

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 September 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

State or other jurisdiction of  
incorporation or organization

46-4995704

(I.R.S. Employer  
Identification No.)

9 Fishers Lane, Suite E  
Sparta, NJ

(Address of principal executive offices)

07871

(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  
(Title of each class)

PLXP  
(Trading Symbol)

The NASDAQ Capital Market  
(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 November 6, 2019, there were 9,151,854 shares of common stock, \$0.001 par value, issued and outstanding.

**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.

**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™



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**

	September 30, 2019	December 31, 2018
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 18,509,487	\$ 14,250,267
Accounts receivable	-	18,234
Prepaid expenses and other current assets	250,363	421,933
Deferred financing costs	-	174,976
<b>TOTAL CURRENT ASSETS</b>	<b>18,759,850</b>	<b>14,865,410</b>
<b>NON-CURRENT ASSETS</b>		
Property and equipment, net	1,392,206	1,394,230
Lease assets	699,996	-
Goodwill	2,061,022	2,061,022
Security deposit	73,666	67,714
<b>TOTAL ASSETS</b>	<b>\$ 22,986,740</b>	<b>\$ 18,388,376</b>
<b>LIABILITIES, SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued liabilities	\$ 1,290,839	\$ 687,257
Accrued bonus and severance	907,130	1,048,393
Accrued interest	40,508	60,366
Current portion of term loan, net of discount and fees	3,626,168	2,909,709
Other current liabilities	309,239	26,935
<b>TOTAL CURRENT LIABILITIES</b>	<b>6,173,884</b>	<b>4,732,660</b>
<b>NON-CURRENT LIABILITIES</b>		
Accrued interest, net of current portion	462,708	309,440
Term loan, net of discount, fees and current portion	1,548,864	4,280,385
Warrant liability	10,118,838	2,537,317
Accrued dividends	741,089	-
Other liabilities	488,599	84,281
<b>TOTAL LIABILITIES</b>	<b>19,533,982</b>	<b>11,944,083</b>
Series A convertible preferred stock: \$0.001 par value; liquidation value of \$15,000,000; 45,000 shares authorized, 15,000 and 0 shares issued and outstanding	13,661,578	-
<b>Commitments and contingencies</b>		
<b>STOCKHOLDERS' EQUITY (DEFICIT)</b>		
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; 9,122,990 and 8,743,950 shares issued and outstanding	9,123	8,744
Additional paid-in capital	74,720,150	72,871,317
Accumulated deficit	(84,938,093)	(66,435,768)
<b>TOTAL STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>(10,208,820)</b>	<b>6,444,293</b>
<b>TOTAL LIABILITIES, SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>\$ 22,986,740</b>	<b>\$ 18,388,376</b>

See accompanying notes to unaudited consolidated financial statements.

**PLx Pharma Inc.**  
**UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
<b>REVENUES:</b>				
Federal grant	\$ 41,106	\$ 216,530	\$ 541,571	\$ 465,446
<b>TOTAL REVENUES</b>	<u>41,106</u>	<u>216,530</u>	<u>541,571</u>	<u>465,446</u>
<b>OPERATING EXPENSES:</b>				
Research and development	1,214,029	1,219,144	3,805,617	3,032,426
General and administrative	2,503,314	1,800,159	7,180,674	5,870,745
<b>TOTAL OPERATING EXPENSES</b>	<u>3,717,343</u>	<u>3,019,303</u>	<u>10,986,291</u>	<u>8,903,171</u>
<b>OPERATING LOSS</b>	<u>(3,676,237)</u>	<u>(2,802,773)</u>	<u>(10,444,720)</u>	<u>(8,437,725)</u>
<b>OTHER INCOME (EXPENSE):</b>				
Interest income	111,621	77,276	329,063	219,374
Interest and other expense	(230,053)	(290,773)	(805,147)	(849,457)
Change in fair value of warrant liability	5,498,391	(408,803)	(7,581,521)	7,017,923
<b>TOTAL OTHER INCOME (EXPENSE)</b>	<u>5,379,959</u>	<u>(622,300)</u>	<u>(8,057,605)</u>	<u>6,387,840</u>
<b>INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES</b>	<u>1,703,722</u>	<u>(3,425,073)</u>	<u>(18,502,325)</u>	<u>(2,049,885)</u>
Income taxes	-	-	-	-
<b>NET INCOME (LOSS)</b>	<u>\$ 1,703,722</u>	<u>\$ (3,425,073)</u>	<u>\$ (18,502,325)</u>	<u>\$ (2,049,885)</u>
Preferred dividends and beneficial conversion feature	(311,136)	-	(13,433,397)	-
<b>NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS</b>	<u>\$ 1,392,586</u>	<u>\$ (3,425,073)</u>	<u>\$ (31,935,722)</u>	<u>\$ (2,049,885)</u>
Net income (loss) per common share - basic	<u>\$ 0.09</u>	<u>\$ (0.39)</u>	<u>\$ (3.60)</u>	<u>\$ (0.23)</u>
Net income (loss) per common share - diluted	<u>\$ 0.09</u>	<u>\$ (0.39)</u>	<u>\$ (3.60)</u>	<u>\$ (0.23)</u>
Weighted average shares of common shares - basic	<u>8,921,345</u>	<u>8,735,790</u>	<u>8,860,168</u>	<u>8,730,303</u>
Weighted average shares of common shares - diluted	<u>8,936,255</u>	<u>8,735,790</u>	<u>8,860,168</u>	<u>8,730,303</u>

