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

FORM 10-Q

(Mark one)

☒ **Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Quarterly Period Ended June 30, 2019

Or

☐ **Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File Number 001-36351

PLx Pharma Inc.

(Exact name of registrant as specified in its charter)

Delaware	**46-4995704**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)
9 Fishers Lane, Suite E Sparta, NJ	**07871**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(713) 842-1249**

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

Common Stock, $0.001 par value	PLXP	The NASDAQ Capital Market
(Title of each class)	(Trading Symbol)	(Name of each exchange on which registered)

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

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☐ Smaller reporting company ☒

Emerging Growth Company ☒

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

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

As of August 7, 2019, there were 9,044,267 shares of common stock, $0.001 par value, issued and outstanding.

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PLx Pharma Inc.

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In this quarterly report, we refer to PLx Pharma Inc., together with its subsidiaries, as the "Company," "we," "our" or "us." All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect" or the negative version of these words and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A "Risk Factors." In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances included herein may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to bring our lead product candidates, Vazalore 81 mg and 325 mg (formerly Aspertec 81 mg and 325 mg, respectively), to market-readiness;
- our ability to maintain regulatory approval of Vazalore 325 mg or obtain and maintain regulatory approval of Vazalore 81 mg and any future product candidates;
- the benefits of the use of Vazalore;
- the projected dollar amounts of future sales of established and novel gastrointestinal("GI")-safer technologies for non-steroidal anti-inflammatory drugs ("NSAIDs") and other analgesics;
- our ability to successfully commercialize our Vazalore products, or any future product candidates;
- the rate and degree of market acceptance of our Vazalore products or any future product candidates;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to scale up manufacturing of our Vazalore products to commercial scale;
- our ability to successfully build a specialty sales force and commercial infrastructure or collaborate with a firm that has these capabilities;
- our ability to compete with companies currently producing GI-safer technologies for NSAIDs and other analgesics;
- our reliance on third parties to conduct our clinical studies;
- our reliance on third-party contract manufacturers to manufacture and supply our product candidates for us;
- our reliance on our collaboration partners' performance over which we do not have control;
- our ability to retain and recruit key personnel, including development of a sales and marketing function;
- our ability to obtain and maintain intellectual property protection for our Vazalore products or any future product candidates;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act");
- our ability to identify, develop, acquire and in-license new products and product candidates;
- our ability to successfully establish and successfully maintain appropriate collaborations and derive significant revenue from those collaborations, including but not limited to any milestone payments or royalties;
- legal, political judicial and regulatory changes;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statement made by us in this quarterly report speaks only as of the date on which it is made. We disclaim any duty to update any of these forward-looking statements after the date of this quarterly report to confirm these statements to actual results or revised expectations.

Other risks may be described from time to time in our filings made under applicable securities laws. New risks emerge from time to time. It is not possible for our management to predict all risks. All forward-looking statements in this quarterly report speak only as of the date made and are based on our current beliefs and expectations. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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NOTE REGARDING TRADEMARKS

We own various U.S. federal trademark registrations and applications and unregistered trademarks and service marks, including:

- PLX®
- PLXPHARMA®
- PLXGUARD™
- VAZALORE™
-  ™
- First Liquid-Filled Aspirin capsules™
- PLX PHARMA INC.
- ASPIRIN THERAPY VAZALORE™ Aspirin Capsules Pain Reliever/Fever Reducer (NSAID)
- ASPIRIN THERAPY VAZALORE™ Aspirin Capsules Pain Reliever/Fever Reducer (NSAID)

Solely for convenience, the trademarks and trade names in this quarterly report are sometimes referred to without the TM symbol, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies, products or services.

PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

PLx Pharma Inc.
UNAUDITED CONSOLIDATED BALANCE SHEETS

	June 30, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 21,256,643	$ 14,250,267
Accounts receivable	193,732	18,234
Prepaid expenses and other current assets	266,542	421,933
Deferred financing costs	-	174,976
TOTAL CURRENT ASSETS	21,716,917	14,865,410
NON-CURRENT ASSETS		
Property and equipment, net	1,364,181	1,394,230
Lease assets	574,953	-
Goodwill	2,061,022	2,061,022
Security deposit	67,714	67,714
TOTAL ASSETS	$ 25,784,787	$ 18,388,376
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 1,501,848	$ 687,257
Accrued bonus and severance	711,937	1,048,393
Accrued interest	49,480	60,366
Current portion of term loan, net of discount and fees	3,594,495	2,909,709
Current lease liabilities	296,797	26,935
TOTAL CURRENT LIABILITIES	6,154,557	4,732,660
NON-CURRENT LIABILITIES		
Accrued interest, net of current portion	417,205	309,440
Term loan, net of discount, fees and current portion	2,467,370	4,280,385
Warrant liability	15,617,229	2,537,317
Accrued dividends	429,953	-
Other liabilities	377,963	84,281
TOTAL LIABILITIES	25,464,277	11,944,083
Series A convertible preferred stock: $0.001 par value; liquidation value of $15,000,000; 45,000 shares designated, 15,000 and 0 issued and outstanding	13,661,578	-
Commitments and contingencies		
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock; $0.001 par value; 955,000 shares authorized; none issued and outstanding	-	-
Common stock; $0.001 par value; 100,000,000 shares authorized; 8,871,369 and 8,743,950 shares issued and outstanding	8,871	8,744
Additional paid-in capital	73,291,876	72,871,317
Accumulated deficit	(86,641,815)	(66,435,768)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(13,341,068)	6,444,293
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 25,784,787	$ 18,388,376

See accompanying notes to unaudited consolidated financial statements.

PLx Pharma Inc.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
REVENUES:				
Federal grant	$ 182,905	$ 167,459	$ 500,465	$ 248,916
TOTAL REVENUES	182,905	167,459	500,465	248,916
OPERATING EXPENSES:				
Research and development	1,598,884	734,246	2,591,588	1,813,282
General and administrative	2,433,200	1,830,586	4,677,360	4,070,586
TOTAL OPERATING EXPENSES	4,032,084	2,564,832	7,268,948	5,883,868
OPERATING LOSS	(3,849,179)	(2,397,373)	(6,768,483)	(5,634,952)
OTHER INCOME (EXPENSE)				
Interest income	135,092	75,175	217,442	142,098
Interest and other expense	(280,232)	(283,285)	(575,094)	(558,684)
Change in fair value of warrant liability	(5,352,977)	(997,921)	(13,079,912)	7,426,726
TOTAL OTHER INCOME (EXPENSE)	(5,498,117)	(1,206,031)	(13,437,564)	7,010,140
INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES	(9,347,296)	(3,603,404)	(20,206,047)	1,375,188
Income taxes	-	-	-	-
NET INCOME (LOSS)	$ (9,347,296)	$ (3,603,404)	$ (20,206,047)	$ 1,375,188
Preferred dividends and beneficial conversion feature	$ (301,735)	$ -	$ (13,122,261)	$ -
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (9,649,031)	$ (3,603,404)	$ (33,328,308)	$ 1,375,188
Net income (loss) per common share - basic	$ (1.10)	$ (0.41)	$ (3.80)	$ 0.16
Net income (loss) per common share - diluted	$ (1.10)	$ (0.41)	$ (3.80)	$ 0.16
Weighted average shares of common shares - basic	8,779,909	8,729,962	8,779,096	8,727,514
Weighted average shares of common shares - diluted	8,779,909	8,729,962	8,779,096	8,727,514

See accompanying notes to unaudited consolidated financial statements.

PLx Pharma Inc.
UNAUDITED CONSOLIDATED STATEMENTS OF CHANGES IN TEMPORARY EQUITY AND STOCKHOLDERS' EQUITY (DEFICIT)

	Temporary Equity		Permanent Equity				
	Series A Redeemable Convertible Preferred Stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	-	$ -	8,722,823	$ 8,723	$ 71,939,917	$ (67,332,248)	$ 4,616,392
Share-based compensation expense					281,505		281,505
Common shares issued to vendor			3,375	4	22,496		22,500
Net income						4,978,592	4,978,592
Balance at March 31, 2018	-	-	8,726,198	8,727	72,243,918	(62,353,656)	9,898,989
Share-based compensation expense					236,095		236,095
Common shares issued to vendor			5,558	5	22,495		22,500
Net loss						(3,603,404)	(3,603,404)
Balance at June 30, 2018	-	$ -	8,731,756	$ 8,732	$ 72,502,508	$ (65,957,060)	$ 6,554,180
Balance at December 31, 2018	-	$ -	8,743,950	$ 8,744	$ 72,871,317	$ (66,435,768)	$ 6,444,293
Share-based compensation expense					66,232		66,232
Issuance of Series A Preferred Stock, net of issuance costs	15,000	13,661,578					-
Series A Preferred - beneficial conversion feature at issuance					12,692,308		12,692,308
Series A Preferred - conversion feature deemed dividend					(12,692,308)		(12,692,308)
Common shares issued to vendor			8,228	8	22,492		22,500
Series A Preferred - declared dividends					(128,218)		(128,218)
Net loss						(10,858,751)	(10,858,751)
Balance at March 31, 2019	15,000	13,661,578	8,752,178	8,752	72,831,823	(77,294,519)	(4,453,944)
Share-based compensation expense					276,505		276,505
Common shares issued to vendor			4,218	4	22,496		22,500
Common shares issued, net of issuance costs - ATM			114,973	115	462,787		462,902
Series A Preferred - declared dividends					(301,735)		(301,735)
Net loss						(9,347,296)	(9,347,296)
Balance at June 30, 2019	15,000	$ 13,661,578	8,871,369	$ 8,871	$ 73,291,876	$ (86,641,815)	$ (13,341,068)

See accompanying notes to unaudited consolidated financial statements.

PLx Pharma Inc.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended June 30, 2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	$ (20,206,047)	$ 1,375,188
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	95,132	89,451
Share-based compensation	342,737	517,600
Amortization of debt discounts and issuance costs	121,771	122,883
Change in fair value of warrant liability	13,079,912	(7,426,726)
Provision for obsolete inventory	-	475,417
Loss on sale of property and equipment	12,398	-
Changes in operating assets and liabilities		
Accounts receivable	(175,498)	(108,204)
Inventory	-	(229,043)
Prepaid expenses and other assets	155,391	(144,888)
Lease assets	137,581	-
Accounts payable and accrued liabilities	958,536	(239,937)
Accrued bonus and severance	(336,456)	(345,398)
Accrued interest	96,879	110,432
Other current and long-term liabilities	(148,990)	(10,706)
Net cash used in operating activities	(5,866,654)	(5,813,931)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(12,892)	(665,728)
Proceeds from sale of property and equipment	11,442	-
Net cash used in investing activities	(1,450)	(665,728)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of convertible Series A preferred stock	13,661,578	-
Net proceeds from issuance of common stock	462,902	-
Repayments of term loan	(1,250,000)	-
Net cash provided by financing activities	12,874,480	-
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	7,006,376	(6,479,659)
Cash and cash equivalents, beginning of period	14,250,267	24,404,368
Cash and cash equivalents, end of period	$ 21,256,643	$ 17,924,709
SUPPLEMENTAL INFORMATION		
Cash paid during the period for:		
Income taxes	$ -	$ -
Interest	$ 344,046	$ 325,313
NON-CASH INVESTING AND FINANCING TRANSACTIONS		
Property and equipment included in accounts payable	$ 76,031	$ -
Preferred stock beneficial conversion feature and dividends	$ 13,122,261	$ -
Value of common shares issued to vendor for services	$ 45,000	$ 45,000

See accompanying notes to unaudited consolidated financial statements.

PLx Pharma Inc.
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2019

NOTE 1. BACKGROUND AND ORGANIZATION

Business Operations

PLx Pharma Inc., together with its subsidiaries PLx Opco Inc. and PLx Chile SpA, is a late-stage startup specialty pharmaceutical company focusing initially on commercializing two patent-protected lead products: Vazalore ™ 325 mg and Vazalore ™ 81 mg (referred to together as "Vazalore"). Vazalore 325 mg is approved by the U.S. Food and Drug Administration ("FDA") for over-the-counter distribution and is the first ever liquid-filled aspirin capsule.

PLx Chile SpA was formed on September 12, 2011 as a wholly-owned subsidiary of PLx Opco Inc. The Company dissolved its wholly-owned and dormant subsidiary Dipexium Pharmaceuticals Ireland Limited in December 2018.

NOTE 2. LIQUIDITY AND GOING CONCERN

The accompanying unaudited consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations, the ability to generate sufficient cash from operations and potential other funding sources, in addition to cash on-hand, to meet its obligations as they become due. The Company has not generated any revenue from sale of products, and has incurred operating losses in each year since it commenced operations. As of June 30, 2019, the Company had an accumulated deficit of $86.6 million. The Company expects to continue to incur significant expenses and increasing operating losses for the foreseeable future as the Company continues the development and commercialization of its candidates. However, based on the Company's expected operating cash requirements and capital expenditures, the Company believes its cash on hand at June 30, 2019 is adequate to fund obligations for at least twelve months from the date that these financial statements are issued.

