Debt Instrument [Line Items]			
Term loan, maximum borrowings	\$		25,000,000.0
Debt instrument maturity date	Feb. 01, 2024		
Repayment of term loan	\$		20,000,000.0
Debt instrument maturity date option to extend	Jul. 01, 2026		
Debt instrument interest rate description	Borrowings under the 2021 Amended Credit Agreement revolving credit facility accrue interest monthly at a floating interest rate equal to the greater of (i) the Prime Rate plus 1.75% or (ii) 5.00%.		
Line of credit facility, fee description	unused revolving line		

facility fee equal to 0.25% per annum of the average unused portion of the revolving line, multiplied by the difference between the total amount available to be borrowed (the “Revolving Commitment Amount”) and the greater of the average outstanding revolver balance and 25% of the Revolving Commitment Amount.

[Silicon Valley Bank \[Member\]](#)
[| Revolving Credit Facility](#)
[\[Member\] | Repaid In Year](#)
[One \[Member\]](#)

[Debt Instrument \[Line Items\]](#)

[Line of credit facility,](#)
[termination fees, percentage](#)

2.00%

[Silicon Valley Bank \[Member\]](#)
[| Revolving Credit Facility](#)
[\[Member\] | Repaid In Year](#)
[Two \[Member\]](#)

[Debt Instrument \[Line Items\]](#)

[Line of credit facility,](#)
[termination fees, percentage](#)

1.00%

[Silicon Valley Bank \[Member\]](#)
[| Revolving Credit Facility](#)
[\[Member\] | Repaid In Year](#)
[Three And Thereafter](#)
[\[Member\]](#)

[Debt Instrument \[Line Items\]](#)

[Line of credit facility,](#)
[termination fees, percentage](#)

0.00%

[Silicon Valley Bank \[Member\]](#)
[| 2021 Term Loan \[Member\]](#)

[Debt Instrument \[Line Items\]](#)

[Term loan, principal amount](#) \$ 55,000,000.0

[Long-term debt, net](#) 55,000,000.0

[Total revolver balance](#) 25,000,000.0

[Debt instrument interest rate](#)
[description](#)

Term loan borrowings under the 2021 credit

			facility accrue interest monthly at a floating interest rate equal to the greater of (i) prime rate plus 2.75% or (ii) 6.0% per annum
Interest on final payment		4.75%	4.75%
Term loan, payment description			interest-only period of 24 months (if the second tranche is undrawn), or 36 months (if the second tranche is drawn), principal is due in equal monthly installments
Silicon Valley Bank [Member] 2021 Term Loan [Member] Second Anniversary [Member]			
Debt Instrument [Line Items]			
Term loan, principal amount	20,000,000.0		
Silicon Valley Bank [Member] 2021 Term Loan [Member] Maximum [Member]			
Debt Instrument [Line Items]			
Term loan, principal amount	75,000,000.0		
Silicon Valley Bank [Member] 2021 Term Loan [Member] Revolving Credit Facility [Member]			
Debt Instrument [Line Items]			
Repayments of lines of credit		\$	
		15,000,000.0	
Repayment of term loan	\$ 48,100,000		
Term loan, maximum borrowings		\$	
		20,000,000.0	
Term loan, remaining borrowings			\$ 5,000,000.0
2024 Convertible Notes [Member]			
Debt Instrument [Line Items]			
Term loan, principal amount		\$	
		201,300,000	
Debt instrument maturity date		May 01, 2024	
Debt instrument conversion carrying amount per share		\$ 1,000	\$ 1,000
Debt instrument interest rate	3.375%	3.375%	3.375%
Debt instrument interest rate	3.375%		9.71%
Debt instrument frequency of periodic payment		semi- annually	