See accompanying notes to unaudited consolidated financial statements.

**PLx Pharma Inc.**  
**UNAUDITED CONSOLIDATED STATEMENTS OF CHANGES IN SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**

	Temporary Equity		Permanent Equity				
	Series A 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
Stock-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
Stock-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
Share-based compensation expense					247,536		247,536
Common shares issued to vendor			6,407	7	22,493		22,500
Net loss						(3,425,073)	(3,425,073)
Balance at September 30, 2018	-	\$ -	8,738,163	\$ 8,739	\$ 72,772,537	\$ (69,382,133)	\$ 3,399,143
Balance at December 31, 2018	-	\$ -	8,743,950	\$ 8,744	\$ 72,871,317	\$ (66,435,768)	\$ 6,444,293
Stock-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)
Stock-based compensation expense					276,505		276,505
Common shares issued to vendor			4,218	4	22,496		22,500
Common shares issued for cash			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)
Share-based compensation expense					260,577		260,577
Common shares issued to vendor			1,155	1	(1)		-
Common shares issued for cash			250,466	251	1,478,834		1,479,085
Series A Preferred - declared dividends					(311,136)		(311,136)
Net income						1,703,722	1,703,722
Balance at September 30, 2019	15,000	\$ 13,661,578	9,122,990	\$ 9,123	\$ 74,720,150	\$ (84,938,093)	\$ (10,208,820)

See accompanying notes to unaudited consolidated financial statements.

**PLx Pharma Inc.**  
**UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOW**

	<b>Nine months ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (18,502,325)	\$ (2,049,885)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	126,692	145,218
Share-based compensation	603,314	765,136
Amortization of debt discounts and issuance costs	172,438	185,139
Change in fair value of warrant liability	7,581,521	(7,017,923)
Provision for obsolete inventory	-	770,619
Loss on sale of property and equipment	12,398	-
Changes in operating assets and liabilities:		
Accounts receivable	18,234	(22,107)
Inventory	-	(524,245)
Prepaid expenses and other assets	165,618	458,997
Lease assets	12,538	-
Accounts payable and accrued liabilities	820,711	55,405
Accrued bonus and severance	(141,263)	(94,629)
Accrued interest	133,410	166,442
Other current and long-term liabilities	(25,912)	(50,406)
Net cash used in operating activities	<u>(9,022,626)</u>	<u>(7,212,239)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(145,661)	(654,870)
Proceeds from sale of property and equipment	11,442	-
Net cash used in investing activities	<u>(134,219)</u>	<u>(654,870)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Net proceeds from issuance of Series A convertible preferred stock	13,661,578	-
Net proceeds from issuance of common stock	1,941,987	-
Repayments of term loan	(2,187,500)	-
Net cash provided by financing activities	<u>13,416,065</u>	<u>-</u>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>4,259,220</b>	<b>(7,867,109)</b>
Cash and cash equivalents, beginning of period	14,250,267	24,404,368
Cash and cash equivalents, end of period	<u>\$ 18,509,487</u>	<u>\$ 16,537,259</u>
<b>SUPPLEMENTAL INFORMATION</b>		
Cash paid during the period for:		
Income taxes	\$ -	\$ -
Interest	\$ 486,902	\$ 497,136
<b>NON-CASH INVESTING AND FINANCING TRANSACTIONS</b>		
Property and equipment included in accounts payable	\$ 2,847	\$ -
Preferred stock beneficial conversion feature and dividends	\$ 13,433,397	\$ -
Value of common shares issued to vendor for services	\$ 45,000	\$ 67,500

See accompanying notes to unaudited consolidated financial statements.

