Table of Contents

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, 2022

Or

☐ **Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934 Commission File Number 001-36351**

Commission File Number 001-36351

PLx Pharma Inc.

(Exact name of registrant as specified in its charter)

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

Registrant's telephone number, including area code **(973) 409-6541**

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 8, 2022, there were 29,137,692 shares of common stock, $0.001 par value, issued and outstanding.

PLx Pharma Inc.

Table of Contents

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 subsidiary, 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:

- the potential results of the strategic review process we are undertaking with Raymond James & Associates, Inc. to explore and evaluate strategic alternatives with the goal of enhancing stockholder value;
- our ability to maintain regulatory approval of VAZALORE® 81 mg and VAZALORE® 325 mg (referred to together as "VAZALORE") and any future product candidates;
- the benefits of the use of VAZALORE;
- the projected dollar amounts of future sales of established and novel technologies designed to deliver oral non-steroidal anti-inflammatory drugs ("NSAIDs") and other analgesics while limiting direct contact with the stomach lining;
- our ability to successfully further 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 and maintain a specialty sales force and commercial infrastructure or collaborate with a firm that has these capabilities;
- our ability to compete with companies currently producing gastrointestinal("GI")-safety designed technologies for oral 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 third-party warehouse and distribution centers to store and deliver our products to retail trade locations;
- our reliance on retail trade customers to maintain an adequate supply of VAZALORE on store shelves or displays;
- our ability to obtain supply of raw materials;
- our reliance on our current and any potential 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 need for or ability to obtain additional financing;
- 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;
- any impact of the COVID-19 pandemic on our business and financial results;
- any impact of difficult macroeconomic conditions, such as inflation and reductions in consumer spending, on the demand for our products;
- our financial performance;
- developments and projections relating to our competitors or our industry;
- our failure to meet the continued listing requirements of the Nasdaq Stock Market which could result in a delisting of our common stock;
- our ability to access additional capital due to fluctuations in the U.S. stock market; and
- our ability to identify, evaluate and complete any strategic alternative that yields value for our stockholders.

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 conform 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, trade names and service marks, including:

- PLX®
- PLX PHARMA®
- 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 ® or ™ symbols, 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. CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

PLx Pharma Inc.
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except share and per share data)

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 25,834	$ 69,392
Accounts receivable	139	634
Inventory, net	3,178	2,458
Prepaid expenses and other current assets	1,070	992
TOTAL CURRENT ASSETS	30,221	73,476
NON-CURRENT ASSETS		
Property and equipment, net	768	858
Goodwill	2,061	2,061
Other assets	174	247
TOTAL ASSETS	$ 33,224	$ 76,642
LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 5,069	$ 10,600
Accrued bonuses	1,112	1,163
Other current liabilities	131	116
TOTAL CURRENT LIABILITIES	6,312	11,879
NON-CURRENT LIABILITIES		
Warrant liability	536	12,818
Accrued dividends	129	129
Other liabilities	46	136
TOTAL LIABILITIES	7,023	24,962
Series A convertible preferred stock: $0.001 par value; liquidation value of $12,642,000; 45,000 shares authorized, 12,642 issued and outstanding at September 30, 2022 and December 31, 2021	13,708	13,708
Series B convertible preferred stock: $0.001 par value; liquidation value of $2,492,722; 25,000 shares authorized, 2,364 issued and outstanding at September 30, 2022 and December 31, 2021	2,306	2,306
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock; $0.001 par value; 930,000 shares authorized; none issued and outstanding at September 30, 2022 and December 2021	-	-
Common stock; $0.001 par value; 100,000,000 shares authorized; 29,137,692 and 27,539,229 shares issued and outstanding at September 30, 2022 and December 31, 2021	29	28
Additional paid-in capital	189,572	183,912
Accumulated deficit	(179,414)	(148,274)
TOTAL STOCKHOLDERS' EQUITY	10,187	35,666
TOTAL LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY	$ 33,224	$ 76,642

See accompanying notes to unaudited consolidated financial statements.

PLx Pharma Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
REVENUES:				
Net sales	$ 386	$ 6,616	$ 2,952	$ 6,616
TOTAL REVENUES	386	6,616	2,952	6,616
Costs of sales	1,460	3,913	3,449	3,913
GROSS (LOSS) PROFIT	(1,074)	2,703	(497)	2,703
OPERATING EXPENSES:				
Research and development	623	1,552	1,833	3,494
Selling, marketing and administrative	9,142	11,013	41,243	19,147
TOTAL OPERATING EXPENSES	9,765	12,565	43,076	22,641
OPERATING LOSS	(10,839)	(9,862)	(43,573)	(19,938)
OTHER INCOME (EXPENSE):				
Interest income (expense), net	119	4	151	(2)
Change in fair value of warrant liability	2,223	(11,784)	12,282	(29,747)
TOTAL OTHER INCOME (EXPENSE)	2,342	(11,780)	12,433	(29,749)
LOSS BEFORE INCOME TAXES	(8,497)	(21,642)	(31,140)	(49,687)
Income taxes	-	-	-	-
NET LOSS	(8,497)	(21,642)	(31,140)	(49,687)
Preferred dividends	-	-	-	(2,525)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (8,497)	$ (21,642)	$ (31,140)	$ (52,212)
Net loss per common share, basic and diluted	$ (0.30)	$ (0.80)	$ (1.11)	$ (2.34)
Weighted average shares of common shares, basic and diluted	28,603,426	26,911,855	27,949,292	22,342,538

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

PLx Pharma Inc.