Net proceeds from offering of convertible senior notes	\$		
		194,800,000	
Debt discount and issuance costs	6,500,000	\$	\$ 68,900,000
		68,900,000	
Number of shares issued upon conversion of \$1,000 debt principal amount shares			37.3413
Debt instrument convertible initial conversion price per share of common stock \$ / shares		\$ 26.78	\$ 26.78
Number of days within 30 consecutive trading days in which the closing price of the entity's common stock must exceed the conversion price for the notes to be convertible into common stock TradingDay			20
Number of consecutive trading days during which the closing price of the entity's common stock must exceed the conversion price for at least 20 days in order for the notes to be convertible into common stock TradingDay			30
Percentage of the closing sales price of the entity's common stock that the conversion price must exceed in order for the notes to be convertible			130.00%
Number of consecutive business days immediately after any five consecutive trading day period during the note measurement period TradingDay			5
Number of consecutive trading days before five consecutive business days during the note measurement period TradingDay			10
Liability component of Convertible Notes recorded as long-term debt		136,700,000	
Equity component of Convertible Notes recorded as additional paid-in capital	\$	64,500,000	
Debt instrument effective interest rate period			7 years
Debt issuance costs			\$ 6,500,000
Debt issuance costs allocated to liability component			4,400,000
Debt issuance costs allocated to equity component reduction to additional paid-in capital			2,100,000
Interest expense	\$	4,100,000	12,200,000
Amortization of debt discount	\$	2,400,000	\$ 7,200,000

2024 Convertible Notes
[Member] | Maximum
[Member]

Debt Instrument [Line Items]

Debt instrument conversion obligation trading price as percentage of product common stock closing sale price and conversion rate 98.00%

2024 Convertible Notes [Member] | Repaid In Year Two [Member]

Debt Instrument [Line Items]

Number of days within 30 consecutive trading days in which the closing price of the entity's common stock must exceed the conversion price for the notes to be convertible into common stock | TradingDay 20

Number of consecutive trading days during which the closing price of the entity's common stock must exceed the conversion price for at least 20 days in order for the notes to be convertible into common stock | TradingDay 30

Percentage of the closing sales price of the entity's common stock that the conversion price must exceed in order for the notes to be convertible 130.00%

Debt instrument redemption date May 06, 2020

Redemption price percentage of principal amount to be redeemed 100.00%

**Debt - Schedule of Annual
Principal and Interest
Payments Due Under Term
Loan (Detail)
\$ in Thousands**

**Sep. 30, 2021
USD (\$)**

Long-term Debt, Fiscal Year Maturity [Abstract]

Total \$ 55,100

2015 Term Loan [Member]

Long-term Debt, Fiscal Year Maturity [Abstract]

2021 568

2022 3,346

2023 10,907

2024 20,710

2025 19,587

Thereafter 13,523

Total 68,641

Less interest (11,029)

Less unamortized portion of final payment (2,525)

Total \$ 55,087

Debt - Summary of Carrying Value of Convertible Notes (Detail) - USD (\$) \$ in Thousands	9 Months Ended		
	Sep. 30, 2021	Sep. 30, 2020	Dec. 31, 2020
<u>Debt Instrument [Line Items]</u>			
<u>Amortization of debt discount and debt issuance costs</u>	\$ 7,842	\$ 6,947	
<u>Carrying value 2024 Convertible Notes</u>	170,418		\$ 162,786
<u>2024 Convertible Notes [Member]</u>			
<u>Debt Instrument [Line Items]</u>			
<u>Gross proceeds</u>	201,250		
<u>Gross proceeds, Portion of proceeds allocated to equity component (additional paid-in capital)</u>	(64,541)		
<u>Debt issuance costs</u>	(6,470)		
<u>Debt issuance costs, Portion of issuance costs allocated to equity component (additional paid-in capital)</u>	2,075		
<u>Amortization of debt discount and debt issuance costs</u>	38,104		
<u>Carrying value 2024 Convertible Notes</u>	\$ 170,418		

**Stock-Based Compensation -
Schedule of Relevant Data
Used to Estimate Fair Value
of Stock Option Grants
(Detail)**

3 Months Ended **9 Months Ended**
Sep. 30, 2021 **Sep. 30, 2020** **Sep. 30, 2021** **Sep. 30, 2020**

Share-based Payment Arrangement [Abstract]

<u>Risk-free interest rates, Minimum</u>	0.96%	0.47%	0.96%	0.47%
<u>Risk-free interest rates, Maximum</u>	1.12%		1.28%	1.79%
<u>Expected dividend yield</u>	0.00%	0.00%	0.00%	0.00%
<u>Expected term (in years)</u>	6 years	6 years	6 years	6 years
<u>Expected volatility, Minimum</u>	71.80%	72.50%	71.80%	65.40%
<u>Expected volatility, Maximum</u>	71.90%		72.40%	72.50%