**PLx Pharma Inc.**  
**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 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 September 30, 2019, the Company had an accumulated deficit of \$84.3 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 September 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 September 30, 2019 and the results of operations for the three and nine months ended September 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 September 30, 2019, the Company had cash and cash equivalents of approximately \$18.5 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 September 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 September 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 September 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 \$5.3 million 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 September 30, 2019, the Company did not have any finance leases.

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### **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 nine months ended September 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 \$41,106 and \$216,530 of revenue under this arrangement during the three months ended September 30, 2019 and 2018, respectively. The Company recognized \$541,571 and \$465,446 of revenue under this arrangement during the nine months ended September 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 September 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.

[Table of Contents](#)**Income (Loss) per Share**

In periods of net loss, basic loss per share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period. The Series A convertible preferred stock contains non-forfeitable rights to dividends, and therefore are considered to be participating securities; in periods of net income, the calculation of basic earnings per share excludes from the numerator net income attributable to the Series A convertible preferred stock and excludes the impact of those shares from the denominator.

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. For periods of net income, diluted earnings per share is computed using the more dilutive of the “two class method” or the “treasury method.” Dilutive earnings per share under the “two class method” is calculated by dividing net income available to common stockholders as adjusted for the participating impacts of the Series A convertible preferred stock, by the weighted-average number of shares outstanding plus the dilutive impact of all other potential dilutive common shares, consisting primarily of common shares underlying common stock options and stock purchase warrants using the treasury stock method. Dilutive earnings per share under the “treasury method” is calculated by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the dilutive 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. For the three months ended September 30, 2019, the “two class method” was more dilutive.

The Company has calculated basic and diluted earnings per share for the three months ended September 30, 2019 as follows:

	<b>Basic earnings per share</b>	<b>Diluted earnings per share</b>
Net income	\$ 1,703,722	\$ 1,703,722
Preferred stock dividends	(311,136)	(311,136)
Impact of participation rights	(555,508)	(555,508)
Net income available for common shares	<u>\$ 837,078</u>	<u>\$ 837,078</u>
Weighted average outstanding common shares	8,921,345	8,921,345
Impact of stock options	-	14,910
Weighted average outstanding common shares	<u>8,921,345</u>	<u>8,936,255</u>
Earnings per share	<u>\$ 0.09</u>	<u>\$ 0.09</u>

Due to net losses, none of the potential dilutive securities had a dilutive impact during the nine months ended September 30, 2019 and 2018 or for the three months ended September 30, 2018.

The number of anti-dilutive share for the three months ending September 30, 2019 and 2018 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 income per share, was 10,306,370 and 3,911,302 shares, respectively.

The number of anti-dilutive shares for the nine months ended September 30, 2019 and 2018, 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 10,503,537 and 3,911,302 shares as of September 30, 2019 and 2018, respectively.

**Reclassifications**

Certain reclassifications have been made to the prior-year financial statements to conform to the current-year presentation. These reclassifications had no effect on the reported results of operations.

**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.

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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 9.0% at September 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 September 30, 2019 and December 31, 2018, \$5.3 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 \$123,832 and \$215,291, and long-term unamortized discounts and issuance cost of \$13,636 and \$94,615, respectively. Total interest expense recognized for the three months ended September 30, 2019 and 2018 was \$230,053 and \$290,773, respectively. Total interest expense recognized for the nine months ended September 30, 2019 and 2018 was \$792,750 and \$849,457, 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 365,439 shares under the agreement generating gross proceeds of approximately \$2,153,887 and net proceeds of approximately \$1,941,987 after deducting legal and commission costs. As of September 30, 2019, approximately \$10.3 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 September 30, 2019, the carrying value of the temporary equity was \$13.7 million net of approximately \$1.3 million in offering costs.

The Company recognized \$311,136 (or \$20.74 per share of Series A Preferred Stock) and \$741,089 (or \$49.41 per share of Series A Preferred Stock) of total dividends on the Series A Preferred Stock during the three and nine months ended September 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.

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**Stock Options**

Following is a summary of option activities for the nine months ended September 30, 2019:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding, December 31, 2018	1,206,709	\$ 17.93	7.0	\$ -
Granted	714,350	\$ 5.76		
Exercised, cancelled or forfeited	(176,380)	\$ 8.70		
Outstanding, September 30, 2019	<u>1,744,679</u>	\$ 13.88	7.1	\$ 150,450
Exercisable, September 30, 2019	<u>991,662</u>	\$ 20.15	5.5	\$ 49,349

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 nine months ended September 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 September 30, 2019, the Company had \$2.5 million in unamortized expense related to unvested options which is expected to be expensed over a weighted average of 2.3 years.