NOTE 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting and Principles of Consolidation

The accompanying interim consolidated financial statements are unaudited. These unaudited interim consolidated financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all the information and footnotes required by U.S. Generally Accepted Accounting Principles ("GAAP") for complete financial statements. The December 31, 2018 consolidated balance sheet included herein was derived from audited consolidated financial statements as of that date. Certain information and footnote disclosure normally included in financial statements prepared in accordance with GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the SEC. The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim consolidated financial statements are read in conjunction with the audited financial statements and notes previously filed in its Annual Report on Form 10-K for the year ended December 31, 2018. In the opinion of management, the unaudited interim consolidated financial statements reflect all the adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of June 30, 2019 and the results of operations for the three and six months ended June 30, 2019 and 2018.

The accompanying consolidated financial statements include the accounts of the Company and its direct and indirect wholly-owned subsidiaries, PLx Opco Inc. and PLx Chile SpA. All significant intercompany balances and transactions have been eliminated within the consolidated financial statements. The Company operates in one business segment.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, determining the fair value of tangible and intangible assets and liabilities acquired in business combinations, the fair value of warrant liabilities and other financial instruments, stock-based compensation, allowance for inventory obsolescence, allowance for doubtful accounts, contingent liabilities, the fair value and depreciable lives of long-lived tangible and intangible assets, and deferred taxes and the associated valuation allowance. Actual results could differ from those estimates.

Foreign Currency
The functional currency of the Company's foreign subsidiaries has been designated as the U.S. dollar. Foreign currency transaction gains and losses, excluding gains and losses on intercompany balances where there is no current intent to settle such amounts in the foreseeable future, are included in the determination of net loss. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

Cash and Cash Equivalents
The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. The Company maintains cash and cash equivalents in a financial institution that at times exceeds federally insured limits. Management believes that the Company's credit risk exposure is mitigated by the financial strength of the banking institution in which the deposits are held. As of June 30, 2019, the Company had cash and cash equivalents of approximately $21.3 million in U.S. bank accounts which were not fully insured by the Federal Deposit Insurance Corporation.

Allowance for Uncollectible Accounts Receivable
An allowance for uncollectible accounts receivable is estimated based on historical experience, credit quality, age of the accounts receivable balances, and economic conditions that may affect a customer's ability to pay. The allowance for uncollectible accounts receivable was zero as of June 30, 2019 and December 31, 2018, respectively.

Inventory
Inventory is stated at the lower of cost or net realizable value, using the average cost method. Inventory as of June 30, 2019 and December 31, 2018 was comprised of raw materials for the manufacture of Vazalore. The Company regularly reviews inventory quantities on hand and assesses the need for an allowance for obsolescence. The allowance for obsolete inventory was approximately $0.6 million and $1.0 million as of June 30, 2019 and December 31, 2018, respectively, resulting in net inventory of zero for both periods.

Fair Value of Financial Instruments
Certain financial instruments (cash and cash equivalents, receivables, and accounts payable) classified as current assets and liabilities are carried at cost, which approximates fair value, because of the short-term maturities of those instruments. The fair value of the term loan approximates its face value of $6,250,000 based on the Company's current financial condition and on the variable nature of the term loan's interest feature as compared to current rates. For disclosures concerning fair value measurements, see Note 7.

Property and Equipment
Property and equipment are stated at cost less accumulated depreciation. The Company capitalizes additions that have a tangible future economic life. Maintenance and repairs that do not improve or extend the lives of property and equipment are charged to operations as incurred. Depreciation expense is computed using the straight-line method over the estimated useful lives of each class of depreciable assets. Management reviews property and equipment for possible impairment whenever events or circumstances indicate the carrying amount of an asset may not be recoverable. If there is an indication of impairment, management prepares an estimate of future cash flows (undiscounted and without interest charges) expected to result from the use of the asset and its eventual disposition. If these cash flows are less than the carrying amount of the asset, an impairment loss is recognized to write down the asset to its estimated fair value.

Leases
At the inception of a contract, the Company determines if the arrangement is, or contains, a lease. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Rent expense is recognized on a straight-line basis over the lease term.

The Company has made certain accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combines lease and non-lease elements of its operating leases. Operating lease ROU assets are included in leased assets and operating lease liabilities are included in other current and non-current liabilities in the Company's consolidated balance sheets. As of June 30, 2019, the Company did not have any finance leases.

Goodwill
Goodwill is not amortized but is subject to periodic review for impairment. Goodwill is reviewed annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. Management performs its review of goodwill on its one reporting unit.

The Company performs a one-step test in its evaluation of the carrying value of goodwill, if qualitative factors determine it is necessary to complete a goodwill impairment test. In the evaluation, the fair value of the relevant reporting unit is determined and compared to the carrying value. If the fair value is greater than the carrying value, then the carrying value is deemed to be recoverable, and no further action is required. If the fair value estimate is less than the carrying value, goodwill is considered impaired for the amount by which the carrying amount exceeds the reporting unit's fair value, and a charge is reported in impairment of goodwill in the Company's consolidated statements of operations.

The Company has not identified any events or changes in circumstances that indicate that a potential impairment of goodwill occurred during the six months ended June 30, 2019 and 2018.

Revenue Recognition
The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers; (ii) identification of distinct performance obligations in the contract; (iii) determination of contract transaction price; (iv) allocation of contract transaction price to the performance obligations; and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation. The Company recognizes revenues upon the satisfaction of its performance obligations (upon transfer of control of promised goods or services to customers) in an amount that reflects the consideration to which it expects to be entitled to in exchange for those goods or services. Deferred revenue results from cash receipts from or amounts billed to customers in advance of the transfer of control of the promised services to the customer and is recognized as performance obligations are satisfied. When sales commissions or other costs to obtain contracts with customers are considered incremental and recoverable, those costs are deferred and then amortized as selling and marketing expenses on a straight-line basis over an estimated period of benefit.

The Company's current sole revenue arrangement is a cost-reimbursable federal grant with the National Institutes of Health. The Company recognizes revenue on this grant as grant-related expenses are incurred by the Company or its subcontractors. The Company recognized $182,905 and $167,459 of revenue under this arrangement during the three months ended June 30, 2019 and 2018, respectively. The Company recognized $500,465 and $248,916 of revenue under this arrangement during the six months ended June 30, 2019 and 2018, respectively.

The Company has not incurred incremental costs to obtain contracts with customers or material costs to fulfill contracts with customers and did not have any material contract assets or liabilities as of June 30, 2019 and December 31, 2018.

Research and Development Expenses
Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses consist of direct and indirect costs associated with specific projects and include fees paid to various entities that perform research related services for the Company combined with reimbursable costs related to the federal grant with the National Institutes of Health.

Share-Based Compensation
The Company recognizes expense in its consolidated statements of operations for the fair value of all share-based compensation to key employees, nonemployee directors and advisors, generally in the form of stock options and stock awards. The Company uses the Black-Scholes option valuation model to estimate the fair value of stock options on the grant date. Compensation cost is amortized on a straight-line basis over the vesting period for each respective award.

Income Taxes
Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred income tax assets to the amount expected to be realized.

Tax benefits are initially recognized in the financial statements when it is more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions are initially, and subsequently, measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts.

Income (Loss) per Share
Basic income (loss) per share is computed by dividing net income (loss) available to common stockholders by the weighted average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common shares underlying common stock options and stock purchase warrants using the treasury stock method, and convertible preferred stock using the if-converted method. None of the potential dilutive securities had a dilutive impact during the three and six months ended June 30, 2019 and 2018. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all potential dilutive common shares is anti-dilutive.

The number of anti-dilutive shares, consisting of common shares underlying (i) common stock options, (ii) stock purchase warrants, and (iii) convertible preferred stock, which have been excluded from the computation of diluted loss per share, was 10,422,494 shares and 3,841,302 shares as of June 30, 2019 and 2018, respectively.

Reclassifications
Certain reclassifications have been made to the prior-year financial statements to conform to the current-year presentation.

Recent Accounting Developments

Recently Adopted Guidance
In February 2016, the Financial Accounting Standards Board (the "FASB") issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. The Company adopted this guidance effective January 1, 2019 using the following practical expedients:

- the Company did not reassess if any expired or existing contracts are or contain leases; and
- the Company did not reassess the classification of any expired or existing leases.

Additionally, the Company made ongoing accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combines lease and non-lease elements of its operating leases.

Upon adoption of the new guidance on January 1, 2019, the Company recorded a ROU of $712,534 and recognized a lease liability of $789,543, with no resulting cumulative effect adjustment to retained earnings.

In June 2018, the FASB issued guidance with respect to the accounting for nonemployee share-based payment awards. The guidance generally aligns the accounting for nonemployee awards to that for employees. The guidance is effective for fiscal years beginning after December 15, 2018. The Company adopted this guidance on January 1, 2019 and the adoption did not have a material impact on its financial statements.

Unadopted Guidance
In August 2018, the FASB issued guidance with respect to the disclosure requirements for fair value measurements. The guidance intends to improve the effectiveness of the disclosures relating to recurring and nonrecurring fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019. Portions of the guidance are to be adopted prospectively while other portions are to be adopted retroactively. Early adoption is permitted. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

The Company does not believe that any other recently issued effective standards, or standards issued but not yet effective, if adopted, would have a material effect on the accompanying consolidated financial statements.

Subsequent Events
The Company's management reviewed all material events through the date the consolidated financial statements were issued for subsequent event disclosure consideration.

NOTE 4. DEBT

Term Loan Facility
On August 9, 2017, the Company entered into a Loan and Security Agreement with Silicon Valley Bank ("SVB") that provides for a Term Loan Facility (the "Term Loan Facility" and all amounts borrowed thereunder, the "Term Loan"). Under the Term Loan Facility, the Company borrowed an initial amount of $7.5 million, and had the right to borrow an additional $7.5 million on or before December 31, 2018, provided that the Company met certain conditions; the Company did not meet those conditions.

The Term Loan Facility carries interest at a floating rate of 4.0% above the prime rate per annum (for a total interest rate of 9.5% at June 30, 2019), with interest payable monthly. All outstanding principal and accrued and unpaid interest under the Term Loan will be due and payable on February 9, 2021.

The Company may elect to prepay the Term Loan Facility prior to the maturity date subject to defined prepayment fees. The Term Loan Facility includes a final payment fee equal to 8.0% of the original principal amount, which is being accrued using the effective interest method over the term.

The Term Loan Facility is collateralized by substantially all of the Company's assets, contains certain restrictive covenants, and contains customary events of default. Upon the occurrence of an event of default all amounts owed by the Company would begin to bear interest at a rate that is 5.00% above the rate effective immediately before the event of default and may be declared immediately due and payable by SVB.

In connection with entry into the Term Loan Facility, the Company issued to SVB and one of its affiliates, stock purchase warrants to purchase an aggregate of 58,502 shares of the Company's common stock at an exercise price of $6.41 per share. The warrants are immediately exercisable, have a 10-year term, contain a cashless exercise provision, and are classified in equity.

As of June 30, 2019 and December 31, 2018, $6.3 million and $7.5 million of the Term Loan was outstanding, respectively, and was presented in the accompanying consolidated balance sheets net of current unamortized discounts and issuance costs of $155,505 and $215,291, and long-term unamortized discounts and issuance cost of $32,630 and $94,615, respectively. Total interest expense recognized for the three months ended June 30, 2019 and 2018 was $267,834 and $283,285, respectively. Total interest expense recognized for the six months ended June 30, 2019 and 2018 was $562,696 and $558,684, respectively.

NOTE 5. STOCKHOLDERS' EQUITY

Common Stock

Equity Distribution Agreement
In March 2019, the Company entered into an equity distribution agreement with JMP Securities, Inc. ("JMP"). Pursuant to the terms of the agreement, the Company may sell from time to time, at its option, shares of the Company's common stock, through JMP, as sales agent, with an aggregate sales price of up to $12.5 million. Any sales of shares pursuant to the agreement will be made under the Company's effective "shelf" registration statement, which allows it to sell debt or equity securities in one or more offerings up to a total public offering price of $75 million. In 2019, the Company issued 114,973 shares under the agreement generating gross proceeds of approximately $629,000 and net proceeds of approximately $463,000 after deducting legal and commission costs. As of June 30, 2019, approximately $11.9 million remained available under the agreement.

Convertible Preferred Stock
In December 2018, the Company entered into a purchase agreement with certain accredited investors for the private placement of $15.0 million of Series A Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock") pending stockholders' approval, which approval was subsequently obtained on February 19, 2019. Accordingly, the Company completed the private placement on February 20, 2019, raising $15.0 million through the issuance of 15,000 shares of Series A Preferred Stock. The Series A Preferred Stock was issued at $1,000 per share and is convertible into common shares at a conversion price of $2.60 per share, subject to certain adjustments. Holders of the Series A Preferred Stock will be entitled to an initial dividend rate of 8.0% per annum, which will stop accruing on the date of the FDA's approval of the supplemental sNDA of Vazalore 325 mg and Vazalore 81mg. The dividends are compounded quarterly and payable in cash or shares of Series A Preferred Stock at the Company's option. The Series A Preferred Stock carries a liquidation preference equal to its stated value of $1,000 plus accrued and unpaid dividends.