CONSOLIDATED STATEMENTS OF CHANGES IN SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(Unaudited)
(in thousands, except share data)

For the Three and Nine Months Ended September 30, 2022 and 2021

	Temporary Equity				Permanent Equity				
	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	12,642	$ 13,708	2,364	$ 2,306	27,539,229	$ 28	$ 183,912	$ (148,274)	$ 35,666
Stock-based compensation expense							1,088		1,088
Net loss								(10,785)	(10,785)
Balance at March 31, 2022	12,642	13,708	2,364	2,306	27,539,229	28	185,000	(159,059)	25,969
Stock-based compensation expense							1,050		1,050
Common shares issued					633,239		1,330		1,330
Net loss								(11,858)	(11,858)
Balance at June 30, 2022	12,642	13,708	2,364	2,306	28,172,468	28	187,380	(170,917)	16,491
Stock-based compensation expense							1,107		1,107
Common shares issued					965,224	1	1,085		1,086
Net loss								(8,497)	(8,497)
Balance at September 30, 2022	12,642	$ 13,708	2,364	$ 2,306	29,137,692	$ 29	$ 189,572	$ (179,414)	$ 10,187
Balance at December 31, 2020	15,000	$ 13,662	8,000	$ 7,723	13,911,633	$ 14	$ 91,203	$ (102,149)	$ (10,932)
Stock-based compensation expense							573		573
Series A Preferred - declared dividends							(217)		(217)
Series B Preferred - declared dividends							(105)		(105)
Financing					8,924,700	9	66,873		66,882
Net loss								(11,540)	(11,540)
Balance at March 31, 2021	15,000	13,662	8,000	7,723	22,836,333	23	158,327	(113,689)	44,661
Stock-based compensation expense							558		558
Settlement of dividends on Preferred Stock with adjustment of conversion price		2,603		386					-
Conversion of Preferred Stock to Common Stock	(2,358)	(2,557)	(5,636)	(5,803)	3,000,000	3	8,358		8,361
Exercise of Warrants					308,675		3,040		3,040
Net loss								(16,505)	(16,505)
Balance at June 30, 2021	12,642	13,708	2,364	2,306	26,145,008	26	170,283	(130,194)	40,115
Stock-based compensation expense							741		741
Issuance of common stock, net of issuance costs					448,268		7,578		7,578
Exercise of Warrants					883,746	1	4,100		4,101
Net loss								(21,642)	(21,642)

Balance at September 30, 2021	12,642	$	13,708	2,364	$	2,306	27,477,022	$	27	$	182,702	$	(151,836)	$	30,893

See accompanying notes to unaudited consolidated financial statements.

PLx Pharma Inc.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Nine months ended September 30, 2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (31,140)	$ (49,687)
Adjustments to reconcile net loss to net cash used in operating activities:		
Inventory reserve	1,211	$ -
Depreciation and amortization	90	86
Stock-based compensation	3,245	1,872
Amortization of right of use assets	73	72
Amortization of debt discounts and issuance costs	-	3
Change in fair value of warrant liability	(12,282)	29,747
Loss on disposal of property and equipment	-	157
Changes in operating assets and liabilities		
Accounts receivable	495	(3,253)
Inventory	(1,931)	(2,047)
Prepaid expenses and other assets	(78)	(223)
Accounts payable and accrued liabilities	(5,531)	5,590
Accrued bonuses	(51)	(345)
Accrued interest	-	(598)
Other current and long-term liabilities	(75)	(131)
Net cash used in operating activities	(45,974)	(18,757)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from disposal of property and equipment	-	94
Net cash provided by investing activities	-	94
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of common stock	2,416	74,461
Proceeds from exercise of warrants	-	4,932
Repayments of long-term debt	-	(625)
Net cash provided by financing activities	2,416	78,768
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(43,558)	60,105
Cash and cash equivalents, beginning of period	69,392	22,449
Cash and cash equivalents, end of period	$ 25,834	$ 82,554
SUPPLEMENTAL INFORMATION		
Cash paid during the period for:		
Income taxes	$ -	$ -
Interest	$ -	$ 6
NON-CASH INVESTING AND FINANCING TRANSACTIONS		
Cashless exercise of warrants	$ -	$ 1,879
Preferred stock conversion feature and dividends	$ -	$ 2,525
Conversion of preferred stock	$ -	$ 8,361

See accompanying notes to unaudited consolidated financial statements.

PLx Pharma Inc.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2022
(unaudited)

NOTE 1. BACKGROUND AND ORGANIZATION

Business Operations

PLx Pharma Inc. (the “Company”, “we”, “our” or “us”), together with its subsidiary PLx Opco Inc., is a commercial-stage drug delivery platform technology company focused on improving how and where active pharmaceutical ingredients (“APIs”) are absorbed in the gastrointestinal ("GI") tract via its clinically-validated and patent-protected PLxGuard™ technology. The Company has two Food and Drug Administration (“FDA”) approved products, VAZALORE® 81 mg and VAZALORE® 325 mg (referred to together as “VAZALORE”), which are liquid-filled aspirin capsules for over-the-counter distribution ("OTC").

Impact of COVID-19 Pandemic on Financial Statements

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a “pandemic”, or a worldwide spread of a new disease. Many countries imposed and continue to enforce quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses.

The Company has not experienced a significant disruption or delay in the development, manufacturing or sales of VAZALORE due to COVID-19, and has not otherwise experienced any significant negative impact on its financial condition, results of operations or cash flows. However, the extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the remaining duration of the pandemic, travel restrictions and social distancing in the United States and other countries as well as, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the pandemic. The unaudited consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Recent Developments

In August 2022, the Company engaged Raymond James & Associates, Inc. (“Raymond James”) as financial advisor to explore and evaluate its strategic alternatives with the goal of enhancing stockholder value. The strategic review process is underway and the strategic alternatives to be considered may include, without limitation, exploring the potential for a possible merger, business combination, or investment into the Company. In conjunction with the exploration of strategic alternatives, the Company has been streamlining its sales and marketing plan in order to preserve its capital and cash resources.