**Stock-Based Compensation -
Summary of Stock Option
Activity (Detail)**

**9 Months
Ended
Sep. 30, 2021
\$ / shares
shares**

Share-based Payment Arrangement [Abstract]

<u>Shares Issuable Under Options, Beginning balance shares</u>	4,592,000
<u>Shares Issuable Under Options, Granted shares</u>	587,000
<u>Shares Issuable Under Options, Exercised shares</u>	(42,682)
<u>Shares Issuable Under Options, Cancelled shares</u>	(837,000)
<u>Shares Issuable Under Options, Ending balance shares</u>	4,299,337
<u>Shares Issuable Under Options, Options vested and expected to vest at September 30, 2021 shares</u>	4,299,000
<u>Shares Issuable Under Options, Options exercisable at September 30, 2021 shares</u>	3,302,000
<u>Weighted Average Exercise Price Per Share, Beginning balance \$ / shares</u>	\$ 17.77
<u>Weighted Average Exercise Price Per Share, Granted \$ / shares</u>	8.30
<u>Weighted Average Exercise Price Per Share, Exercised \$ / shares</u>	3.40
<u>Weighted Average Exercise Price Per Share, Cancelled \$ / shares</u>	18.81
<u>Weighted Average Exercise Price Per Share, Ending balance \$ / shares</u>	16.42
<u>Weighted Average Exercise Price Per Share, Options vested and expected to vest at September 30, 2021 \$ / shares</u>	16.42
<u>Weighted Average Exercise Price Per Share, Options exercisable at September 30, 2021 \$ / shares</u>	\$ 17.91

Stock-Based Compensation - Additional Information (Detail)	3 Months Ended	9 Months Ended		
	Sep. 30, 2021 USD (\$) \$ / shares shares	Sep. 30, 2021 USD (\$) Installment \$ / shares shares	Sep. 30, 2020 \$ / shares shares	Dec. 31, 2020 \$ / shares shares
<u>Share-based Compensation Arrangement by Share-based Payment Award [Line Items]</u>				
<u>Number of options exercised</u>	42,682			
<u>Aggregate intrinsic value of stock options exercised \$</u>	\$ 386,138			
<u>Options to purchase common stock, outstanding</u>	4,299,337	4,299,337	4,753,623	4,592,000
<u>Weighted average remaining contractual term</u>	6 years		6 years 6 months	
<u>Weighted average exercise price \$ / shares</u>	\$ 16.42	\$ 16.42	\$ 17.74	\$ 17.77
<u>Weighted average grant date fair value of options granted \$ / shares</u>		\$ 5.28	\$ 8.86	
<u>Unrecognized stock-based compensation expense \$</u>	\$ 6,700,000	\$ 6,700,000		
<u>Unrecognized compensation costs, weighted-average recognition periods</u>		2 years 6 months		
<u>Restricted Stock Units (RSUs) [Member]</u>				
<u>Share-based Compensation Arrangement by Share-based Payment Award [Line Items]</u>				
<u>Share based compensation, number of shares granted</u>	1,169,320			
<u>Weighted average grant date fair value, shares granted, per share \$ / shares</u>		\$ 10.79		
<u>Awards vesting right</u>		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		

Stock-based compensation expense recognized \$	0	\$ 0
Share based compensation award, vested		626,000
Performance achievement conditions percentage related to vesting of shares..		150.00%
Unrecognized stock-based compensation expense \$	\$ 21,900,000	\$ 21,900,000
Unrecognized compensation costs, weighted-average recognition periods		2 years 3 months 18 days
Restricted Stock Units (RSUs) [Member] Maximum [Member]		
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]		
Share based compensation award, vested		159,150
Restricted Stock Units (RSUs) [Member] First Anniversary [Member]		
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]		
Share based compensation, award vesting installments Installment		4
Restricted Stock Units (RSUs) [Member] Second Anniversary [Member]		
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]		
Share based compensation, award vesting installments Installment		4
Restricted Stock Units (RSUs) [Member] Third Anniversary [Member]		
Share-based Compensation Arrangement by Share-		

based Payment Award [Line Items]

Share based compensation, award vesting installments | Installment 4

Restricted Stock Units (RSUs) [Member] | Fourth Anniversary [Member]

Share-based Compensation Arrangement by Share-based Payment Award [Line Items]