The Series A Preferred Stock is classified as temporary equity due to the presence of certain contingent cash redemption features. A beneficial conversion feature in the amount of $12.7 million was bifurcated from the host instrument and accounted for separately as an increase in additional paid-in capital in equity, and resulted in a deemed dividend during the three months ended March 31, 2019 of $12.7 million which was accounted for as a decrease in additional paid-in capital in equity due to the Company's accumulated deficit position. At June 30, 2019, the carrying value of the temporary equity was net of approximately $1.3 million in offering costs.

The Company recognized $301,735 (or $0.03 per share) and $429,953 (or $0.05 per share) of total dividends on the Series A Preferred Stock during the three and six months ended June 30, 2019, respectively. No dividends were recognized on common stock during any of the periods presented.

Warrants
In June 2017, the Company issued stock purchase warrants to purchase 2,646,091 shares of common stock at an exercise price of $7.50 per share. The warrants, exercisable beginning six months and one day after issuance, have a 10-year term and are liability classified due the holders' right to require the Company to repurchase the warrants for cash upon certain deferred fundamental transactions.

In connection with the entry into the Term Loan Facility, the Company issued to SVB and one of its affiliates stock purchase warrants to purchase an aggregate of 58,502 shares of the Company's common stock at an exercise price of $6.41 per share (see Note 4). These warrants are immediately exercisable, have a 10-year term, contain a cashless exercise provision, and are classified in equity.

Stock Options
Following is a summary of option activities for the six months ended June 30, 2019:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2018	1,206,709	$ 17.93	7.0	$ -
Granted	714,350	$ 5.76		
Exercised, cancelled or forfeited	(137,755)	$ 9.22		
Outstanding, June 30, 2019	1,783,304	$ 13.73	7.7	$ 1,427,487
Exercisable, June 30, 2019	954,954	$ 20.80	6.1	$ 84,564

On September 13, 2018, the Company's shareholders approved the 2018 Incentive Plan (the "2018 Plan"). The 2018 Plan provides that the Company may grant equity interests to employees, consultants and members of the Board of Directors in the form of incentive and nonqualified stock options, restricted stock and restricted stock units, stock appreciation rights and various other forms of stock-based awards. 1,250,000 shares are authorized to be issued pursuant to the 2018 Plan.

The Company granted 714,350 options during the six months ended June 30, 2019 with an aggregate fair value of approximately $2.9 million calculated using the Black-Scholes model on the grant date. Variables used in the Black-Scholes model include: (1) discount rate range from 1.9% to 2.5%, (2) expected life of 6.0 years, (3) expected volatility of 82%, and (4) zero expected dividends.

As of June 30, 2019, the Company had $2.9 million in unamortized expense related to unvested options which is expected to be expensed over a weighted average of 2.6 years.

During the three months ended June 30, 2019 and 2018, the Company recorded $276,505 and $236,095, respectively, in total share-based compensation expense related to the stock options and stock bonuses. During the six months ended June 30, 2019 and 2018, the Company recorded $342,737 and $517,600, respectively, in total compensation expense related to the stock options and stock bonuses. Substantially all share-based compensation expense is classified as general and administrative expenses in the accompanying unaudited consolidated statements of operations.

NOTE 6. COMMITMENTS AND CONTINGENCIES

Lease Agreements
The Company presently leases office space under operating lease agreements, expiring on December 31, 2019, July 31, 2021 and October 3, 2021. The office leases require the Company to pay for its portion of taxes, maintenance and insurance. Rental expense under these agreements was $94,137 and $24,368 for the three months ended June 30, 2019 and 2018, respectively. Rental expense under these agreements was $184,481 and $57,137 for the six months ended June 30, 2019 and 2018, respectively. Rent expense for 2018 excludes New York lease costs as it was not restated for the new lease guidance.

All the Company's existing leases as of June 30, 2019 are classified as operating leases. As of June 30, 2019, the Company has four operating leases for facilities and office equipment with remaining terms expiring from 2019 through 2022 and a weighted average remaining lease term of 2.1 years. Many of the Company's existing leases have fair value renewal options, none of which the Company considers certain of being exercised or included in the minimum lease term. Discount rates used in the calculation of the Company's lease liability is approximately 9.5%. In addition, the Company is the lessor for office space in New York that it sublets to a tenant; the sublease expires in 2021.

Lease costs, net of sublease income, for the six months ended June 30, 2019 consisted of the following:

Operating lease cost	$ 172,132
Variable lease costs	12,349
Sublease income	(117,033)
Total lease costs	$ 67,448

A maturity analysis of the Company's operating leases follows:

Future undiscounted cash flows:

2019	$	184,705
2020		320,484
2021		203,141
Total		708,330
Discount factor		(67,778)
Lease liabilty		640,552
Current lease liability		(296,797)
Non-current lease liability	$	343,755

Patent License Agreement with the Board of Regents of the University of Texas ("NSAIDs")
On January 8, 2003, the Company entered into a patent license agreement with the Board of Regents of The University of Texas System (the "University"), under which it acquired an exclusive license for several patents and patent applications both inside and outside of the United States relating to gastrointestinal safer formulations of NSAIDs. Additionally, the Company acquired worldwide rights to commercialize licensed products which allow for the Company to grant sublicenses subject to royalty payments.

Under terms of the agreement, the Company is responsible for conducting clinical trials involving investigational use of a licensed product for the determination of metabolic and pharmacologic actions in humans, the side effects associated with increasing doses, examination of suspected indications, determination of the potential short-term side effects in humans and for establishing the safety, efficacy, labeled indications and risk-benefit profile in humans. The patent license agreement also requires the Company to provide reimbursement for all expenses incurred by The University of Texas Health Science Center at Houston for filing, prosecuting, enforcing and maintaining patent rights and requires an annual nonrefundable license management fee. In addition, the Company is obligated to pay certain milestone payments in future years relating to royalties resulting from the approval to sell licensed products and the resulting sales of such licensed products. The Company recognized total expenses of $225,000 and $3,099 related to the University in the three months ended June 30, 2019 and 2018, respectively. The Company recognized total expenses of $250,000 and $49,119 related to the University in the six months ended June 30, 2019 and 2018, respectively.

Investor Relations Agreement
On March 21, 2017, the Company entered into an agreement with an investor relations firm which expired in June 2019. The Company agreed to pay a monthly fee of $15,000 starting May 1, 2017. The $15,000 monthly fee is $7,500 payable in cash and $7,500 payable in shares of the Company's common stock. The Company issued 12,446 and 8,933 shares of common stock during the six months ended June 30, 2019 and 2018, respectively, as full payment for services during such period.

NOTE 7. FAIR VALUE MEASUREMENTS

Fair value is defined as the price that would be received in the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company has categorized all investments recorded at fair value based upon the level of judgment associated with the inputs used to measure their fair value.

Hierarchical levels, directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities, are as follows:

- Level 1: Quoted prices in active markets for identical assets or liabilities that the organization has the ability to access at the reporting date.
- Level 2: Inputs other than quoted prices included in Level 1, which are either observable or that can be derived from or corroborated by observable data as of the reporting date.
- Level 3: Inputs include those that are significant to the fair value of the asset or liability and are generally less observable from objective resources and reflect the reporting entity's subjective determinations regarding the assumptions market participants would use in pricing the asset or liability.

Financial assets and liabilities measured at fair value on a recurring basis
The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the hierarchy.

The stock purchase warrants issued in June 2017 contain certain cash settlement features and, accordingly, the Company considered them to be liabilities and accounted for them at fair value using Level 3 inputs. The Company determined the estimated fair value of this warrant liability using a binomial asset pricing model that consisted of a conditional probability weighted expected return method that values the Company's equity securities assuming various possible future outcomes to estimate the allocation of value within one or more of the scenarios. Using this method, unobservable inputs included the Company's equity value, expected timing and probability of possible outcomes, risk free interest rates and stock price volatility.

The Series A Preferred Stock contains a contingent put option and, accordingly, the Company considered it to be a liability and accounted for it at fair value using Level 3 inputs. The Company determined the fair value of this liability was *de minimis* at issuance and as of June 30, 2019 due to the remote possibly of its occurrence, a Level 3 unobservable input.

The following table sets forth a summary of changes in the fair value of Level 3 liabilities measured at fair value on a recurring basis for the three months ended June 30, 2019:

Description	Balance at March 31, 2019	Established in 2019	Change in Fair Value	Balance at June 30, 2019
Warrant liability	$ 10,264,252	$ -	$ 5,352,977	$ 15,617,229
Put option	$ -	$ -	$ -	$ -

The following table sets forth a summary of changes in the fair value of Level 3 liabilities measured at fair value on a recurring basis for the six months ended June 30, 2019:

Description	Balance at December 31, 2018	Established in 2019	Change in Fair Value	Balance at June 30, 2019
Warrant liability	$ 2,537,317	$ -	$ 13,079,912	$ 15,617,229
Put option	$ -	$ -	$ -	$ -

The following table identifies the carrying amounts of such liabilities at June 30, 2019 and December 31, 2018:

	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 15,617,229	$ 15,617,229
Put option	$ -	$ -	$ -	$ -
Balance at June 30, 2019	$ -	$ -	$ 15,617,229	$ 15,617,229

	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 2,537,317	$ 2,537,317
Balance at December 31, 2018	$ -	$ -	$ 2,537,317	$ 2,537,317

Financial assets and liabilities carried at fair value on a non-recurring basis
The Company does not have any financial assets or liabilities measured at fair value on a non-recurring basis.

Non-financial assets and liabilities carried at fair value on a recurring basis
The Company does not have any non-financial assets or liabilities measured at fair value on a recurring basis.

Non-financial assets and liabilities carried at fair value on a non-recurring basis
The Company measures its long-lived assets, including property and equipment and including goodwill, at fair value on a non-recurring basis when they are deemed to be impaired. No such impairment was recognized in the three and six months ended June 30, 2019 and 2018.

NOTE 8. SUBSEQUENT EVENTS

Subsequent to June 30, 2019, the Company issued 171,743 shares under the JMP equity distribution agreement generating net proceeds of $1.1 million after deducting commission costs.

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

Statements in this Quarterly Report on Form 10-Q (the "Quarterly Report") that are not strictly historical are forward-looking statements and include statements about products in development, results and analyses of pre-clinical studies, clinical trials and studies, research and development expenses, cash expenditures, and alliances and partnerships, among other matters. You can identify these forward-looking statements because they involve our expectations, intentions, beliefs, plans, projections, anticipations, or other characterizations of future events or circumstances. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those in the forward-looking statements as a result of any number of factors. These factors include, but are not limited to, risks relating to our ability to conduct and obtain successful results from ongoing clinical trials, commercialize our technology, obtain regulatory approval for our product candidates, contract with third parties to adequately test and manufacture our proposed therapeutic products, protect our intellectual property rights and obtain additional financing to continue our development efforts. We do not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.

We urge you to read this entire Quarterly Report, including the "Risk Factors" referenced under Part II. Item 1A, the financial statements, and related notes. As used in this Quarterly Report, unless the context otherwise requires, the words "we," "us," "our," "the Company" and "PLx Pharma" refers to PLx Pharma Inc. and its subsidiaries. The information contained herein is current as of the date of this Quarterly Report (June 30, 2019), unless another date is specified. We prepare our interim financial statements in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP"). Our financials and results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2019. The interim financial statements presented in this Quarterly Report as well as other information relating to the Company contained in this Quarterly Report should be read in conjunction and together with the reports, statements and information filed by us with the United States Securities and Exchange Commission (the "SEC").

Our Management's Discussion and Analysis of Financial Condition and Results of Operations is provided in addition to the accompanying financial statements and notes to assist readers in understanding our results of operations, financial condition and cash flows.

Overview

We are a late-stage specialty pharmaceutical company initially focused on developing our clinically-validated and patent-protected PLxGuard delivery system to provide more effective and safer products. Our PLxGuard delivery system works by releasing active pharmaceutical ingredients into the duodenum, the first part of the small intestine immediately below the stomach, rather than in the stomach itself. We believe this may improve the absorption of many drugs currently on the market or in development and reduces gastrointestinal ("GI") side effects common in an acute setting — including erosions, ulcers and bleeding — associated with aspirin and ibuprofen, and potentially other drugs.

The U.S. Food and Drug Administration (the "FDA") approved our lead product, Vazalore 325 mg, which is a novel formulation of aspirin using the PLxGuard delivery system intended to provide better antiplatelet effectiveness for cardiovascular disease prevention as compared to the current standard of care, enteric-coated aspirin and significantly reduce GI side effects as compared with immediate-release aspirin. Vazalore 325 mg (formerly PL2200 Aspirin 325 mg and Aspertec 325 mg) was originally approved under the drug name aspirin, and the proprietary name 'Vazalore' was granted subsequent to the FDA approval. A companion 81 mg dose of the same novel formulation — Vazalore 81 mg — is in late-stage development and will be the subject of a supplemental New Drug Application ("sNDA"), leveraging the already approved status of Vazalore 325 mg. We are focused on manufacturing, scale-up and label finalization for Vazalore 325 mg aspirin dosage form and preparing an sNDA for Vazalore 81 mg maintenance dosage form. Our goal is to begin selling both products in the United States by mid-2020, subject to approval by the FDA.