NOTE 2. GOING CONCERN

During the nine months ended September 30, 2022, the Company had a net loss of $31.1 million and used cash in operations of $46.0 million. As of September 30, 2022, the Company had an accumulated deficit of approximately $179.4 million. Due to the difficult macroeconomic environment that has put pressure on the rate of acceptance of VAZALORE in the marketplace and on our commercial resources combined with restrictive capital markets, the Company engaged Raymond James in August 2022 to explore and evaluate strategic alternatives. There is no assurance that such activities will result in any agreements or transactions that will enhance stockholder value or provide additional capital. The rate of acceptance of VAZALORE in the marketplace, together with the uncertainty with regards to completing a transaction or the ability to raise additional capital, creates substantial doubt about the Company’s ability to continue as a going concern for at least one year from the date that the accompanying financial statements are issued.

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 and the Company’s 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’s unaudited consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty.

NOTE 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting and Principles of Consolidation

The accompanying 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, 2021 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, 2021. 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, 2022 and the results of operations for the three and nine months ended September 30, 2022 and 2021.

The accompanying unaudited consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, PLx Opco Inc. All significant intercompany balances and transactions have been eliminated within the unaudited consolidated financial statements.

Use of Estimates

The preparation of our unaudited consolidated 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 consolidated financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying unaudited consolidated financial statements, estimates are used for, but not limited to, the fair value of warrant liability, the fair value of stock-based compensation, trade promotional allowances, and allowance for inventory obsolescence. Actual results could differ from those estimates.

Inventory

Inventory is stated at the lower of cost or net realizable value, using the first-in first-out method based on actual costs. Inventory as of September 30, 2022 and December 31, 2021 was comprised of the following:

Description	September 30, 2022	December 31, 2021
	(in thousands)	
Raw Materials	$ 361	$ 132
Work-in-Progress	-	338
Finished Goods	2,817	1,988
Total Inventory	$ 3,178	$ 2,458

The Company regularly reviews inventory quantities on hand and assesses the need for an allowance for obsolescence based on estimates of net realizable value. During the three and nine months ended September 30, 2022, the Company reserved $0.9 million and $1.2 million, respectively, for obsolete finished goods.

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 revenue 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 began generating revenue in the U.S. from its sales of VAZALORE in 81 mg and 325 mg doses in the third quarter of 2021 and recognizes revenue, at a point in time, when control of a promised good is transferred to a customer in an amount that reflects consideration that the Company expects to be entitled to in exchange for that good. This occurs either when the finished goods are received by the customer or when a product is picked up by the customer or the customer's carrier. The Company recognized total revenue from sales of VAZALORE of $0.4 million with 58% of net sales for the 81 mg dose and 42% of net sales for the 325 mg dose for the three months ended September 30, 2022. The Company recognized total revenue from sales of VAZALORE of $3.0 million with 70% of net sales for the 81 mg dose and 30% of net sales for the 325 mg dose for the nine months ended September 30, 2022. For the three and nine months ending September 30, 2021, total revenue from sales of VAZALORE was $6.6 million with 81 mg dose representing 67% of the net sales.

Nature of Goods and Services

The Company generates revenue from the sale of its VAZALORE products through a broad distribution platform that includes drugstores, mass merchandisers, grocery stores, and e-commerce channels, all of which sell its products to consumers. Finished goods products are typically shipped FOB destination and accordingly, the Company recognizes revenue upon delivery to the customer or pick-up by the customer's carrier.

Satisfaction of Performance Obligations

The Company had no unsatisfied performance obligations or deferred revenue as of September 30, 2022.

Variable Consideration

Provisions for certain customer promotional programs, product returns and discounts to customers are accounted for as variable consideration and recorded as a reduction in sales, based on an estimate of future returns, and customer prompt payment discounts, redemption of coupons by consumers and trade promotional allowances paid to customers. These allowances cover extensive promotional activities, primarily comprised of cooperative advertising, slotting, coupons, periodic price reduction arrangements, and other in-store displays.

The reserves for sales returns and consumer and trade promotion obligations are established based on the Company's best estimate of the amounts necessary to settle future and existing obligations for products sold as of the balance sheet date. The Company uses trend experience and coupon redemption inputs to determine coupon reserve requirements and uses forecasted customer and sales organization inputs, and historical trend analysis for consumer brands to determine the reserves for other promotional activities and sales returns. The balance of reserves for sales returns and consumer and trade promotion obligations, reflected in the accompanying unaudited consolidated balance sheets in accounts payable and accrued liabilities, was $1.0 million and $1.3 million as of September 30, 2022 and December 31, 2021, respectively.

Advertising

Advertising costs are expensed as they are incurred. The Company incurred advertising costs of $1.4 million and $16.6 million during the three and nine months ended September 30, 2022, respectively, which are included in selling, marketing, and administrative ("SM&A") expenses in the unaudited consolidated statements of operations. During the three and nine months ended September 30, 2021 the Company incurred advertising costs of $2.7 million.

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 Company's Series A convertible preferred stock (the "Series A Preferred Stock") and Series B convertible preferred stock (the "Series B Preferred Stock" and, together with the Series A Preferred Stock, collectively the "Preferred Stock") contain 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 Preferred Stock and excludes the impact of those shares from the denominator.

In 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 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.

Due to net losses, none of the participating securities nor potential dilutive securities had a dilutive impact during the three and nine months ended September 30, 2022 and 2021.