Share based compensation, award vesting installments | Installment 4

Restricted Stock Units (RSUs) [Member] | Chief Executive Officer [Member]

Share-based Compensation Arrangement by Share-based Payment Award [Line Items]

Share based compensation, number of shares granted 106,100

**Stock-Based Compensation -
Summary of of RSU Activity
(Detail) - Restricted Stock
Units (RSUs) [Member]**

**9 Months Ended
Sep. 30, 2021
\$ / shares
shares**

Share-based Compensation Arrangement by Share-based Payment Award [Line Items]

<u>Number of Shares, Beginning balance shares</u>	2,193,000
<u>Number of Shares, Granted shares</u>	1,169,320
<u>Number of Shares, Vested/Released shares</u>	(626,000)
<u>Number of Shares, Cancelled shares</u>	(490,000)
<u>Number of Shares, Ending balance shares</u>	2,246,000
<u>Weighted Average Grant Date Fair Value Per Share, Beginning balance \$ / shares</u>	\$ 14.15
<u>Weighted Average Grant Date Fair Value Per Share, Granted \$ / shares</u>	10.79
<u>Weighted Average Grant Date Fair Value Per Share, Vested/Released \$ / shares</u>	14.57
<u>Weighted Average Grant Date Fair Value Per Share, Cancelled \$ / shares</u>	13.42
<u>Weighted Average Grant Date Fair Value Per Share, Ending balance \$ / shares</u>	\$ 12.45

Stock-Based Compensation - Stock-Based Compensation Expense Related to Stock Options, and RSUs and Shares Purchased Under Employee Stock Purchase Plan (Detail) - USD (\$) \$ in Thousands	3 Months Ended		9 Months Ended	
	Sep. 30, 2021	Sep. 30, 2020	Sep. 30, 2021	Sep. 30, 2020
<u>Share-based Compensation Arrangement by Share-based Payment Award [Line Items]</u>				
<u>Stock-based compensation expense</u>	\$ 4,196	\$ 4,959	\$ 12,811	\$ 13,397
<u>Research and Development [Member]</u>				
<u>Share-based Compensation Arrangement by Share-based Payment Award [Line Items]</u>				
<u>Stock-based compensation expense</u>	1,166	1,403	3,469	4,692
<u>Selling, General and Administrative [Member]</u>				
<u>Share-based Compensation Arrangement by Share-based Payment Award [Line Items]</u>				
<u>Stock-based compensation expense</u>	\$ 3,030	\$ 3,556	\$ 9,342	\$ 8,705

Net Loss per Share - Schedule of Basic and Diluted Net Loss Per Share Attributable to Common Stockholders (Detail) - USD (\$) \$ / shares in Units, shares in Thousands, \$ in Thousands	3 Months Ended			9 Months Ended				
	Sep. 30,	Jun. 30,	Mar. 31,	Sep. 30,	Jun. 30,	Mar. 31,	Sep. 30,	Sep. 30,
	2021	2021	2021	2020	2020	2020	2021	2020
<u>Numerator:</u>								
<u>Net loss</u>	\$ (30,312)	\$ (22,208)	\$ (28,556)	\$ (24,638)	\$ (32,619)	\$ (36,802)	\$ (81,076)	\$ (94,059)
<u>Net loss:</u>	\$ (30,312)	\$ (22,208)	\$ (28,556)	\$ (24,638)	\$ (32,619)	\$ (36,802)	\$ (81,076)	\$ (94,059)
<u>Denominator:</u>								
<u>Weighted average common shares outstanding, basic and diluted</u>	50,265			49,298			50,027	43,563
<u>Net loss per share, basic and diluted</u>	\$ (0.60)			\$ (0.50)			\$ (1.62)	\$ (2.16)

Net Loss per Share - Schedule of Common Stock Equivalents Excluded from Calculation of Diluted Net Loss Per Share, as Including them Would have Anti- dilutive Effect (Detail) - shares	3 Months Ended		9 Months Ended	
	Sep. 30, 2021	Sep. 30, 2020	Sep. 30, 2021	Sep. 30, 2020

Antidilutive Securities Excluded From Computation Of Earnings Per Share [Line Items]