Our commercialization strategy will target both the over-the-counter ("OTC") and prescription markets, taking advantage of the existing OTC distribution channels for aspirin while leveraging the FDA approval of Vazalore 325 mg and expected approval for Vazalore 81 mg for OTC and prescription use when recommended by physicians for cardiovascular disease treatment and prevention. Given our clinical demonstration of better antiplatelet efficacy (as compared with enteric-coated aspirin) and better GI safety, we intend to use a physician-directed sales force to inform physicians — and, by extension, consumers — about our product's clinical results in an effort to command both greater market share and a higher price for our novel and innovative aspirin product. Our product pipeline also includes other oral nonsteroidal anti-inflammatory drugs ("NSAIDs") using the PLxGuard delivery system that may be developed, including a clinical-stage, GI-safer ibuprofen — PL1200 Ibuprofen 200 mg — for pain and inflammation.

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Note 3 of the Notes to Unaudited Consolidated Financial Statements included elsewhere herein describes the significant accounting policies used in the preparation of the financial statements. Certain of these significant accounting policies are considered to be critical accounting policies, as defined below.

A critical accounting policy is defined as one that is both material to the presentation of our financial statements and requires management to make difficult, subjective or complex judgments that could have a material effect on our financial condition and results of operations. Specifically, critical accounting estimates have the following attributes: (1) we are required to make assumptions about matters that are highly uncertain at the time of the estimate; and (2) different estimates we could reasonably have used, or changes in the estimate that are reasonably likely to occur, would have a material effect on our financial condition or results of operations.

Estimates and assumptions about future events and their effects cannot be determined with certainty. We base our estimates on historical experience and on various other assumptions believed to be applicable and reasonable under the circumstances. These estimates may change as new events occur, as additional information is obtained and as our operating environment changes. These changes have historically been minor and have been included in the financial statements as soon as they became known. Based on a critical assessment of our accounting policies and the underlying judgments and uncertainties affecting the application of those policies, management believes that our financial statements are fairly stated in accordance with U.S. GAAP and present a meaningful presentation of our financial condition and results of operations. We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our consolidated financial statements:

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, determining the fair value of tangible and intangible assets and liabilities acquired in business combinations, the fair value of warrant liabilities and other financial instruments, stock-based compensation, allowance for inventory obsolescence, allowance for doubtful accounts, contingent liabilities, the fair value and depreciable lives of long-lived tangible and intangible assets, and deferred taxes and the associated valuation allowance. Actual results could differ from those estimates.

Fair Value Measurements

Fair value is defined as the price that would be received in the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company has categorized all investments recorded at fair value based upon the level of judgment associated with the inputs used to measure their fair value.

Hierarchical levels, directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities, are as follows:

- Level 1: Quoted prices in active markets for identical assets or liabilities that the organization has the ability to access at the reporting date.
- Level 2: Inputs other than quoted prices included in Level 1, which are either observable or that can be derived from or corroborated by observable data as of the reporting date.
- Level 3: Inputs include those that are significant to the fair value of the asset or liability and are generally less observable from objective resources and reflect the reporting entity's assumptions about the assumptions market participants would use in pricing the asset or liability.

The Company's financial instruments (cash and cash equivalents, receivables, accounts payable and accrued liabilities) are carried in the consolidated balance sheet at cost, which reasonably approximates fair value based on their short-term nature. The Company's warrant and put option liabilities are recorded at fair value, with changes in fair value being reflected in the statements of operations for the period of change. The fair value of the term loan approximates its face value of $6.3 million based on the Company's current financial condition and on the variable nature of term loan's interest feature as compared to current rates.

Research and Development Expenses
Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses consist of direct and indirect costs associated with specific projects and include fees paid to various entities that perform research related services for the Company.

Share-Based Compensation
The Company recognizes expense in the consolidated statements of operations for the fair value of all share-based compensation to key employees, nonemployee directors and advisors, generally in the form of stock options and stock awards. The Company uses the Black-Scholes option valuation model to estimate the fair value of stock options on the grant date. Compensation cost is amortized on a straight-line basis over the vesting period for each respective award.

Adopted Accounting Guidance
For a discussion of significant accounting guidance recently adopted or unadopted accounting guidance that has the potential of being significant, see Note 3 of the Notes to Unaudited Consolidated Financial Statements included elsewhere herein.

RESULTS OF OPERATIONS

Comparison of Three Months Ended June 30, 2019 and 2018

Revenue

Total revenues were $182,905 for the three months ended June 30, 2019, compared to revenues of $167,459 for the three months ended June 30, 2018. Revenue in both the 2019 and 2018 periods is attributable to work performed under a federal grant from the National Institutes of Health.

Operating Expenses

Total operating expenses were approximately $4.0 million during the three months ended June 30, 2019, a 57% increase from operating expenses of approximately $2.6 million in the comparable period in 2018. Operating expenses for the three months ended June 30, 2019 and 2018 were as follows:

	Three Months Ended June 30,		Increase (Decrease)	
	2019	2018	$	%
Operating Expenses				
Research and development expenses	$ 1,598,884	$ 734,246	$ 864,638	118%
General and administrative expenses	2,433,200	1,830,586	602,614	33%
Total operating expenses	$ 4,032,084	$ 2,564,832	$ 1,467,252	57%

Research and Development Expenses

Research and development expenses totaled approximately $1.6 million in the three months ended June 30, 2019, compared to $0.7 million in the prior year period. The expenses in both periods included continued product development and manufacturing activities for Vazalore. The increase is due to the manufacturing of the registration batches to provide data for the sNDA submission.

General and Administrative Expenses

General and administrative expenses totaled approximately $2.4 million in the three months ended June 30, 2019, compared to $1.8 million in the prior year period. The $0.6 million increase is due to commercial related activities to support the upcoming launch of $0.4 million and payment to the University of Texas associated with the patent license agreement of $0.2 million.

Other income (expense), net

Other income (expense), net totaled approximately $5.5 million of net other expense in the three months ended June 30, 2019, compared to $1.2 million of net other expense in the prior year period. The change is largely attributable to the non-cash change in fair value of warrant liability primarily due to the fluctuation of the price of the Company's common stock ($5.4 million of net other expense in the three months ended June 30, 2019, compared to $1.0 million of other expense in the comparable 2018 period).

Comparison of Six Months Ended June 30, 2019 and 2018

Revenue

Total revenues were $500,465 for the six months ended June 30, 2019, compared to revenues of $248,916 for the six months ended June 30, 2018. Revenue in both the 2019 and 2018 periods is attributable to work performed under a federal grant from the National Institutes of Health.

Operating Expenses

Total operating expenses were approximately $7.3 million during the six months ended June 30, 2019, a 24% increase from operating expenses of approximately $5.9 million in the comparable period in 2018. Operating expenses for the six months ended June 30, 2019 and 2018 were as follows:

	Six Months Ended June 30,		Increase (Decrease)	
	2019	2018	$	%
Operating Expenses				
Research and development expenses	$ 2,591,588	$ 1,813,282	$ 778,306	43%
General and administrative expenses	4,677,360	4,070,586	606,774	15%
Total operating expenses	$ 7,268,948	$ 5,883,868	$ 1,385,080	24%

Research and Development Expenses

Research and development expenses totaled approximately $2.6 million in the six months ended June 30, 2019, compared to $1.8 million in the prior year period. The expenses in both periods included continued product development and manufacturing activities for Vazalore. The increase is due to the manufacture of the registration batches which provide data to be submitted in our sNDA filing.

General and Administrative Expenses

General and administrative expenses totaled approximately $4.7 million in the six months ended June 30, 2019, compared to $4.1 in the prior year period. This increase is due to commercial related activities to support the upcoming launch of $0.4 million and payment to the University of Texas associated with the patent license agreement of $0.2 million.

Other income (expense), net

Other income (expense), net totaled approximately $13.4 million of net other expense in the six months ended June 30, 2019, compared to $7.0 million of net other income in the prior year period. The change is largely attributable to the non-cash change in fair value of warrant liability primarily due to the fluctuation of the price of the Company's common stock ($13.1 million of net other expense in the six months ended June 30, 2019, compared to $7.4 million of other income in the comparable 2018 period).

LIQUIDITY AND CAPITAL RESOURCES

Financial Condition

The following table summarizes the primary uses and sources of cash for the periods indicated:

	Six Months Ended June 30,	
	2019	2018
Net cash used in operating activities	$ (5,866,654)	$ (5,813,931)
Net cash used in investing activities	$ (1,450)	$ (665,728)
Net cash provided by financing activities	$ 12,874,480	$ -

Net Cash Used in Operating Activities

Net cash used in operating activities of $5.9 million for the six months ended June 30, 2019 primarily reflects our net loss for the period of $20.2 million adjusted for various non-cash charges and income, including (i) $13.1 million change in fair value of warrant liability reflected as other expense, (ii) $0.3 million of share-based compensation, (iii) $0.1 million of amortization of debt discounts and issuance costs, and (iv) net operating asset/liability changes of approximately $0.7 million.

Net cash used in operating activities of approximately $5.8 million for the six months ended June 30, 2018 primarily reflects our net income for the period of approximately $1.4 million adjusted for various non-cash charges and income, including (i) approximately $7.4 million change in fair value of warrant liability reflected as other income, (ii) approximately $0.5 million for an increase to inventory obsolescence reserve, (iii) net operating asset/liability changes of approximately $1.0 million, partially offset by (iv) approximately $0.5 million of share- based compensation, (v) $0.1 million of amortization of debt discounts and issuance costs, and (vi) $0.1 million of depreciation expense.

Net Cash Used in Investing Activities

Net cash used in investing activities totaled $1,450 and approximately $0.7 million in the six months ended June 30, 2019 and 2018, respectively, relating to the purchase of property and equipment, net of proceeds from the sale of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled approximately $12.9 million in the six months ended June 30, 2019. Financing activities in the 2019 period consisted of approximately $13.7 million of Series A Convertible Preferred Stock ("Series A Preferred Stock") proceeds, net proceeds from the issuance of common stock of $0.5 million offset by $1.3 million debt repayment.

We have an effective shelf registration statement, which allows us to sell debt or equity securities in one or more offerings up to a total public offering price of $75 million. We believe that this shelf registration statement currently provides us additional flexibility with regard to potential financings that we may undertake when market conditions permit or our financial condition may require.

In March, 2019, we entered into an equity distribution agreement with JMP Securities, Inc. ("JMP"). Pursuant to the terms of the agreement, we may sell from time to time, at its option, shares of our common stock, through JMP, as sales agent, with an aggregate sales price of up to $12.5 million. Any sales of shares pursuant to the agreement will be made under our effective "shelf" registration statement. In 2019, we issued 114,973 shares under the agreement generating gross proceeds of approximately $629,000 and net proceeds of approximately $463,000 after deducting legal and commission costs. As of June 30, 2019, approximately $11.9 million remained available under the agreement.

We had no financing activity in the six months ended June 30, 2018.

Future Liquidity and Needs

As of June 30, 2019, we had working capital of approximately $15.6 million, including cash and cash equivalents of $21.3 million. Based on our expected operating cash requirements and capital expenditures, we believe the Company's cash on hand at June 30, 2019 is adequate to fund obligations for at least twelve months from the date that this Quarterly Report is filed.

We have not generated any revenue from the sale of products, and have incurred operating losses in each year since we commenced operations. As of June 30, 2019, we had an accumulated deficit of $86.6 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we continue the development and commercialization of Vazalore and our other product candidates. Even if we do generate revenues, we may never achieve profitability, and even if we do achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. Because of the numerous risks and uncertainties associated with developing biopharmaceutical products, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.

We anticipate that we will need to obtain substantial additional financing in the future to fund our future operations. We may obtain additional financing through public or private equity offerings, debt financings (including related-party financings), a credit facility or strategic collaborations.

Additional financing may not be available to us when we need it or it may not be available to us on favorable terms, if at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no understandings, commitments or agreements relating to any of these types of transactions. If we are unable to raise additional funds when needed, we may be required to sell or license our technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves. Without additional funding — or, alternatively, a partner willing to collaborate and fund development — we will be unable to continue development of PL1200 Ibuprofen or any other development-stage products in our pipeline.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are not required to provide the information required by this item as we are considered a smaller reporting company, as defined in Section 229.10(f)(1) of Regulation S-K.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures
Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted 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 in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on an evaluation under the supervision, and with the participation, of the Company's management, the Company's principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act were effective as of June 30, 2019 to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting
There were no changes in the Company's internal control over financial reporting during the quarter ended June 30, 2019 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Inherent Limitations Over Internal Controls
The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. The Company's internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;
(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and
(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Management, including the Company's principal executive officer and principal financial officer, does not expect that the Company's internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls with respect to future periods is subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are parties to legal proceedings that we believe to be ordinary, routine litigation incidental to the business of present or former operations. It is management's opinion, based on the advice of counsel, that the ultimate resolution of such litigation will not have a material adverse effect on our financial condition, results of operations or cash flows.