The following table sets forth the potential dilutive securities:

	September 30, 2022	September 30, 2021
Stock Options	4,203,006	3,498,297
Warrants	6,596,096	6,665,814
Convertible Preferred Stock	6,476,275	6,476,275
Total Potential Dilutive Shares	17,275,377	16,640,386

Recent Accounting Developments

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which is designed to provide financial statement users with more information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. When determining such expected credit losses, the guidance requires companies to apply a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. This guidance is effective on a modified retrospective basis for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company is currently evaluating ASU 2016-13 and its impact on its financial position, results of operations and cash flows.

In August 2020, the FASB issued ASU 2020-06 *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (subtopic 815-40)* that provides new guidance on the accounting for convertible debt instruments and contracts in an entity's own equity. The guidance simplifies the accounting for convertible instruments by reducing the various accounting models that can require the instrument to be separated into a debt component and equity component or derivative component. Additionally, the guidance eliminated certain settlement conditions previously required to be able to classify a derivative in equity. The new guidance is effective on a modified or full retrospective basis for fiscal years beginning after December 15, 2023, including interim periods with those fiscal years. The Company is currently evaluating ASU 2020-06 and its impact on its financial position, results of operations and cash flows.

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.

Subsequent Events

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

NOTE 4. STOCKHOLDERS' EQUITY

Common Stock

On March 5, 2021, the Company completed an underwritten public offering in which the Company issued and sold 7,875,000 shares of the Company's common stock at a price to the public of $8.00 per share (the "Offering"). Gross proceeds of the Offering were $63.0 million before deducting underwriting discounts and commissions and other offering expenses payable by the Company and resulted in net proceeds of $59.0 million after deducting underwriting discounts and commissions and other offering expenses payable by the Company. The underwriters retained a customary 30-day overallotment option to purchase up to 1,181,250 shares of common stock at the public offering price, less underwriting discounts and commission. The overallotment option was exercised on March 16, 2021 for 1,049,700 shares with gross proceeds of $8.4 million and net proceeds of $7.9 million after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Convertible Preferred Stock

Series A 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 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 was initially convertible into common shares at a conversion price of $2.60 per share, subject to certain adjustments. Holders of the Series A Preferred Stock are entitled to an initial dividend rate of 8.0% per annum, which ended on February 26, 2021, the date of the FDA's approval of the supplemental NDA of VAZALORE 325 mg and VAZALORE 81mg. The dividends were compounded quarterly and payable in cash or shares of Series A Preferred Stock at the Company's option or, alternatively, the initial conversion price will be adjusted upon conversion to reflect the impact of the accrued dividends. The Series A Preferred Stock carries a liquidation preference equal to its stated value of $1,000 plus accrued and unpaid dividends.

In June 2021, the Series A Preferred Stock holders converted 2,358 shares of Series A Preferred Stock into shares of common stock pursuant to the original terms of the Series A Preferred Stock. Upon conversion, accrued dividends payable of $2.6 million were settled by adjusting the initial conversion price, resulting in a new conversion price of $2.22 per share. The revision of the conversion price resulted in both the recognition and write-off of a contingent beneficial conversion feature in the amount of $2.2 million which is reflected as a deemed dividend which was accounted for as an increase and decrease to additional-paid-in capital in equity due to the Company's accumulated deficit position. As a result of the conversion, Series A Preferred Stock carrying value was reduced $2.6 million and the Company issued 1,064,517 shares of its common stock to such holders.

As of September 30, 2022, 12,642 shares of Series A Preferred Stock remain outstanding with a conversion price of $2.22 per share. The Series A Preferred Stock is classified as temporary equity due to the presence of certain contingent cash redemption features, and has a carrying value of $13.7 million as of September 30, 2022.

The Company recognized no dividends on the Series A Preferred Stock during the three and nine months ended September 30, 2022. The Company recognized $2,419,893 (or $0.11 per share) of total dividends on the Series A Preferred Stock (including the contingent beneficial conversion feature) during the nine months ended September 30, 2021 (none during the three months ended September 30, 2021).

Series B Preferred Stock

In March 2020, the Company entered into a purchase agreement with certain accredited investors for the private placement of $8.0 million of Series B Preferred Stock pending stockholders' approval, which approval was subsequently obtained on May 15, 2020. Accordingly, the Company completed the private placement on May 15, 2020, raising $8.0 million through the issuance of 8,000 shares of Series B Preferred Stock. The Series B Preferred Stock was issued at $1,000 per share and is convertible into common shares at a conversion price of $3.10 per share, subject to certain adjustments. Holders of the Series B Preferred Stock are entitled to an initial dividend rate of 8.0% per annum, which ended on February 26, 2021, the date of the FDA's approval of the supplemental NDA of VAZALORE 325 mg and VAZALORE 81mg. The dividends are compounded quarterly and payable in cash or shares of Series B Preferred Stock at the Company's option or, alternatively, the initial conversion price will be adjusted upon conversion to reflect the impact of the accrued dividends. The Series B Preferred Stock carries a liquidation preference equal to its stated value of $1,000 plus accrued and unpaid dividends.

In June 2021, certain Series B Preferred Stockholders converted 5,636 shares of Series B Preferred Stock into shares of common stock pursuant to the original terms of the Series B Preferred Stock. Upon conversion, accrued dividends payable of $0.4 million were settled by adjusting the initial conversion price, resulting in a new conversion price of $2.91 per share for those holders (the conversion price for holders that did not convert shares remains at $3.10 per share). As a result of the conversion, Series B Preferred Stock carrying value was reduced by $5.8 million and the Company issued 1,935,483 shares of its common stock to such holders.