During the three months ended September 30, 2019 and 2018, the Company recorded \$260,577 and \$247,536, respectively, in total share-based compensation expense related to the stock options and stock bonuses. During the nine months ended September 30, 2019 and 2018, the Company recorded \$603,314 and \$765,136, 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, October 3, 2021, and June 30, 2024. The office leases require the Company to pay for its portion of taxes, maintenance and insurance. Rental expense under these agreements was \$105,072 and \$29,753 for the three months ended September 30, 2019 and 2018, respectively. Rental expense under these agreements was \$289,553 and \$86,890 for the nine months ended September 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 September 30, 2019 are classified as operating leases. As of September 30, 2019, the Company has five operating leases for facilities and office equipment with remaining terms expiring from 2019 through 2024 and a weighted average remaining lease term of 2.7 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.

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

Operating lease cost	\$	273,392
Variable lease costs		16,161
Sublease income		(175,557)
Total lease costs	\$	<u>113,996</u>

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

Future undiscounted cash flows:

2019	\$	101,280
2020		356,196
2021		262,850
2022		60,819
2023		60,264
2024		30,132
Total		<u>871,541</u>

Discount factor		(107,911)
Lease liability		763,630
Current lease liability		(309,239)
Non-current lease liability	\$	<u>454,391</u>

#### 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 \$10,000 and \$10,667 related to the University in the three months ended September 30, 2019 and 2018, respectively. The Company recognized total expenses of \$260,000 and \$58,522 related to the University in the nine months ended September 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 13,601 and 15,340 shares of common stock during the nine months ended September 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.

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- 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 September 30, 2019 due to the remote possibility 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 September 30, 2019:

Description	Balance at June 30, 2019	Established in 2019	Change in Fair Value	Balance at September 30, 2019
Warrant liability	\$ 15,617,229	\$ -	\$ (5,498,391)	\$ 10,118,838

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 nine months ended September 30, 2019:

Description	Balance at December 31, 2018	Established in 2019	Change in Fair Value	Balance at September 30, 2019
Warrant liability	\$ 2,537,317	\$ -	\$ 7,581,521	\$ 10,118,838

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

	Level 1	Level 2	Level 3	Total
Warrant liability	\$ -	\$ -	\$ 10,118,838	\$ 10,118,838
Balance at September 30, 2019	\$ -	\$ -	\$ 10,118,838	\$ 10,118,838

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	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Warrant liability	\$ -	\$ -	\$ 2,537,317	\$ 2,537,317
Balance at December 31, 2018	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 2,537,317</u>	<u>\$ 2,537,317</u>

**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 nine months ended September 30, 2019 and 2018.

**NOTE 8. SUBSEQUENT EVENTS**

Subsequent to September 30, 2019, the Company issued 28,864 shares under the JMP equity distribution agreement generating net proceeds of \$0.1 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 (September 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 nine months ended September 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.

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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.

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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 \$5.3 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 September 30, 2019 and 2018**

**Revenue**

Total revenues were \$41,106 for the three months ended September 30, 2019, compared to revenues of \$216,530 for the three months ended September 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 \$3.7 million during the three months ended September 30, 2019, a 23% increase from operating expenses of approximately \$3.0 million in the comparable period in 2018. Operating expenses for the three months ended September 30, 2019 and 2018 were as follows:

	Three Months Ended		Increase (Decrease)	
	September 30,		\$	%
	2019	2018		
Operating Expenses				
Research and development expenses	\$ 1,214,029	\$ 1,219,144	\$ (5,115)	0%
General and administrative expenses	2,503,314	1,800,159	703,155	39%
Total operating expenses	<u>\$ 3,717,343</u>	<u>\$ 3,019,303</u>	<u>\$ 698,040</u>	23%

**Research and Development Expenses**

Research and development expenses totaled approximately \$1.2 million in the three months ended September 30, 2019 and in the prior year period. The expenses in both periods included continued product development and manufacturing activities for VAZALORE.

**General and Administrative Expenses**

General and administrative expenses totaled approximately \$2.5 million in the three months ended September 30, 2019, compared to \$1.8 million in the prior year period. The \$0.7 million increase is due to commercial related activities to support the upcoming launch.