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Quarterly Report, please carefully consider the risk factors described in our most recent Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2018, under the heading "Part I – Item 1A. Risk Factors." The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that our management currently deems to be immaterial, also may adversely affect our business, financial condition, and/or operating results. There have been no material changes to those risk factors since their disclosure in our most recent Annual Report on Form 10-K, as amended.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

On June 28, 2019, the Company entered into a Manufacturing Services Agreement dated as of June 28, 2019 with Thermo Fisher Scientific's Pharma Services business (the "MSA"). The MSA provides for the non-exclusive manufacture and supply of the Company's Vazalore 81mg and Vazalore 325mg capsules and for certain validation and stability services. The MSA expires on December 31, 2025. The MSA may be terminated by either party as a result of the breach or bankruptcy of the other party, and by the Company as a result of the products' discontinuance in the market or certain actions that prevent the products to be sold in the territory. The MSA contains representations, warranties and indemnity obligations customary for agreements of this type. A copy of the MSA has been filed as Exhibit 10.1 hereto and is incorporated herein by reference.

ITEM 6. EXHIBITS

The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Quarterly Report.

INDEX TO EXHIBITS

Number	Description
10.1	Manufacturing Services Agreement, dated June 28, 2019, between the Company and Patheon Pharmaceuticals Inc.* +
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of the Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of the Principal Executive Officer and Principal Financial and Accounting Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	XBRL Instance Document.*
101.SCH	XBRL Taxonomy Extension Schema Document.*
101.CAL	XBRL Taxonomy Calculation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	XBRL Taxonomy Label Linkbase Document.*
101.PRE	XBRL Taxonomy Presentation Linkbase Document.*

* Filed herewith.

\+ Filed with confidential portions omitted pursuant to a request for confidential treatment. The omitted portions have been separately filed with the SEC.

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.

PLX PHARMA INC.

Date: August 9, 2019

/s/ Natasha Giordano
By: Natasha Giordano
Title: President and Chief Executive Officer
(Principal Executive Officer)

/s/ Rita O'Connor
By: Rita O'Connor
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

Manufacturing Services Agreement

Effective Date: June 28, 2019

PARTIES

PATHEON PHARMACEUTICALS INC.
a corporation existing under the laws of the State of Delaware, with a principal place of business at 2110 East Galbraith Road, Cincinnati, OH 45237 ("**Patheon**"),

- and -

PLx OPCO INC., DBA PLX PHARMA INC.
a corporation existing under the laws of the State of Delaware, with its principal place of business at 8285 El Rio, Suite 130, Houston, TX 77054 ("**Client**").

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

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17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

With effect from the date stated at the start of this Agreement (the "**Effective Date**"), the parties have agreed to the following terms:

1. Interpretation

1.1 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party; or

(b) a business entity which is controlled by a party, either directly or indirectly; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party;

For this definition, "control" means the lawful right to determine (by ownership of shares or otherwise) the election of the majority of directors (or equivalent managers) of a business entity;

"**Annual Volume**" means, for the purpose of the Price, minimum volume of Product to be manufactured in any Year as set out in the "Annual Volume Forecast" section of Appendix 1;

"**API**" means the active material aspirin (references to "Active Materials" or "Active Pharmaceutical Ingredient" in this Agreement will mean "API");

"**Applicable Laws**" means any and all national, state, regional, local, or other jurisdictional laws, regulations, orders, and rules relating to the subject matter, specifically including, without limitation, those related to or affecting the manufacture, distribution, and marketing of the Product in the Territory;

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal, with competent jurisdiction over a party, the Manufacturing Services, or this Product (or its use);

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in Patheon's resident jurisdiction, Client's resident jurisdiction, or the jurisdiction where the Manufacturing Site is located;

"**Capital Equipment Agreement**" means the Amended and Restated Capital Expenditure and Equipment Agreement between the parties effective May 28, 2019 as may be amended that addresses the rights and responsibilities of the parties regarding capital equipment and facility modifications that are required to perform the Manufacturing Services under this Agreement;

"**cGMPs**" means, as applicable, current good manufacturing practices as described in:

(a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(b) Commission Directive (EU) 2017/1572 (art. 2); and

(c) Division 2 of Part C of the Food and Drug Regulations (Canada);

together with current final industry-accepted Health Canada, FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

"**Client Intellectual Property**" means Intellectual Property generated or derived by Client before or after entering into this Agreement, or by Patheon while performing any Manufacturing Services which Intellectual Property is specific to, or dependent upon, the Product or Client's technology, including, without limitation, the controlled or modified release drug delivery systems and technology used in connection with Client's Product (which, for the purposes of this Agreement, will include variations and modifications of these systems and technology);

"**Components**" means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture or package Product in accordance with the Processing Instructions, including the API;

"**Confidential Information**" has the meaning specified in Section 11.1;

"**DEA**" means the Drug Enforcement Administration of the United States Department of Justice;

"**Deficient Product**" has the meaning specified in Section 6.1(a);

"**Disclosing Party**" has the meaning specified in Section 11.1;

"**EMA**" means the European Medicines Agency;

"**FDA**" means the United States Food and Drug Administration;

"**Firm Order**" has the meaning specified in Section 5.1(d);

"**Health Canada**" means the department of the Canadian Government known as Health Canada and includes, among other relevant branches, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

"**Initial Product Term**" has the meaning specified in Section 8.1;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

"**Invention**" means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means, at a point in time, all inventories of Components and work-in-process under Patheon's care or control used for the manufacture or packaging of Product;

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

"**Long Term Forecast**" has the meaning specified in Section 5.1(a);

"**Manufacturing Services**" means the manufacturing, quality control, quality assurance, stability testing, packaging, and related services, as set out in Appendix 1, for the manufacture of Product for distribution in the Territory;

"**Manufacturing Site**" means the facility located at 2110 East Galbraith Road, Cincinnati, OH 45237 where the Manufacturing Services will be performed;

"**Minimum Market Requirement**" has the meaning specified in Section 2.1;

"**Minimum Order Quantity**" means, for each manufacturing campaign ordered, the minimum number of units or batches of a Product that Client must purchase, as set out in Appendix 1;

"**Obsolete Stock**" has the meaning specified in Section 5.2(b);

"**Patheon Competitor**" means a business that derives greater than 50% of its revenues from performing contract pharmaceutical or biopharmaceutical development or commercial manufacturing services;

"**Patheon Intellectual Property**" means Intellectual Property generated or derived by Patheon or its Affiliates before performing any Manufacturing Services, developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property is not specific to, or dependent upon, the Product or Client Intellectual Property, including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products or drug delivery systems unrelated to the Product or Client Intellectual Property;

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

"**Price**" means the fees to be charged by Patheon for:

(a) performing the Manufacturing Services;

(b) the cost of Components; and

(c) any separate cost items and other fees,

as set out in Appendix 1;

"**Processing Instructions**" means the agreed file, for each Product, which contains documents relating to the Product, including, without limitation:

(a) quality control testing methods for API and Components;

(b) manufacturing instructions, directions, and processes;

(c) any storage requirements for the API, Components, or Product;

(d) all environmental, health and safety information for the Product including material safety data sheets; and

(e) the finished Product quality control testing methods, packaging instructions and shipping requirements for the Product;

"**Product**" means 81mg & 325mg Aspirin using the PL2200 (proprietary name, Vazalore) technology in a liquid filled Hydroxypropyl Methylcellulose(HPMC) capsule (LFHC);

"**Product Claims**" has the meaning specified in Section 6.1(a);

"**Quality Agreement**" means a separate agreement that sets out the quality assurance standards for the Manufacturing Services;

"**Recall**" has the meaning specified in Section 6.2(a);

"**Recipient**" has the meaning specified in Section 11.1;

"**Regulatory Approval**" has the meaning specified in Section 7.5(a);

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

"**Regulatory Authority**" means the FDA, EMA, and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical or biopharmaceutical products, including the Products, in the Territory;

"**Release Date**" means in relation to each batch of Product the scheduled date by which the Product will be released by Patheon's quality department (by confirmation or certification) as agreed in the Quality Agreement and made available for shipment, and as confirmed by Patheon in a Firm Order;

"**Representatives**" means, a party's directors, officers, employees, advisers, agents, consultants, subcontractors, service partners or professional advisors;

"**Rolling Forecast**" has the meaning specified in Section 5.1(b);

"**Technical Dispute**" has the meaning specified in Appendix 2;

"**Territory**" means the United States;

"**Third Party Rights**" means the Intellectual Property of any third party; and

"**Year**" means in the first year of this Agreement, the time from the Effective Date up to and including December 31 of the same calendar year, and after that will mean a calendar year.

1.2 Interpretation.

The division of this Agreement into Sections, Subsections, and Appendices, and the insertion of headings, are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, or Appendix refers to the specified Section, or Appendix to this Agreement. In this Agreement, the term "**this Agreement**" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, or Appendix of this Agreement. Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

2. Patheon's Manufacturing Services

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services as set out in Appendix 1 for the Price and in accordance with the Quality Agreement. Subject to the preceding sentence, Patheon will convert API and Components into Product, and provide supportive Manufacturing Services such as quality assurance (for example quality controls, analytical testing, and stability programs), primary and secondary packaging, and any other related Manufacturing Services as agreed between the parties.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

Patheon will manufacture a minimum of [***] of Client's requirements for Product in those countries in the Territory offered for sale by Client or its Affiliates (the "**Minimum Market Requirement**") through December 31, 2021. The parties will meet in June of 2021 to discuss the Minimum Market Requirement for Product in subsequent Years, but the inability of the parties to agree on the Minimum Market Requirement for Product in subsequent Years will not affect the validity of this Agreement.

2.2 Subcontracting.

Patheon may subcontract the Manufacturing Services to any of its Affiliates, with the consent of the Client. Patheon will remain exclusively liable to Client for any breach of this Agreement or negligence by its Affiliates in the course of performing: (i) the subcontracted Manufacturing Services; or (ii) obligations under the Quality Agreement. Patheon may also arrange for non-Affiliate subcontractors to perform specific services with the consent of Client ("**Third Party Subcontractors**"). Patheon will be liable to Client for the failure by any Third Party Subcontractor to perform any part of the subcontracted services. But Patheon's liability for Third Party Subcontractors will remain subject to all limitations on Patheon's liability as set out in this Agreement. Patheon will have no liability arising from the performance of services by Third Party Subcontractors: (i) that are required by Client; or (ii) to the extent that the Third Party Subcontractor is following the direct instructions of Client.

3. Client's Obligations

3.1 Payment.

Client will pay Patheon the applicable Price in accordance with Sections 4 and 5. All cost items that are designated as "Costs Not Included in the Price" as specified in Appendix 1 will be considered not included in the Price and will be subject to additional fees to be mutually agreed and paid by Client.

3.2 Processing Instructions.

Before the start of commercial manufacturing of Product under this Agreement, Client will give Patheon a copy of the Processing Instructions, which must be accompanied by the applicable API, Component and finished product specifications (if applicable, precisely matching the specifications approved by the applicable Regulatory Authority). If the Processing Instructions or accompanying documents received are amended or no longer reflect those currently approved by the Regulatory Authority, then Client will give Patheon a copy of the revised documents (if applicable, precisely matching the revised specifications approved by the applicable Regulatory Authority). Upon acceptance of the revised Processing Instructions and accompanying documents, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance. At Patheon's request, Client will provide a copy of the sections relevant to Patheon's services of the Quality Module (Drug Product section) of the Common Technical Document that relates to the application submitted by or on behalf of Client to the Regulatory Authority.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

3.3 Components.

(a) Patheon will supply all Components required to manufacture the Product.

(b) If Client asks Patheon to qualify an additional supplier for the API or any Component, the parties must agree on the scope of work to be performed by Patheon and the additional fees to be paid by Client. For any API or any Component, it is contemplated that this work will likely include: (i) laboratory testing to confirm the API or Component meets existing specifications; (ii) manufacture of an experimental batch of Product that will be placed on three months accelerated stability; and (iii) manufacture of full-scale validation batches that will be placed on concurrent stability (one batch may be the registration batch if manufactured at full scale).

(c) Patheon will promptly advise Client if it encounters API or Component supply problems, including delays or delivery of non-conforming API or Components from a Client designated additional supplier. The parties will cooperate to reduce or eliminate any supply problems from these additional suppliers. If supply problems persist, Patheon may suspend the Manufacturing Services affected by the problems until it is satisfied that the Client has resolved the problems with its supplier or appointed an alternative supplier. Client will qualify or certify (as appropriate) all Client designated additional suppliers on an annual basis at its expense and, at Patheon's request, will provide Patheon with copies of the relevant section of annual reports. If Patheon agrees to certify or qualify a Client designated additional supplier on behalf of Client, it will do so for an additional fee payable by Client.

4. Price and Price Adjustments

4.1 First Year Pricing.

The Price for each Product is listed in Appendix 1 and may be adjusted under this Section 4.

4.2 Annual Price Adjustments.

Patheon may adjust the Price effective January 1st of each Year as follows:

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

(a) Conversion Fee Portion of the Price. Patheon may adjust the conversion fee portion of the Price annually for inflation in accordance with Appendix 3 [***].

(b) Component Costs. [***].

(c) Pricing Basis. Client acknowledges that the Price in any Year is agreed based upon the applicable Minimum Market Requirement, Annual Volume and Minimum Order Quantity for that Year. [***].