As of September 30, 2022, 2,364 shares of Series B Preferred Stock remain outstanding with a conversion price of $2.91 per share and 2,000 shares remain outstanding with a conversion price of $3.10 per share. The Series B Preferred Stock is classified as temporary equity due to the presence of certain contingent cash redemption features, and has a carrying value of $2.3 million as of September 30, 2022.

The Company recognized no dividends on the Series B Preferred Stock during the three and nine months ended September 30, 2022. The Company recognized $105,065 (or $0.005 per share) of total dividends on the Series B Preferred Stock during the nine months ended September 30, 2021 (none during the three months ended September 30, 2021).

ATM Offering

On August 6, 2021, the Company entered into an Equity Distribution Agreement with JMP Securities LLC (“JMP”), as sales agent, and commenced an at-the-market offering (the “ATM Offering”) pursuant to which the Company may sell from time to time, at its option, shares of the Company’s common stock, having an aggregate offering price of up to $75.0 million. Sales of the common stock under the ATM Offering are made under the Company’s previously filed and currently effective shelf registration statement on Form S-3 and the sales agreement prospectus that forms a part of such registration statement. The aggregate compensation payable to JMP is 3.0% of the gross proceeds from each sale of the Company’s common stock. Under the ATM Offering, the Company sold 965,224 shares and raised gross proceeds of $1.1 million and net proceeds of $1.1 million during the three months ended September 30, 2022. During the nine months ended September 30, 2022, the Company sold 1,598,463 shares and raised gross proceeds of $2.5 million and net proceeds of $2.4 million under the ATM Offering. As of September 30, 2022, $64.4 million remained available under the ATM Offering. The Company sold 448,268 shares and raised gross proceeds of $8.0 million and net proceeds of $7.6 million during the three months ended September 30, 2021.

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 to the holders’ right to require the Company to repurchase the warrants for cash upon certain deferred fundamental transactions (“June 2017 Warrants”). See Note 7 for the fair value measurement of the warrant liability.

In connection with the entry into a term loan facility with Silicon Valley Bank (“SVB”) on August 9, 2017, which was paid in full on February 9, 2021, 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 (“SVB Warrants”). These warrants are immediately exercisable, have a 10-year term, contain a cashless exercise provision, and are classified in equity.

In November 2020, the Company issued warrants to purchase 5,230,910 shares of common stock which have an exercise price of $4.31 per share, contain a cashless exercise provision, will expire five years from the date of issuance and are equity classified (the “November 2020 Warrants”).

During the third quarter of 2021, holders of 20,364 of the June 2017 Warrants and 871,099 of the November 2020 Warrants exercised the warrants pursuant to their original terms. As a result of the warrants exercised, 20,364 of the warrants were exercised on a cashless basis and 871,099 of the warrants were exercised for $3.8 million in cash, additional-paid-in-capital was increased $4.1 million, and the Company issued an aggregate of 883,746 shares of common stock upon exercise of such warrants.

For the nine months ended September 30, 2021, holders of 188,590 of the June 2017 Warrants and 1,081,099 of the November 2020 Warrants exercised the warrants pursuant to their original terms. As a result of the warrants exercised, 152,226 of the warrants were exercised on a cashless basis and 1,117,463 of the warrants were exercised for $4.9 million in cash, additional-paid-in-capital was increased $7.1 million and the Company issued an aggregate of 1,192,421 shares of common stock upon exercise of such warrants.

The following is a summary of warrant activity for the nine months ended September 30, 2022:

Description	Outstanding 12/31/2021	Exercised	Outstanding 9/30/22	Exercise Price	Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
June 2017 Warrants	2,457,501	-	2,457,501	$ 7.50	4.7	$ -
November 2020 Warrants	4,109,344	-	4,109,344	$ 4.31	3.1	$ -
SVB Warrants	29,251	-	29,251	$ 6.41	4.9	$ -
Total Warrants	6,596,096	-	6,596,096	$ 5.51	3.7	$ -

Stock Options

The following is a summary of stock option activity for the nine months ended September 30, 2022:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2021	3,498,297	$ 10.07	7.27	$ 7,456
Granted	810,000	$ 4.89		
Exercised, cancelled, or forfeited	(105,291)	$ 12.59		
Outstanding, September 30, 2022	4,203,006	$ 9.01	7.15	$ -
Exercisable, September 30, 2022	2,280,006	$ 11.08	5.82	$ -

On September 13, 2018, the Company's stockholders approved the 2018 Incentive Plan (as amended from time to time, the "2018 Plan"). The 2018 Plan provides that the Company may grant equity interests to employees, consultants, and members of the Company's Board of Directors (the "Board" or "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. On November 10, 2020, the Company held its 2020 annual meeting of stockholders at which the Company's stockholders approved an amendment to the 2018 Plan, to increase the number of shares of the Company's common stock issuable under the 2018 Plan by 1,750,000 shares. On November 9, 2021, the Company held its 2021 annual meeting of stockholders at which the Company's stockholders approved an amendment to the 2018 Plan to increase the number of shares of the Company's common stock issuable under the 2018 Plan by 4,000,000 shares (the "Plan Amendment"). The Board of Directors previously approved the Plan Amendment on August 3, 2021, subject to stockholder approval. There are 7,000,000 shares authorized for issuance pursuant to the 2018 Plan, of which 3,667,650 shares are available for issuance under the 2018 Plan.

Prior to the approval of the 2018 Plan, the Company granted options to employees, directors, advisors, and consultants from two former plans which were frozen upon the adoption of the 2018 Plan. The Company is no longer authorized to grant awards under either of the former plans.