<u>Common stock equivalents excluded from calculation of diluted net loss per share, as including them would have anti-dilutive effect</u>	14,492	14,559	14,444	13,946
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Shares Issuable Upon Conversion of the 2024 Convertible Notes [Member]

Antidilutive Securities Excluded From Computation Of Earnings Per Share [Line Items]

<u>Common stock equivalents excluded from calculation of diluted net loss per share, as including them would have anti-dilutive effect</u>	7,515	7,515	7,515	7,515
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Stock Options [Member]

Antidilutive Securities Excluded From Computation Of Earnings Per Share [Line Items]

<u>Common stock equivalents excluded from calculation of diluted net loss per share, as including them would have anti-dilutive effect</u>	4,676	4,986	4,579	4,946
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Restricted Stock Units (RSUs) [Member]

Antidilutive Securities Excluded From Computation Of Earnings Per Share [Line Items]

<u>Common stock equivalents excluded from calculation of diluted net loss per share, as including them would have anti-dilutive effect</u>	2,301	2,058	2,350	1,485
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Commitments and Contingencies - Additional Information (Detail)	Jun. 30, 2019 USD (\$) ft ²	Jan. 31, 2018 USD (\$)	Feb. 28, 2017 USD (\$)	Jan. 31, 2016	Jul. 31, 2015	Feb. 28, 2021 USD (\$)	1 Months Ended			3 Months Ended		9 Months Ended						
							Nov. 30, 2019 USD (\$)	Sep. 30, 2019 USD (\$)	Dec. 31, 2017 USD (\$)	Sep. 30, 2021 USD (\$)	Sep. 30, 2020 USD (\$)	Sep. 30, 2021 USD (\$)	Sep. 30, 2020 USD (\$)	Sep. 30, 2021 USD (\$)	Feb. 02, 2018	May 31, 2013		
Commitment And Contingencies [Line Items] Operating lease term																		42 years
Lease termination date		Apr. 30, 2025																
Total operating lease cost										\$ 586,000	\$ 571,000	\$ 1,737,000	\$ 1,711,000					
Operating lease, remaining lease term										2 years 4 months 24 days		2 years 4 months 24 days						
Right-of-Use Asset Obtained in Exchange for Operating Lease Liability													\$ 433,000					
Milestone payment						\$ 1,000,000.0												
Definitive Agreement [Member] Commitment And Contingencies [Line Items] Research and development milestone payment GeneQuine Biotherapeutics GmbH ("GeneQuine") [Member] Definitive Agreement [Member]									\$ 500,000									
Commitment And Contingencies [Line Items] License agreement, upfront fee paid									\$ 2,000,000.0									
Milestone, Revenue recognized												0						
Research and development milestone payment GeneQuine Biotherapeutics GmbH ("GeneQuine") [Member] Definitive Agreement [Member] Investigational New Drug		\$ 750,000																
Commitment And Contingencies [Line Items] Research and development milestone payment GeneQuine Biotherapeutics GmbH ("GeneQuine") [Member] Definitive Agreement [Member] Maximum [Member]								\$ 750,000										
Commitment And Contingencies [Line Items] Additional milestone payments Xenon Pharmaceuticals, Inc. ("Xenon") [Member] Definitive Agreement [Member]										51,500,000								
Commitment And Contingencies [Line Items] License agreement, upfront fee paid									3,000,000.0									
Milestone, Revenue recognized Xenon Pharmaceuticals, Inc. ("Xenon") [Member] Definitive Agreement [Member] Sales Related Milestone Payments [Member]												0						
Commitment And Contingencies [Line Items] Additional milestone payments									75,000,000.0									

[Xenon Pharmaceuticals, Inc.](#)
[\("Xenon"\) \[Member\]](#) |
[Definitive Agreement](#)
[\[Member\]](#) | [Maximum](#)
[\[Member\]](#)

Commitment And
Contingencies [Line Items]
[Additional milestone payments](#)

40,800,000

[Evonik Corporation \[Member\]](#)
Commitment And
Contingencies [Line Items]
[Supply agreement period](#)

5
years

[Manufacturing and Supply](#)
[Agreement with Patheon UK](#)
[Limited \[Member\]](#)

Commitment And
Contingencies [Line Items]

[Operating lease, straight-line](#)
[cost](#)
[Total operating lease cost](#)

58,000,000 171,000,000

[Operating lease, remaining](#)
[lease term](#)