(d) Tier Pricing. If the Pricing is divided into Annual Volume tiers, Client will be invoiced during the Year based on the tier corresponding to the Annual Volume forecast. Within 30 days after the end of each Year or on termination of this Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by Client during the Year at the actual applicable Pricing tiers. If the reconciliation shows an overpayment, Patheon will issue a credit to Client for the amount of the overpayment within 60 days after the end of the Year or will reimburse the overpayment within 60 days after termination. The parties will work together in good faith to resolve any disagreement over the reconciliation.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client by October 1 of each Year (unless otherwise agreed in writing) a letter stating the adjusted Pricing to be effective for Product to be delivered on or after January 1 of the next Year including any Firm Orders accepted by Patheon before that date. Any omitted adjustment in a Year does not waive Patheon's right to apply that adjustment cumulatively with the next permitted adjustment.

4.3 Price Adjustments at any Time.

The Prices may be adjusted by Patheon at any time upon 30 days written notice to Client as follows:

(a) Extraordinary Increases in Component Costs. [***].

(b) Changes. The scope of the Manufacturing Services is set by the agreed Processing Instructions, the Regulatory Approvals, the Quality Agreement and any assumptions, inclusions, exclusions and other parameters set out in Appendix 1. Changes to the scope of the Manufacturing Services and related changes to the Price must be agreed in writing by the parties (using a "**Change of Scope**" agreement, or similar, setting out the agreed activities and costs of implementation) and are subject to the change control provisions of the Quality Agreement. Where Patheon requests a change to the Manufacturing Services, the change will be implemented following written approval of Client.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

5. Purchasing Product

5.1 Orders and Forecasts.

(a) Long Term Forecast. On or before June 1 and December 1 of each Year, Client will give Patheon a non-binding written forecast of Client's volume requirements for the Product from Patheon for each of the next five Years ("**Long Term Forecast**"). If Patheon foresees any capacity constraint affecting any portion of the Long Term Forecast, it will notify Client and the parties will agree on a revised Long Term Forecast within Patheon's expected capacity.

(b) Rolling Forecast. Upon execution of this Agreement, Client will give Patheon a written forecast of the volume of Product that Client expects to order in each of the next 15 months (the "**Rolling Forecast**"). The Rolling Forecast must be consistent with the Long Term Forecast. Client will provide an updated Rolling Forecast on or before the tenth day of each month. Each updated Rolling Forecast supersedes all previous Rolling Forecasts.

(c) Orders. On or before the tenth day of each month, Client will issue a new purchase order for any required Product. Each purchase order must meet the Minimum Order Quantity and specify the purchase order number, quantities by Product type, and requested release dates for the Product (which must occur at least 90 days after Patheon's receipt of the purchase order).

(d) Acceptance of Purchase Orders. To the extent that a purchase order covers Product that is forecast in the Rolling Forecast, Patheon will accept the purchase order by sending an acknowledgement to Client, including the confirmed Release Dates. If Patheon fails to acknowledge receipt of a purchase order within ten Business Days, the purchase order will be considered accepted by Patheon. An accepted purchase order will be binding on the parties (a "**Firm Order**"), except that either party may request to change any Release Date beyond 90 days after the first day of the next month. The parties will negotiate in good faith and agree on any requested alternative release date. Neither party may unreasonably reject an alternative release date requested under this Section 5.1(d), but, if the parties cannot agree, the original Release Date confirmed by Patheon will apply.

(e) Cancellation or Postponement. Patheon will determine the manufacturing schedule of all Product covered by Firm Orders. If Client cancels or reduces a Firm Order, or wishes to postpone the applicable Release Date (subject to Section 5.1(d)), [***].

(f) Capacity Reservation. In Year 2021 of this Agreement, Patheon will use the Rolling Forecast to reserve its manufacturing capacity in Year 2022 for Product by reference to the Rolling Forecast provided on December 1, 2021. In all subsequent Years, Patheon will reserve its manufacturing capacity by reference to the Rolling Forecast applicable at October 1 of the previous Year. The relevant forecast for each Year will be referred to as the "**Yearly Forecast Volume.**" Client agrees to purchase and Patheon agrees to provide [***] and the Yearly Forecast Volume will not be less than [***].

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At the end of each Year beginning in 2022, if the aggregate actual volume of Product ordered by Client with a confirmed Release Date within the Year, taking into account any Product paid for but not ordered, ("**Actual Yearly Volume**") is less than [***] of the Yearly Forecast Volume, [***]. But if the Actual Yearly Volume is less than [***] of the Yearly Forecast Volume, [***]. The respective amount will calculated as follows:

[***]

If the quantity of Product requested by Client in a Year (in purchase orders received by Patheon) exceeds the Yearly Forecast Volume for that Year, Patheon will use commercially reasonable efforts to supply the additional Product volumes. Patheon will not be considered to have accepted any purchase order for additional Product volumes without written confirmation.

5.2 Obsolete Stock.

(a) Client understands and acknowledges that Patheon will rely on Firm Orders, and the Rolling Forecast in ordering the Components required to meet anticipated Firm Orders. Patheon may purchase the Components in sufficient volumes, and reasonably in advance of the expected use of the Component (taking into account lead times), to meet the production requirements for Products covered by anticipated Firm Orders or to meet the production requirements of any longer period agreed to by the parties.

(b) Client will reimburse Patheon for the cost of Client-specific Components ordered by Patheon in relation to Firm Orders or under the second sentence of Section (a) that are not used in the Manufacturing Services within six months after the forecasted month for which the purchases have been made or if the Components have expired or are rendered obsolete due to changes in any forecast, Processing Instructions, GMP, artwork or Applicable Laws during the period (collectively, "**Obsolete Stock**"). This reimbursement will include Patheon's cost to purchase and destroy the Obsolete Stock (plus an 8% handling fee). If any non-expired Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client. Alternatively, Client will have the option to purchase Obsolete Stock from Patheon at Patheon's cost [***].

5.3 Storage.

Unless otherwise agreed, if: (i) Client fails to take possession or arrange for the destruction of Obsolete Stock within [***] days of receipt of written notice from Patheon identifying the Obsolete Stock; or (ii) Product is not collected by Client within [***] days of the Release Date notified by Patheon, Client will pay Patheon [***]. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship Product held by it longer than [***] days to Client at Client's expense on 14 days' written notice to Client. If Patheon is unable to store any material due to capacity constraints, Patheon may use an Affiliate or qualified third party to store (outside the Manufacturing Site) any material under this Agreement. After the limited storage periods stated above, Client will assume all risk of loss or damage to materials and Client will be responsible for having appropriate insurance coverage in place for this risk.

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5.4 Invoices and Payment.

For shipments of Product, Patheon will issue invoices to Client on or after the Release Date of the Product. Otherwise, Patheon will issue invoices for Manufacturing Services on completion. Patheon will also submit to Client, with each shipment of Product, a duplicate copy of the invoice covering the shipment. Invoices will be sent by email to the email address given by Client to Patheon in writing. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within 30 days of the date of the invoice. If any portion of an invoice is disputed, Client will pay Patheon for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Interest on undisputed past due accounts will accrue at [***] per month. Patheon may, on giving 30 days' notice to Client, suspend all Manufacturing Services, including release and shipment of Product, until all undisputed past due invoices have been paid in full. Patheon will have no liability to Client for losses caused by this suspension, including without limitation, losses due to delayed Product delivery or Product shortages.

5.5 Delivery and Shipping.

Delivery of Product and any other materials will be made EXW (Incoterms 2010) from Patheon's Manufacturing Site. Subject to Section 8.3, risk of loss or of damage to Product will remain with Patheon until Patheon loads the Product onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. But if Client fails to collect Product within [***] days after it has been released for shipment by Patheon, Client will assume all risk of loss or damage to the released Product. Patheon may, in accordance with Client's instructions and as agent for Client, at Client's risk, arrange for shipping (to Client or any third party nominated by Client), the cost for this service to be included in the Price.

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6. Product Claims and Recalls

6.1 Product Claims.

(a) Rejection. Client may reject any manufactured Product that it reasonably considers to be deficient based on documentation provided by Patheon or Client's own inspection or testing of delivered Product.

(b) Product Claims.

(i) Client may claim a remedy (a "**Product Claim**") for any portion of any batch of Product for which Patheon did not perform the Manufacturing Services in accordance with the agreed Processing Instructions, cGMPs, or Applicable Laws ("**Deficient Product**"). Client will inspect Product manufactured by Patheon, or batch documentation provided by Patheon, upon receipt and will give Patheon written notice of all Product Claims within [***] days after receipt (or, in the case of any deficiency not reasonably susceptible to discovery upon receipt, within [***] days after discovery by Client, but not after the expiration date of the Product). If Client fails to provide a Product Claim within the applicable [***] day period, then the Product will be considered to have been accepted by Client on the [***] day. Patheon will have no liability for any deficiency for which it has not received notice within the applicable [***] day period.

(ii) This Section 6 sets out the only liability of Patheon for Deficient Products. Patheon will provide a remedy for Product Claims as specified in Section 10.2, but Patheon will have no obligation for any Product Claims to the extent the Deficient Product was caused by: (i) deficiencies in the Processing Instructions, specifications, the safety, efficacy, or marketability of the Product or its distribution; (ii) a defect in the API or an incorporated Component that was not reasonably discoverable by Patheon using the test methods set out in the Processing Instructions; (iii) actions of Client or third parties occurring after the Product is delivered by Patheon; (iv) packaging design or labelling defects or omissions for which Patheon has no responsibility; or (v) any other breach by Client of its obligations under this Agreement. If after a full investigation as set out in the Quality Agreement and this Section 6.1(b)(ii), it is determined that Patheon manufactured Product in accordance with the agreed Processing Instructions, but a batch or portion of batch of Product is not released, Client will pay Patheon the Price for the Product.

(c) Determination of Deficiency. Upon receipt of a Product Claim, Patheon will have ten days to advise Client by notice in writing whether it disagrees with the contents of the Product Claim. If the parties fail to agree within ten days after Patheon's notice to Client as to whether any Product identified in the Product Claim is Deficient Product, the parties will investigate the matter in accordance with the Quality Agreement. If, after joint testing or investigation has been performed, the parties still cannot agree on the root cause, the provisions of Appendix 2 will apply and, after the required negotiation, the dispute will be handled as a Technical Dispute.

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(d) Shortages and Price Disputes. Claims for shortages in the amount of Product shipped by Patheon or a Price dispute will be dealt with by reasonable agreement of the parties. Any claim for a shortage or a Price dispute will be considered waived by Client if it has not been presented within [***] days of the date of the relevant invoice.

6.2 Product Recalls and Returns.

(a) Records and Notice. The parties will each maintain records necessary to permit a Recall of any Product delivered to Client or customers of Client. Each party will promptly notify the other of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product in accordance with the Quality Agreement. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. "**Recall**" will mean any action: (i) by Client to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); (ii) by any Regulatory Authority to detain or destroy any of the Product; or (iii) by either party to refrain from selling or shipping quantities of the Product to third parties which would be subject to a Recall if sold or shipped.

(b) Recalls. If: (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled; (ii) a court of competent jurisdiction orders a Recall; or (iii) Client determines that any Product should be Recalled or that a "**Dear Doctor**" letter is required relating the restrictions on the use of any Product, then Patheon will co-operate as reasonably required by Client, having regard to all Applicable Laws.

(c) Recalled Product. To the extent that a Recall results from, or arises from Deficient Product, Patheon will be responsible for the reasonable documented out-of-pocket expenses of the Recall and will use its commercially reasonable efforts to replace the Deficient Product with replacement Products as per Section 10. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense.

6.3 Disposition of Deficient Product.

Client will not dispose of any damaged, returned, or Deficient Product for which it intends to assert a Product Claim against Patheon without Patheon's prior written authorization to do so unless Patheon has failed to respond to a Product Claim within 60 days. Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of return and disposition of any Deficient Products. In all other circumstances, Client will bear the cost of return and disposition, including all applicable fees for Manufacturing Services.

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7. Co-operation and Regulatory Affairs

7.1 Governance.

Each party will without delay upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet on a frequency agreed between the parties to review the current status of the business relationship, including review of key performance indicators such as on-time delivery and right first time and manage any issues that have arisen.

7.2 Governmental Agencies.

Subject to any restrictions in the Quality Agreement, each party may communicate with any Regulatory Authority responsible for granting Regulatory Approval for the Product and any other relevant Authority regarding the Product if, in the opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of the Authority or Applicable Laws. Otherwise, the parties will consult each other in relation to regulatory communications relating to the Product in accordance with the Quality Agreement.

7.3 Records.

Patheon will keep records of the manufacture, testing, and shipping of the Product, and retain samples of the Product as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, Applicable Laws, cGMP and the Quality Agreement. Copies of the records and samples will be retained as and for the period specified in the Quality Agreement. Patheon reserves the right to destroy or return to Client, at Client's sole expense, any document or samples for which the retention period has expired if Client fails to arrange for destruction or return within 30 days of receipt of notice from Patheon.

7.4 Audits.

Subject to the provisions of the Quality Agreement, Patheon will give Client reasonable access during normal business hours or other agreed times to the areas of the Manufacturing Site in which the Product is manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. If Client wishes to audit Patheon beyond the agreed limits, except where the audit is required for cause, Client will pay to Patheon [***]. Under no circumstances will: (a) Client have a right of access to Patheon's financial records; or (b) any Patheon Competitor be permitted access to the Manufacturing Site.