The Company granted 810,000 options during the nine months ended September 30, 2022 with an aggregate fair value of $2.8 million calculated using the Black-Scholes model on the grant date. Variables used in the Black-Scholes model include: (1) discount rate ranging from 1.6% - 4.1%, (2) expected life of 6 years, (3) expected volatility of 82 – 84%, and (4) zero expected dividends. As of September 30, 2022, the Company had $6.6 million in unamortized expense related to unvested options which is expected to be expensed over a weighted average of 1.8 years.

During the three months ended September 30, 2022 and 2021, the Company recorded $1.1 million and $0.7 million, respectively, in total stock-based compensation expense related to the stock options. During the nine months ended September 30, 2022 and 2021, the Company recorded $3.2 million and $1.9 million, respectively, in total stock-based compensation expense related to the stock options Substantially all stock-based compensation expense is classified as SM&A expenses in the accompanying unaudited consolidated statements of operations.

NOTE 5. COMMITMENTS AND CONTINGENCIES

Lease Agreements

The Company leases office space under operating lease agreements, expiring in September 2023 and June 2024. The office leases require the Company to pay for maintenance, and insurance. Rental expense under these agreements was $0.03 million and $0.01 million for the three months ended September 30, 2022 and 2021, respectively, and was $0.09 million and $0.02 million for the nine months ended September 30, 2022 and 2021, respectively.

Operating lease right-of-use assets of $0.2 million are included in other assets in the Company's unaudited consolidated balance sheets. Operating lease liabilities are included in other current and non-current liabilities in the Company's unaudited consolidated balance sheets.

All the Company's existing leases as of September 30, 2022 are classified as operating leases and have a weighted average remaining lease term of 1.4 years. Certain 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. The discount rate used in the calculation of the Company's lease liability ranges from 7.25% to 9.75%.

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

Future undiscounted cash flows:		
2022	$	33,942
2023		117,917
2024		31,838
Total		183,697
Discount factor		(11,928)
Lease liability		171,769
Current lease liability		(125,677)
Non-current lease liability	$	46,092

Purchase Commitments

The Company has supply agreements with its contract manufacturer and packager for VAZALORE which contain minimum annual purchase commitments that started in 2021 and continue through 2025. The minimum annual purchase commitments are intended to ensure that manufactured product is available when required to enable the Company to meet its expected market demand for VAZALORE.

NOTE 6. FAIR VALUE MEASUREMENTS

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

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

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

The Company's financial instruments (cash and cash equivalents, receivables, and accounts payable) are carried in the consolidated balance sheet at cost, which reasonably approximates fair value based on their short-term nature. The Company's warrant liability is recorded at fair value, with changes in fair value being reflected in the statements of operations for the period of change.

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 June 2017 Warrants 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 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 of possible outcomes, risk free interest rates and stock price volatility. Variables used at September 30, 2022 include: (1) the Company stock price of $0.65, (2) the risk-free rate of 4.09%, (3) remaining expected life of 4.7 years, and (4) expected volatility of 84%.

The Series A Preferred Stock and the Series B Preferred Stock both contain a contingent put option and, accordingly, the Company considered the put options to be liabilities and accounted for them at fair value using Level 3 inputs. The Company determined the fair value of these liabilities was *de minimis* at issuance and as of September 30, 2022, due to the remote possibly of its occurrence, a Level 3 unobservable input.

The following table sets forth a summary of changes in the fair value of Level 3 liabilities measured at fair value on a recurring basis for the three and nine months ended September 30, 2022:

Description	Balance at June 30, 2022	Established in 2022	Change in Fair Value	Balance at September 30, 2022
Warrant liability	$ 2,759	$ -	$ (2,223)	$ 536

Description	Balance at December 31, 2021	Established in 2022	Change in Fair Value	Balance at September 30, 2022
Warrant liability	$ 12,818	$ -	$ (12,282)	$ 536

The following table identifies the carrying amounts of such liabilities at September 30, 2022 and December 31, 2021:

Description	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 536	$ 536
Balance at September 30, 2022	$ -	$ -	$ 536	$ 536

Description	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 12,818	$ 12,818
Balance at December 31, 2021	$ -	$ -	$ 12,818	$ 12,818

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 goodwill, at fair value on a non-recurring basis when they are deemed to be impaired. No such impairment was recognized during the three and nine months ended September 30, 2022 and 2021.

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. The information contained herein is current as of the date of this Quarterly Report (September 30, 2022), unless another date is specified. We prepare our interim financial statements in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). Our financials and results of operations for the three and nine months ended September 30, 2022 and 2021 are not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2022. 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 commercial-stage drug delivery platform technology company focused on improving how and where active pharmaceutical ingredients ("APIs") are absorbed in the GI tract via our clinically validated and patent protected PLxGuard™ technology. We believe this platform has the potential to improve the absorption of many drugs currently on the market or in development and to reduce the risk of stomach injury associated with certain drugs.

VAZALORE is an FDA-approved liquid-filled aspirin capsule, available in 81 mg and 325 mg doses. VAZALORE delivers aspirin differently from plain and enteric coated aspirin products. The special complex inside the capsule allows for targeted release of aspirin, limiting its direct contact with the stomach lining. VAZALORE delivers fast, reliable absorption for pain relief plus the lifesaving benefits of aspirin.

Our commercialization strategy targets the over-the-counter market, taking advantage of the existing distribution channels for aspirin. We market VAZALORE to the healthcare professional and the consumer through several sales and marketing channels. Our product pipeline also includes other oral NSAIDs using the PLxGuard drug delivery platform that may be developed, including PL1200 Ibuprofen 200 mg and PL1100 Ibuprofen 400 mg, for pain and inflammation. We are also screening additional compounds outside the NSAID category for possible development using our PLxGuard drug delivery platform.