\$ 61,000,000 \$ 185,000,000
6 years 1 month 6 days 6 years 1 month 6 days

[Manufacturing agreement](#)
[period](#)

10
years

[Operating lease, discount rate](#) 6.10%
[Increase in right of use asset](#) \$ 500,000

[Phase 2 Proof of Concept](#)
[\(PoC\) Clinical Trial \[Member\]](#)
[| GeneQuine Biotherapeutics](#)
[GmbH \("GeneQuine"\)](#)
[\[Member\]](#) | [Definitive](#)
[Agreement \[Member\]](#) |
[Maximum \[Member\]](#)

Commitment And
Contingencies [Line Items]

[Additional milestone payments](#)
[Phase 2 Proof of Concept](#)
[\(PoC\) Clinical Trial \[Member\]](#)
[| Xenon Pharmaceuticals, Inc.](#)
[\("Xenon"\) \[Member\]](#) |
[Definitive Agreement](#)
[\[Member\]](#) | [Maximum](#)
[\[Member\]](#)

\$ 4,500,000

Commitment And
Contingencies [Line Items]
[Additional milestone payments](#)

\$ 5,000,000.0

[Phase1 clinical trial \[Member\]](#)
Commitment And
Contingencies [Line Items]
[Additional milestone payments](#)

\$ 2,000,000.0
2,500,000

[Milestone payment](#)
[Burlington Massachusetts](#)
[\[Member\]](#)

Commitment And
Contingencies [Line Items]

[Operating lease office space](#) 41,873
[ft²](#)
[Minimum monthly lease](#) \$
[payments](#) 108,000,000

[Total operating lease cost](#)
[Operating lease, remaining](#)
[lease term](#)

\$ 500,000 500,000 \$ 1,400,000 1,400,000
3 years 7 months 6 days 3 years 7 months 6 days

[Lessee, operating lease,](#)
[extension term](#)
[Woburn, Massachusetts](#)
[\[Member\]](#)

18 months 18 months

Commitment And
Contingencies [Line Items]

Operating lease term					5 years
Lease termination date				Feb. 29, 2024	
Minimum monthly lease payments				\$ 20,400,000	
Total operating lease cost		\$	\$	\$	\$
		58,000,000	46,000,000	150,000,000	139,000,000
Monthly lease payment	\$	15,000,000			

**Commitments and
Contingencies - Components
of Lease Expense and
Related Cash Flows (Detail) -
USD (\$)
\$ in Thousands**

3 Months Ended 9 Months Ended
Sep. 30, 2021 Sep. 30, 2020 Sep. 30, 2021 Sep. 30, 2020

Commitment And Contingencies [Line Items]

<u>Total operating lease cost</u>	\$ 586	\$ 571	\$ 1,737	\$ 1,711
<u>Operating cash flows from operating leases</u>	855	699	2,450	2,256

Inventory [Member]

Commitment And Contingencies [Line Items]

<u>Total operating lease cost</u>	61	58	185	171
<u>Operating Expense [Member]</u>				

Commitment And Contingencies [Line Items]

<u>Total operating lease cost</u>	\$ 525	\$ 513	\$ 1,552	\$ 1,540
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**Commitments and
Contingencies - Schedule of
Maturities of Lease Liability
Due Under Lease
Agreements (Detail)
\$ in Thousands**

**Sep. 30, 2021
USD (\$)**

Commitments and Contingencies Disclosure [Abstract]

<u>Aggregate Minimum Payments, 2021</u>	\$ 515
<u>Aggregate Minimum Payments, 2022</u>	2,087
<u>Aggregate Minimum Payments, 2023</u>	2,142
<u>Aggregate Minimum Payments, 2024</u>	1,975
<u>Aggregate Minimum Payments, 2025</u>	809
<u>Aggregate Minimum Payments, Thereafter</u>	422
<u>Aggregate Minimum Payments, Present value of imputed interest</u>	(2,115)
<u>Aggregate Minimum Payments, Total</u>	\$ 5,835