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7.5 Regulatory Filings.

(a) Regulatory Authority Documentation. Client will provide copies of all relevant documents related to Patheon's services relating to Regulatory Authority approval for the commercial manufacture, distribution and sale of the Product ("**Regulatory Approval**") to Patheon on request and as required under the Quality Agreement. Patheon will review and verify the accuracy of these documents in accordance with the Quality Agreement. Client is not entitled to submit Regulatory Approvals referring to Patheon or its Affiliates or the Services until approved by Patheon.

(b) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines that any regulatory information given by Client is inaccurate or deficient in any manner whatsoever (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to the date of filing of the relevant application and in any event before any pre-approval inspection or before the Product is placed on the market if a pre-approval inspection is not performed.

(c) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under this Section 7.5 or the Quality Agreement within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents. Client's breach of this requirement will be considered a material breach of this Agreement.

(d) Pharmacovigilance. Client will be responsible, at its expense, for all pharmacovigilance obligations for the Product in accordance with Applicable Laws and the monitoring and management of post-marketing complaints and queries at its cost (including, without limitation, the cost of assistance required of Patheon under the Quality Agreement). Unless required by Applicable Law, neither party will be obliged to exchange with the other party any information or data which it compiles in carrying out pharmacovigilance obligations or activities.

(e) No Patheon Responsibility. Except as otherwise agreed in the Quality Agreement, Patheon will not assume any responsibility for: (a) the submission, accuracy or cost of any application for Regulatory Approval or related documentation (or the success of those applications); (b) any activity that is required by Applicable Laws for Regulatory Approval (including pharmacovigilance and complaints handling, and preparation and submission of any regular quality or other update), other than those required of Patheon; or (c) any dealings with the relevant Regulatory Authority on behalf of Client for Regulatory Approval. If a Regulatory Authority, or other governmental body, requires Patheon to incur fees, costs or activities in relation to the Products which Patheon considers unexpected and extraordinary, then Patheon will notify Client in writing and the parties will discuss in good faith appropriate mutually acceptable actions, including fee/cost sharing, or termination of this Agreement. Patheon will be not be obliged to undertake these activities or to pay for the fees or costs until the parties reach agreement on scope and fees for Patheon's assistance.

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7.6 Release.

The parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Product will not by itself indicate compliance by Patheon with its obligations relating to the Manufacturing Services. Nothing in this Agreement will remove or limit the authority of the relevant quality function (as specified by the Quality Agreement) to determine whether the Product will be released for sale or distribution.

7.7 Withdrawal on Completion.

No later than 90 days following completion or permanent cessation of the Manufacturing Services at the Manufacturing Site, Client will: (a) ensure that any regulatory filings relating to the Product are withdrawn or amended to remove all references to the Manufacturing Site and, as applicable, Patheon or its Affiliates and their facilities (except in an historic context); and (b) provide to Patheon written confirmation of its compliance with this Section 7.7. If this time is not sufficient to meet the requirements of certain Regulatory Authorities, despite Client's reasonable efforts, then Patheon will agree to extend the period based on the written reassurances of Client.

8. Term and Termination

8.1 Initial Term

This Agreement will become effective as of the Effective Date and will continue until December 31, 2025 (the "**Initial Term**"). At least 12 months prior to the end of the Initial Term the parties will discuss whether the Initial Term will be extended.

8.2 Termination for Cause.

(a) Either party may terminate this Agreement upon written notice where the other party has failed to remedy a material breach of this Agreement within 60 days (the "**Remediation Period**") following receipt of a written notice of the breach from the aggrieved party that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate this Agreement under this Section 8.2(a) may only be exercised for a period of 60 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 considered to have waived the breach described in the Breach Notice.

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(b) Either party may immediately terminate this Agreement upon written notice to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy or insolvency is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate this Agreement upon 30 days' prior written notice if any Authority takes any action, or raises any objection, that prevents Client from selling the Product in the Territory.

(d) Client may terminate this Agreement upon six months' prior written notice if it intends to no longer order Manufacturing Services for the Product due to the Product's discontinuance in the market.

(e) Patheon may terminate this Agreement upon six months' prior written notice if Client assigns under Section 13.4(b) any of its rights under this Agreement to an assignee that, in the reasonable opinion of Patheon, is: (i) unlikely to be able to meet the obligations of this Agreement; (ii) a Patheon Competitor; or (iii) an entity with whom Patheon has had prior unsatisfactory business relations (as supported by reasonable evidence of late or unpaid invoices or material disputes).

(f) Patheon may terminate this Agreement if payment in full of overdue, undisputed invoices is not received within 30 days following the date of suspension of Manufacturing Services by Patheon under Section 5.4.

(g) If Client forecasts zero volume for six successive months during the term of this Agreement (excluding the registration period), then Patheon may terminate this Agreement by providing 30 days prior written notice to Client. Within that period, Client may either: (i) withdraw the zero forecast and re-submit a revised volume forecast, after which Patheon will withdraw the termination notice; or (ii) negotiate other terms and conditions on which this Agreement will remain in effect.

8.3 Obligations on Termination.

If this Agreement is completed, expires, or is terminated for any reason, then:

(a) Client will take delivery of and pay for all undelivered Products that are manufactured or packaged in accordance with this Agreement under a Firm Order, at the Price in effect at the time the Firm Order was released;

(b) Client will purchase all Inventory that was purchased (or will be purchased under existing unfulfilled orders for Components), maintained or produced by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2, at Patheon's cost (including all costs incurred by Patheon for the purchase, handling, and processing of the Inventory);

(c) Client, at its own expense, will remove from the Manufacturing Site, within [***] days following the completion, termination, or expiration of this Agreement, all applicable Inventory (whether current or obsolete), supplies, undelivered Product, chattels, related to the Agreement and located at the Manufacturing Site or that is otherwise under Patheon's care and control ("**Client Property**"). Client, at its own expense, will remove from the Manufacturing Site, within [***] days following the completion, termination, or expiration of this Agreement, all equipment or other moveable property owned by Client related to the Agreement and located at the Manufacturing Site or that is otherwise under Patheon's care and control ("**Client Property**").If Client fails to remove Client Property within the applicable [***] day period, Client will pay Patheon [***] per pallet, per month, one pallet minimum after that for storing Client Property and will assume any third party storage charges invoiced to Patheon regarding Client Property (which Patheon may incur at its discretion). Patheon may ship Client Property to Client or to an external warehouse at Client's risk and expense. Patheon will invoice Client for these storage charges as set out in Section 5.3 of this Agreement. If Client fails to remove Client Property within the applicable [***] days following the completion, termination, or expiration of this Agreement, Client will assume all risk of loss or damage to the stored Client Property and it will be Client's responsibility to have appropriate insurance coverage in place for this risk. If Client asks Patheon to destroy any Client Property, Client will be responsible for the cost of destruction; and

(d) any completion, termination or expiration of this Agreement will not affect any prior outstanding obligations or payments due nor will it prejudice any other remedies that the parties may have under this Agreement or any related Capital Equipment Agreement. Completion, termination or expiration of this Agreement for any reason will not affect the obligations and responsibilities of the parties under Sections 5.1(e), 5.1(f), 5.4, 5.5, 8.3, 10, 11, 12, 13.14, 13.15 and 13.16, all of which survive any completion, termination or expiration, as well as any other provisions that are by implication or otherwise intended to survive any completion, termination or expiration. Where Patheon has agreed to provide stability services beyond the final supply of Product, the relevant provisions of this Agreement will survive for the agreed duration of those stability services.

8.4 Technology Transfer.

Following termination of this Agreement for any reason, or at Client's request within six months before the end of the term of this Agreement, Patheon will provide assistance to transfer part or all of Client's manufacturing process, know-how and analytical testing methodology for the Product to Client ("**Technology Transfer**") to assist Client to manufacture the Product. Patheon will also disclose to Client any Patheon Intellectual Property that is reasonably required to manufacture the Product. Patheon will, upon request of Client, prepare a written proposal to perform the Technology Transfer, that will include a reasonable fee for these services, that must be mutually agreed to by the parties. Client will pay the agreed fees for the Technology Transfer performed by Patheon.

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9. Representations, Warranties and Covenants

9.1 Authority.

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations under this Agreement.

9.2 Client Warranties.

(a) Non-Infringement. Client covenants, represents, and warrants that:

(i) the Processing Instructions and specifications for the Product are its or its Affiliate's property and/or that Client may lawfully disclose the Processing Instructions and specifications to Patheon for use in accordance with this Agreement;

(ii) any Client Intellectual Property used by Patheon in performing the Manufacturing Services (A) is Client's or its Affiliate's unencumbered property or Client has a license or other similar right to use the same, (B) may be lawfully used as directed by Client and agreed in this Agreement, and (C) does not infringe and will not infringe any Third Party Rights; and

(iii) there are no actions or other legal proceedings involving Client or its Affiliates that concerns the infringement of Third Party Rights related to any of the Processing Instructions or specifications, or the sale, use, or other disposition of Product made in accordance with the Processing Instructions.

(b) Quality and Compliance. Client covenants, represents, and warrants that:

(i) the Processing Instructions and specifications for the Product conforms to all applicable cGMPs and Applicable Laws; and

(ii) the Product, if labelled and manufactured in accordance with the Processing Instructions and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Product, (ii) will be fit for the purpose intended, and (iii) will be safe for human consumption.

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9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Processing Instructions, cGMPs, and Applicable Laws;

(b) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights;

(c) it will not in the performance of its obligations under this Agreement use the services of any person it knows is debarred or suspended under 21 U.S.C. §335(a) or (b); and

(d) it does not currently have, and it will not hire, as an officer or an employee any person whom it knows has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States Federal Food, Drug, and Cosmetic Act.

9.4 Permits.

(a) Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Product, Processing Instructions or specifications, including, without limitation, all marketing and post-marketing approvals, and any specific approvals referred to in the Quality Agreement.

(b) Patheon will maintain at all relevant times when performing the Manufacturing Services all required governmental permits, licenses, approval, and authorities.

9.5 No Warranty.

PATHEON MAKES NO WARRANTY OR CONDITION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET OUT IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE PRODUCT.

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10. Liability and Remedies

10.1 Consequential and Other Damages.

Under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, indemnity, breach of statutory duty, or otherwise for: (i) any (direct or indirect) delay, penalty, loss of profits, of anticipated savings, of business, of goodwill, or of use of the Product or costs of any substitute services; or (ii) any reliance damages, including but not limited to costs or expenditures incurred to evaluate the viability of entering into this Agreement or to prepare for performance under this Agreement; or (iii) for any other liability, damage, costs, penalty, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 Limitation of Liability.

(a) Remedies for Deficient Product. If Client makes a Product Claim under Section 6.1 and the parties agree the Product is Deficient Product, or the Product is determined to be Deficient Product under Section 6, Patheon will promptly, at Client's election, either:

(i) replace the Product at Patheon's cost (after which Patheon may invoice for the replacement) if Patheon is able to manufacture the replacement Product at the Manufacturing Site; or

(ii) refund 100% of the Price paid for the Deficient Product (by credit or offset against other amounts due to Patheon under this Agreement).

Except for the indemnity set out in Section 10.3 and any claim for expenses related to a Recall under Section 6.2(c), the remedies described in this Section 10.2 will be Client's sole remedy in contract, tort, negligence, equity or otherwise, for Deficient Product.

The remedy under this Section 10.2, if applicable (including in the case of Recall), will apply only to the extent that the affected Deficient Product is returned, destroyed or otherwise disposed of by Client in accordance with this Agreement.

(b) Maximum Liability. In any Year, in addition to the specific remedies under Section 10.2(a) for Deficient Product [***], Patheon's maximum aggregate liability to Client under or in connection with this Agreement (however arising, including contract, tort, negligence, breach of statutory duty, or otherwise) will not exceed [***].

(c) Death, Personal Injury and Fraudulent Misrepresentation. Nothing contained in this Agreement will act to exclude or limit either party's liability for personal injury or death caused by the negligence of either party or fraudulent misrepresentation.

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10.3 Patheon Indemnity.

(a) Patheon agrees to defend and indemnify Client, its officers and employees, against all losses, damages, costs, claims, demands, subpoenas, judgments and liability to, from and in favour of third parties (other than Affiliates) for 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 Manufacturing Services in accordance with the Processing Instructions, cGMPs, and Applicable Laws except to the extent that the losses, damages, costs, claims, demands, subpoenas, judgments, and liability are due to the negligence or wrongful acts of Client, its officers, employees, or Affiliates.

(b) If a claim occurs, Client will: (i) promptly notify Patheon of the claim; (ii) use commercially reasonable efforts to mitigate the effects of the claim; (iii) reasonably cooperate with Patheon in the defense of the claim; and (iv) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense.

10.4 Client Indemnity.

(a) Client agrees to defend and indemnify Patheon, its officers and employees, against all losses, damages, costs, claims, demands, subpoenas, judgments and liability to, from and in favour of third parties (other than Affiliates) for any claim of infringement of any Third Party Rights in or the Products or that relates to the manufacture of the Product by a proprietary process disclosed by Client or to Patheon's use of Client's Intellectual Property to perform the Manufacturing Services, or any portion of them, or any claim of personal injury or property damage to the extent that the injury or damage arises other than from a breach of this Agreement by Patheon, including, without limitation, any representation or warranty contained in this Agreement, except to the extent that the losses, damages, costs, claims, demands, subpoenas, judgments, and liability are due to the negligence or wrongful acts of Patheon, its officers, employees, or Affiliates.