Recent Developments

In August 2022, the Company engaged Raymond James & Associates, Inc. ("Raymond James") as financial advisor to explore and evaluate its strategic alternatives with the goal of enhancing stockholder value. The strategic review process is underway, and the strategic alternatives to be considered may include, without limitation, exploring the potential for a possible merger, business combination, or investment into the Company. In conjunction with the exploration of strategic alternatives, the Company has been streamlining its sales and marketing plan in order to preserve its capital and cash resources.

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with 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 the Consolidated Financial Statements (unaudited) 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 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:

Impact of COVID-19 Pandemic on Financial Statements

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a “pandemic”, or a worldwide spread of a new disease. Many countries imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses.

The Company has not experienced a significant disruption or delay in the development, manufacturing or sales of VAZALORE due to COVID-19, and has not otherwise experienced any significant negative impact on its financial condition, results of operations or cash flows. However, the extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the remaining duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the pandemic. The unaudited consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Use of Estimates

The preparation of our unaudited consolidated 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 consolidated financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying unaudited consolidated financial statements, estimates are used for, but not limited to, the fair value of warrant liability, the fair value of stock-based compensation, trade promotional allowances and allowance for inventory obsolescence. 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 subjective determinations regarding the assumptions market participants would use in pricing the asset or liability.

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 began generating revenue in the U.S. from its sales of VAZALORE in 81 mg and 325 mg doses in the third quarter of 2021 and recognizes revenue when control of a promised good is transferred to a customer in an amount that reflects consideration that the Company expects to be entitled to in exchange for that good. This occurs either when the finished goods are delivered to the customer or when a product is picked up by the customer or the customer's carrier. The Company recognized total revenue from sales of VAZALORE of $0.4 million with 58% of net sales for the 81 mg dose and 42% of net sales for the 325 mg dose for the three months ended September 30, 2022. The Company recognized total revenue from sales of VAZALORE of $3.0 million with 70% of net sales for the 81 mg dose and 30% of net sales for the 325 mg dose for the nine months ended September 30, 2022. For the three and nine months ending September 30, 2021, total revenue from sales of VAZALORE was $6.6 million with 81 mg dose representing 67% of the net sales.

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 manufacturing and regulatory activities, and include fees paid to various entities that perform research-related services for the Company.

Stock-Based Compensation

The Company recognizes expense in the consolidated statements of operations for the fair value of all stock-based compensation to key employees, nonemployee directors and advisors, generally in the form of stock options. 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. The Company accounts for forfeitures as they occur.

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 the Unaudited Consolidated Financial Statements included elsewhere herein.

Non-GAAP Financial Measures

We prepare and publicly release quarterly unaudited financial statements prepared in accordance with GAAP. We also disclose and discuss certain non-GAAP financial measures in our public releases, investor conference calls and filings with the SEC. The non-GAAP financial measures that we disclose include adjusted non-GAAP loss attributable to common stockholders and adjusted non-GAAP net loss per common share. Non-GAAP net loss per share is defined as net loss per share excluding the change in the fair value of warrant liability and dividends related to our preferred stock.

We consider adjusted non-GAAP net loss and adjusted non-GAAP net loss per basic and diluted earnings per share to be an important financial indicator of our operating performance, providing investors and analysts with a useful measure of operating results unaffected by the impact on the financial statements of the volatility of the change in the fair value of the warrant liability and non-cash and non-recurring dividends on our preferred stock. Management uses adjusted non-GAAP net loss and adjusted non-GAAP net loss per share when analyzing our performance. Adjusted non-GAAP net loss and adjusted non-GAAP net loss per share should be considered in addition to, but not in lieu of net loss or net loss per share reported under GAAP.

A reconciliation of adjusted non-GAAP net loss per share to the most directly comparable GAAP finance measure is provided below.

(in thousands, except share and per share data)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Net loss attributable to common stockholders - GAAP	$ (8,497)	$ (21,642)	$ (31,140)	$ (52,212)
Adjustments:				
Change in fair value of warrant liability	(2,223)	11,784	(12,282)	29,747
Preferred dividends	-	-	-	2,525
Adjusted non-GAAP net loss attributable to common stockholders	$ (10,720)	$ (9,858)	$ (43,422)	$ (19,940)
Adjusted non-GAAP net loss per common share - basic and diluted	$ (0.37)	$ (0.37)	$ (1.55)	$ (0.89)
Weighted average shares of common shares - basic and diluted	28,603,426	26,911,855	27,949,292	22,342,538

RESULTS OF OPERATIONS

Comparison of Three Months Ended September 30, 2022 and 2021

Revenue

Total revenues were $0.4 million and $6.6 million for the three months ended September 30, 2022 and 2021, respectively. Net sales in the third quarter of 2022 included $0.3 million of unfavorable adjustments for additional trade allowances and incremental sales returns reserves. The increased trade allowances are used to promote sell through of existing retail inventory. The increased sales returns reserve reflected excess inventory at certain retailers. Net sales in the prior year period benefitted from the commercial launch and initial distribution of VAZALORE 81 mg and 325 mg dosage strengths to US retail channels. The VAZALORE 81 mg dose (consisting of 2 SKUs) represented 58% and 67% of the net sales for the three months ended September 30, 2022 and 2021, respectively.

Cost of Sales

Cost of Sales for the three months ended September 30, 2022 and 2021, were $1.5 million and $3.9 million, respectively, and reflected costs related to outsourced manufacturing and packaging, shipping, quality assurance and royalties. Cost of sales in the current period also included $1.0 million of incremental costs related to expired packaging materials, higher shipping costs, and inventory obsolescence for product not expected to be sold prior to its shelf-life date, which is 12 months prior to expiry.