**Other income (expense), net**

Other income (expense), net totaled approximately \$5.4 million of net other income in the three months ended September 30, 2019, compared to \$0.6 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 (\$5.5 million of other income in the three months ended September 30, 2019, compared to \$0.4 million of other expense in the comparable 2018 period).

**Comparison of Nine Months Ended September 30, 2019 and 2018****Revenue**

Total revenues were \$541,571 for the nine months ended September 30, 2019, compared to revenues of \$465,446 for the nine months ended September 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 \$11.0 million during the nine months ended September 30, 2019, a 23% increase from operating expenses of approximately \$8.9 million in the comparable period in 2018. Operating expenses for the nine months ended September 30, 2019 and 2018 were as follows:

	<b>Nine Months Ended</b>		<b>Increase (Decrease)</b>	
	<b>September 30,</b>			
	<b>2019</b>	<b>2018</b>	<b>\$</b>	<b>%</b>
Operating Expenses				
Research and development expenses	\$ 3,805,617	\$ 3,032,426	\$ 773,191	25%
General and administrative expenses	7,180,674	5,870,745	1,309,929	22%
Total operating expenses	<u>\$ 10,986,291</u>	<u>\$ 8,903,171</u>	<u>\$ 2,083,120</u>	23%

**Research and Development Expenses**

Research and development expenses totaled approximately \$3.8 million in the nine months ended September 30, 2019, compared to \$3.0 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, packaging, stability and analytical costs related of the registration batches which provide data to be submitted in our sNDA filing.

**General and Administrative Expenses**

General and administrative expenses totaled approximately \$7.2 million in the nine months ended September 30, 2019, compared to \$5.9 million in the prior year period. This increase is due to commercial related activities to support the upcoming launch of \$1.1 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 \$8.1 million of net other expense in the nine months ended September 30, 2019, compared to \$6.4 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 (\$7.6 million of other expense in the nine months ended September 30, 2019, compared to \$7.0 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:

	<b>Nine Months Ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
Net cash used in operating activities	\$ (9,022,626)	\$ (7,212,239)
Net cash used in investing activities	\$ (134,219)	\$ (654,870)
Net cash provided by financing activities	\$ 13,416,065	\$ -

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***Net Cash Used in Operating Activities***

Net cash used in operating activities of \$9.0 million for the nine months ended September 30, 2019 primarily reflects our net loss for the period of \$18.5 million adjusted for various non-cash charges and income, including (i) \$7.6 million change in fair value of warrant liability reflected as other expense, (ii) \$0.6 million of share-based compensation, (iii) \$0.2 million of amortization of debt discounts and issuance costs, and (iv) net operating asset/liability changes of approximately \$1.0 million, and all other \$0.2 million.

Net cash used in operating activities of \$7.2 million for the nine months ended September 30, 2018 primarily reflects our net loss for the period of \$2.0 million adjusted for various non-cash charges and income, including (i) \$7.0 million change in fair value of warrant liability reflected as other income, partially offset by (ii) \$0.8 million for an increase to inventory obsolescence reserve, (iii) \$0.8 million of share-based compensation, (iv) \$0.2 million of amortization of debt discounts and issuance costs and (v) \$0.1 million of depreciation expense.

***Net Cash Used in Investing Activities***

Net cash used in investing activities totaled approximately \$0.1 million and \$0.7 million in the nine months ended September 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 \$13.4 million in the nine months ended September 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 \$1.9 million offset by \$2.2 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 our 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 365,439 shares under the agreement generating gross proceeds of approximately \$2.2 million and net proceeds of approximately \$1.9 million after deducting legal and commission costs. As of September 30, 2019, approximately \$10.3 million remained available under the agreement.

We had no financing activity in the nine months ended September 30, 2018.

***Future Liquidity and Needs***

As of September 30, 2019, we had working capital of approximately \$12.6 million, including cash and cash equivalents of \$18.5 million. Based on our expected operating cash requirements and capital expenditures, we believe the Company’s cash on hand at September 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 September 30, 2019, we had an accumulated deficit of \$84.3 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 September 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 September 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**

None.

**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**

<b><u>Number</u></b>	<b><u>Description</u></b>
31.1	<a href="#">Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*</a>
31.2	<a href="#">Certification of the Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*</a>
32.1	<a href="#">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.*</a>
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.

**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.

Date: November 8, 2019

**PLX PHARMA INC.**

/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)

**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: November 8, 2019

/s/ Natasha Giordano

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

**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: November 8, 2019

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

**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 September 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: November 8, 2019

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

Dated: November 8, 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.