Subsequent Events - Additional Information (Detail) - USD (\$) \$ in Thousands	9 Months Ended	
	Jul. 30, 2021	Dec. 31, 2020
Subsequent Event [Line Items]		
Long-term debt, net	\$ 80,087	\$ 44,114
Interest on final payment	4.75%	
Repaid In Year One [Member]		
Subsequent Event [Line Items]		
Debt instrument interest rate	3.00%	
Repaid In Year Two [Member]		
Subsequent Event [Line Items]		
Debt instrument interest rate	2.00%	
Repaid In Year Three [Member]		
Subsequent Event [Line Items]		
Debt instrument interest rate	1.00%	
Repaid In Year Three And Thereafter [Member]		
Subsequent Event [Line Items]		
Debt instrument interest rate	0.00%	
Silicon Valley Bank [Member] Revolving Credit Facility [Member]		
Subsequent Event [Line Items]		
Debt instrument maturity date	Feb. 01, 2024	
Debt instrument maturity date option to extend	Jul. 01, 2026	
Term loan, maximum borrowings	\$ 25,000	
Repayment of term loan	20,000	
Debt instrument interest rate description	Borrowings under the 2021 Amended Credit Agreement revolving credit facility accrue interest monthly at a floating interest rate equal to the greater of (i) the Prime Rate plus 1.75% or (ii) 5.00%.	
Silicon Valley Bank [Member] 2021 Amended Credit Agreement [Member] Second Tranche Undrawn [Member]		
Subsequent Event [Line Items]		
Company liquidity with banks	100,000	
Silicon Valley Bank [Member] 2021 Amended Credit Agreement		

[\[Member\]](#) | [Second Tranche Drawn](#)

[\[Member\]](#)

[Subsequent Event \[Line Items\]](#)

[Company liquidity with banks](#) 120,000

[Silicon Valley Bank \[Member\]](#) |

[2021 Term Loan \[Member\]](#)

[Subsequent Event \[Line Items\]](#)

[Term loan, principal amount](#) 55,000

[Long-term debt, net](#) 55,000

[Total revolver balance](#) 25,000

[Debt instrument interest rate description](#)

Term loan borrowings under the 2021 credit facility accrue interest monthly at a floating interest rate equal to the greater of (i) prime rate plus 2.75% or (ii) 6.0% per annum

[Interest on final payment](#)

4.75%

[Silicon Valley Bank \[Member\]](#) |

[2021 Term Loan \[Member\]](#) |

[Maximum \[Member\]](#)

[Subsequent Event \[Line Items\]](#)

[Term loan, principal amount](#) 75,000

[Silicon Valley Bank \[Member\]](#) |

[2021 Term Loan \[Member\]](#) |

[Second Tranche \[Member\]](#)

[Subsequent Event \[Line Items\]](#)

[Term loan, principal amount](#) 20,000

[Silicon Valley Bank \[Member\]](#) |

[2021 Term Loan \[Member\]](#) |

[Revolving Credit Facility](#)

[\[Member\]](#)

[Subsequent Event \[Line Items\]](#)

[Repayment of term loan](#) \$

48,100

1. The first part of the document discusses the importance of maintaining accurate records of all transactions and activities. It emphasizes the need for transparency and accountability in financial reporting.

2. The second part of the document outlines the various methods and techniques used to collect and analyze data. It includes a detailed description of the experimental procedures and the tools used for data collection.

3. The third part of the document presents the results of the study. It includes a series of tables and graphs that illustrate the findings of the research. The data shows a clear trend in the relationship between the variables being studied.

4. The fourth part of the document discusses the implications of the findings. It highlights the potential applications of the research in various fields and the need for further investigation in this area.

5. The fifth part of the document concludes the study and provides a summary of the key findings. It also includes a list of references and a bibliography of the sources used in the research.

1. The first part of the document discusses the importance of maintaining accurate records of all transactions and activities. It emphasizes the need for transparency and accountability in financial reporting.

2. The second part of the document outlines the various methods and techniques used to collect and analyze data. It highlights the importance of using reliable sources and ensuring the accuracy of the information gathered.

3. The third part of the document focuses on the analysis and interpretation of the collected data. It discusses the various statistical and analytical tools used to identify trends and patterns in the data.

4. The fourth part of the document discusses the implications of the findings and the potential impact of the research. It highlights the need for further research and the importance of sharing the results with the relevant stakeholders.

5. The fifth part of the document provides a conclusion and summarizes the key findings of the study. It emphasizes the importance of ongoing monitoring and evaluation to ensure the continued relevance and effectiveness of the research.