(b) If a claim occurs, Patheon will: (i) promptly notify Client of the claim; (ii) use commercially reasonable efforts to mitigate the effects of the claim; (iii) reasonably cooperate with Client in the defense of the claim; and (iv) permit Client to control the defense and settlement of the claim, all at Client's cost and expense.

10.5 Reasonable Allocation of Risk.

This Agreement (including, without limitation, this Section 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Product. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Product because Client has developed and holds the marketing approval for the Product, Client requires Patheon to manufacture and label the Product strictly in accordance with the Processing Instructions, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Product.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

10.6 Validation Batches.

Where Product is manufactured by Patheon (or any of its Affiliates) under a separate pharmaceutical development or technology transfer agreement (the "**Development Agreement**") and then released by Patheon for commercial sale or distribution by Client, the performance of the applicable pharmaceutical development or technology transfer services including the manufacture of the Product will be governed by the terms of the Development Agreement and will not be subject to the terms and conditions of this Agreement. The terms of this Agreement will apply to any Product after release by Patheon.

11. Confidentiality

11.1 Confidential Information.

"**Confidential Information**" means any information disclosed by the Disclosing Party to the Recipient (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 and its clients' confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any party's Representatives containing Confidential Information will be considered Confidential Information. Confidential Information of a party will also include any information defined as such pursuant to any other agreement between the parties. Samples or materials provided under this Agreement as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. A party's rights and obligations under this Section 11 will apply to any Confidential Information that is disclosed by or received by that party's Representatives. For the purposes of this Section 11, a party receiving Confidential Information under this Agreement (including through its Representatives) is a "**Recipient**", and a party disclosing Confidential Information under this Agreement (including through its Representatives) is the "**Disclosing Party**". The existence, parties to, and terms of this Agreement will be considered Confidential Information. The obligations set forth in this Section 11.1 are in addition to the obligations of the parties as set forth in that one certain Confidentiality Agreement, dated September 29, 2015, which is hereby ratified and confirmed.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information; and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will not be less than those exercised by Recipient for its own confidential or proprietary Confidential Information of a similar nature.

11.3 Exclusions.

The obligations of confidentiality in this Section 11 will not apply to the extent that Confidential Information:

(a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, if the other source is not known by the Recipient to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party for the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information is not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information are covered by exceptions in this Section 11.3, unless the combination itself is covered by any of those exceptions.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

11.4 Photographs and Recordings.

Neither party will take any photographs or videos of the other party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other party's facilities, without that party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in advance of the disclosure and limit the required disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out in this Agreement. If any public disclosure is required by law, the parties will consult concerning the form of announcement prior to the public disclosure being made.

11.6 Marking.

The Disclosing Party will use reasonable efforts to summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information within 30 days of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form.

11.7 Return of Confidential Information.

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies, summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records. The retained copy will remain subject to all confidentiality provisions contained in this Agreement. Client will not unreasonably require the return of Confidential Information that is necessary or useful to perform the Manufacturing Services.

11.8 Remedies.

The parties acknowledge that monetary damages may not be sufficient to remedy a breach by either party of this Section 11 and agree that the non-breaching party will be entitled to seek specific performance, injunctive or other equitable relief to prevent breaches of this Section 11 and to specifically enforce Section 11 in addition to any other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Section 11 but will be in addition to any and all other remedies available at law or in equity.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

12. Intellectual Property

12.1 Inventions.

(a) For the term of this Agreement, Client grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property which Patheon must use in order to perform the Manufacturing Services.

(b) All Client Intellectual Property will be the exclusive property of Client.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Unless Patheon identifies in advance any specific Patheon Intellectual Property that will be subject to a separate licensing agreement between the parties, Patheon grants to Client a non-exclusive, perpetual, paid-up, royalty-free, transferable license of the Patheon Intellectual Property used by Patheon in the manufacture of the Product for use in relation to manufacturing that Product only.

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be considered to be improvements or other modifications of the Product, processes or technology owned or otherwise controlled by the party.

12.2 Intellectual Property.

Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13. Miscellaneous

13.1 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of three years after that. This insurance will have policy limits of not less than: [***]. If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of 30 days' written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will without delay notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

13.2 Independent Contractors.

The parties are independent contractors and this Agreement does not create between the parties any other relationship such as, by way of example only, that of employer and employee, principal and agent, joint-venturers, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.3 No Waiver.

Neither party's failure to require the other party to comply with any provision of this Agreement will be considered a waiver of the provision or any other provision of this Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.4 Assignment.

(a) Patheon may not assign this Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld.

(b) Subject to Section 8.2(e), Client may assign this Agreement or any of its associated rights or obligations without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement, and Client will remain liable under this Agreement.

(c) Despite the preceding provisions of this Section 13.4, either party may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound by the obligations of this Agreement owed to that party.

13.5 Force Majeure.

Neither party will be liable for the failure to perform its obligations under this Agreement if the failure is caused by an event beyond that party's reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, cyber-attacks, fires, floods, storms, interruption of or delay in transportation, lack of or inability to obtain fuel, power or components (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.5 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

13.6 Additional Product and Services.

Additional Product may be added to this Agreement by amendment to this Agreement. If Client requests services other than those expressly set out in this Agreement (such as qualification of a new packaging configuration or shipping studies, or validation of alternative batch sizes), or any cost items that are specifically excluded from the Price, Patheon will provide a written quote of the fee for the additional services and Client will advise Patheon whether it wishes to have the additional services performed by Patheon. The scope of work and fees will be agreed in writing by the parties.

13.7 Notices.

Any notice, approval, instruction or other written communication required or permitted under this Agreement will be sufficient if made or given to the other party by personal delivery or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses or email addresses set out below:

If to Client:

PLx Opco Inc.
9 Fishers Lane
Sparta, NJ 07871
Attention: Rita O'Connor, Chief Financial Officer

Email address: roconnor@plxpharma.com

If to Patheon:

Patheon Pharmaceuticals Inc.
2110 East Galbraith Road
Cincinnati, OH 45237
Attention: Director of Legal Services
Email address: [***]

or to any other addresses or email addresses given to the other party in accordance with the terms of this Section 13.7. Notices or written communications made or given by personal delivery, or email will be considered to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt (supported by reasonable written evidence), whichever is sooner.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

13.8 Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.9 Entire Agreement.

This Agreement, together with its Appendices, Capital Equipment Agreement (if any), and the Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter of the Agreement and supersedes all previous written or oral negotiations, commitments, representations, agreements, transactions, or understandings concerning the subject matter of this Agreement. The basis of the parties' agreement is set out expressly and they have not been induced by or relied on any statement or representation that is not set out in this Agreement. Any modification, amendment, or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement and the Quality Agreement (except that the Quality Agreement will prevail in relation to quality matters).

13.10 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by the parties will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of a party to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both parties.

13.11 No Third Party Benefit or Right.

Nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement (except that Patheon Affiliates acting as subcontractors under this Agreement may enforce Sections 10.1 and 10.2). The rights of the parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any other person.

13.12 Execution in Counterparts.

This Agreement may be executed in two or more counterparts, by original or electronic (including "**pdf**") signature, each of which will be considered an original, but all of which together will constitute one and the same instrument.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

13.13 Use of Name.

Neither party may use the other party's name, trademarks or logo or any variations of them, alone or with any other word or words, without the prior written consent of the other party.

13.14 Taxes.

Client will be financially responsible for all specific and necessary taxes, duties, levies and similar charges (and any related interest and penalties) ("**Tax**"), however designated, imposed as a result of the provision by Patheon of the Manufacturing Services, except for Tax based on net income or gross income that is imposed on Patheon.

The parties agree to cooperate to minimize, wherever possible and appropriate, any applicable Tax, and provide reasonable notice and cooperation in connection with any audit by an Authority. Each party will, from time-to-time at the other party's reasonable request, furnish the other party any direct pay or resale certificates, information regarding out-of-state or out-of-country sales or use of equipment, materials or services, and other exemption certificates or similar information reasonably requested by other party.

13.15 Governing Law and Jurisdiction.

This Agreement, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with them or their subject matter or formation are governed by the laws of the State of New York without regard to any conflicts-of-law principle that directs the application to another jurisdiction's law. Both parties hereby submit to the exclusive jurisdiction of the state or federal courts located in New York, New York. The parties further expressly agree that the UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

13.16 Dispute Resolution.

All disputes that arise under or in connection with this Agreement will be resolved in accordance with Appendix 2.

[Signature page to follow]

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

This Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

PATHEON PHARMACEUTICALS INC.	**PLx OPCO INC., DBA PLX PHARMA INC.**
By:/s/ Miguel Faustino Name: Miguel Faustino Title:VP & GM – Cincinnati Regional Ops Date:28 June 2019	By:/s/ Rita O'Connor Name: Rita O'Connor Title:CFO Date:6/28/19

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

APPENDIX 1 – Commercial Supply Pricing

[***]

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

APPENDIX 2 – Dispute Resolution

Negotiation

If any dispute arises out of this Agreement, the parties will first try to resolve it amicably. Any party may send a notice of a dispute to the other, and each party will appoint, within ten Business Days from receipt of the notice, an appropriate single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a party fails to appoint a representative as required above: for Technical Disputes, the expert determination procedure may be started by either party; and for all other disputes, each party will refer the dispute immediately to the Chief Operating Officer or equivalent (or another senior manager as he/she may designate) ("**Senior Officers**") who will meet and discuss as necessary to try to resolve the dispute amicably.

Mediation

If the Senior Officers fail to resolve the dispute, the parties will attempt in good faith to settle the dispute promptly by confidential mediation under the then current CPR Mediation Procedure, before resorting to litigation. If one party fails to participate in settlement negotiations as provided in this Appendix 2, the other party may initiate mediation prior to the expiration of the applicable negotiation periods. The mediator will be chosen with the assistance of CPR (and CPR's choice will be accepted by the parties in the absence of conflict or bias), unless the parties agree on a specific mediator in writing within five Business Days of the referral to mediation. The mediation will take place in New York, New York and the language of the mediation will be English. Unless otherwise agreed, the parties will select a mediator from the CPR Panels of Distinguished Neutrals.

Except where proceedings are required for the purpose of an interim injunction or other interim equitable relief or to preserve a party's legal position pending the outcome of negotiation or mediation, neither party may commence any court proceedings in relation to a dispute until the required mediation has ended without resolving that dispute, the mediation has not ended within 30 days of its initiation, or a party fails to participate in that mediation. Where a party decides not to take part in mediation in contravention of this Appendix 2, it will send written notice of that decision to the other party.

Technical Disputes

If a dispute arises between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement, including conformance of Product to applicable specifications (a "**Technical Dispute**"), the parties will use all reasonable efforts to resolve the dispute by amicable negotiations as provided above. If the parties are unable to resolve a Technical Dispute by negotiation, the Technical Dispute will, at the written request of either party, be referred for determination to an expert in the following manner:

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

(a) Appointment of Expert. Within ten Business Days after the written request, the parties will appoint a single agreed expert with experience and expertise in the subject matter of the dispute. If the parties fail to agree the appointment within that period, then either party may request that a neutral from the International Institute of Conflict Prevention and Resolution appoints a suitable expert (and both parties will accept that appointment in the absence of evident conflict or bias). As a condition of the expert's appointment, the parties will ensure that the expert agrees to disclose any actual or potential conflicts of interest promptly as they arise. The parties do not intend that the expert acts as an arbitrator.

(b) Procedure. The parties will require the expert to provide an opinion on each referred issue (with reasonably detailed reasoning) within 15 Business Days (or as agreed by the parties with the expert). Each party will give to the expert all the evidence and information within their respective possession or control as the expert may reasonably request, which they will disclose promptly and in any event within five Business Days of a written request from the expert to do so. At all times the parties will co-operate in good faith and seek to narrow and limit the issues to be determined.

(c) Final and Binding. The determination of the expert will, except for fraud or manifest error or where an unapproved conflict of interest is discovered, be final and binding upon the parties with respect to the referred Technical Dispute.

(d) Costs. Each party will bear its own costs for any matter referred to an expert under this Appendix 2 and, in the absence of express agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

17 CFR 240.24b-2, confidential information has been omitted in places marked "[***]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

APPENDIX 3 – Conversion Fee Annual Price Adjustment

[***]

Exhibit 31.1

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

I, Natasha Giordano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PLx Pharma 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: August 9, 2019

/s/ Natasha Giordano
Natasha Giordano
President and
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

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

I, Rita O'Connor, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PLx Pharma 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: August 9, 2019

/s/ Rita O'Connor
Rita O'Connor
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of PLx Pharma Inc. (the "Company") for the quarterly period ended June 30, 2019 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

This certification is provided solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Dated: August 9, 2019

/s/ Natasha Giordano
Natasha Giordano
President and
Chief Executive Officer
(principal executive officer)

Dated: August 9, 2019

/s/ Rita O'Connor
Rita O'Connor
Chief Financial Officer
(principal financial officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.