Operating Expenses

Total operating expenses were $9.8 million for the three months ended September 30, 2022, compared to operating expenses of $12.6 million for the three months ended September 30, 2021. The prior year period reflected higher costs associated with the initial commercial launch of VAZALORE. In the third quarter of 2022, operating costs reflected the Company’s disciplined spending approach, including reductions in sales and marketing expenses.

Operating expenses for the three months ended September 30, 2022 and 2021 were as follows:

	Three Months Ended September 30,		(Decrease)	
	2022	2021	$	%
	(in thousands, except percentages)			
Operating Expenses				
Research and development expenses	$ 623	$ 1,552	$ (929)	(60)%
SM&A expenses	9,142	11,013	(1,871)	(17)%
Total operating expenses	$ 9,765	$ 12,565	$ (2,800)	(22)%

Research and Development Expenses

Research and development expense consists of expenses incurred while performing research and development activities to discover, develop, or improve potential product candidates we seek to develop. This includes conducting preclinical studies and clinical trials, manufacturing and other development efforts, and activities related to regulatory filings for product candidates. We recognize research and development expenses as they are incurred. Our research and development expenses primarily consist of (i) direct and indirect costs associated with specific projects and manufacturing activities, and (ii) fees paid to various entities that perform research related services for us.

Research and development expenses were $0.6 million for the three months ended September 30, 2022 compared to $1.6 million for the three months ended September 30, 2021. The decrease reflects the non-recurrence of the prior year costs for clinical studies and pre-launch manufacturing related activities for VAZALORE.

Selling, Marketing and Administrative ("SM&A") Expenses

SM&A expenses include costs related to functions such as sales, marketing, corporate management, insurance, and legal costs. Broker commissions are incurred and expensed as SM&A costs in the underlying consolidated statements of operations when the underlying sales take place. SM&A expenses also include costs for advertising (excluding the costs of cooperative advertising programs, which are reflected in net sales), contract field force, and consumer promotion costs (such as on-shelf advertisements and displays). SM&A costs are expensed as incurred.

SM&A expenses totaled $9.1 million for the three months ended September 30, 2022, compared to $11.0 million for the three months ended September 30, 2021. The prior year SM&A expenses included higher costs associated with extensive VAZALORE launch activities which commenced in the third quarter of 2021, including deployment of a cardiovascular specialty field force and a national media television campaign. In the third quarter of 2022, the Company's SM&A expenses reflected lower media spend and non-recurrence of launch related activity. Additionally, in August 2022, the Company significantly reduced its cardiovascular care specialist team. Non-cash stock-based compensation was $1.1 million in the current period versus $0.7 million in the prior year period.

Other income (expense), net

Other income (expense), net totaled $2.3 million of other income and $11.8 million of other expense for the three months ended September 30, 2022 and 2021, respectively. The variance 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.

Comparison of Nine Months Ended September 30, 2022 and 2021

Revenue

Total revenues were $3.0 million and $6.6 million for the nine months ended September 30, 2022 and 2021, respectively. Net sales for the nine months of 2022 included $0.7 million of unfavorable adjustments for additional trade allowances and incremental sales returns reserve. The increased trade allowances related to retailer programs to promote sell through of existing retail inventory. The increased sales returns reserve reflected excess inventory at certain retailers. Net sales in the prior year period benefitted from the commercial launch and initial distribution of VAZALORE 81 mg and 325 mg dosage strengths to US retail channels during the third quarter of 2021. The VAZALORE 81 mg dose (consisting of 2 SKUs) represented 70% and 67% of net sales for the nine months ended September 30, 2022 and 2021, respectively.

Cost of Sales

Cost of Sales for the nine months ended September 30, 2022 and 2021 were $3.4 million and $3.9 million, respectively, and reflected costs related to outsourced manufacturing and packaging, shipping, quality assurance and royalties. Cost of sales in the current period also included $1.6 million of incremental costs related to expired packaging materials, higher shipping costs, and inventory obsolescence for product not expected to be sold prior to its shelf-life date, which is 12 months prior to expiry.

Operating Expenses

Total operating expenses were $43.1 million for the nine months ended September 30, 2022, compared to operating expenses of $22.7 million for the nine months ended September 30, 2021. The prior year period reflected costs associated with the initial commercial launch of VAZALORE. Operating expenses for the nine months ended September 30, 2022 and 2021 were as follows:

	Nine Months Ended September 30,		Increase (Decrease)	
	2022	2021	$	%
	(in thousands, except percentages)			
Operating Expenses				
Research and development expenses	$ 1,833	$ 3,494	$ (1,661)	(48)%
SM&A expenses	41,243	19,147	22,096	115%
Total operating expenses	$ 43,076	$ 22,641	$ 20,435	90%

Research and Development Expenses

Research and development expense consists of expenses incurred while performing research and development activities to discover, develop, or improve potential product candidates we seek to develop. This includes conducting preclinical studies and clinical trials, manufacturing and other development efforts, and activities related to regulatory filings for product candidates. We recognize research and development expenses as they are incurred. Our research and development expenses primarily consist of (i) direct and indirect costs associated with specific projects and manufacturing activities, and (ii) fees paid to various entities that perform research related services for us.

Research and development expenses were $1.8 million for the nine months ended September 30, 2022 compared to $3.5 million for the nine months ended September 30, 2021. The decrease reflects the non-recurrence of the prior year costs for clinical studies and pre-launch manufacturing-related activities for VAZALORE.

SM&A Expenses

SM&A expenses include costs related to functions such as sales, marketing, corporate management, insurance, and legal costs. Broker commissions are incurred and expensed as SM&A costs in the underlying consolidated statements of operations when the underlying sales take place. SM&A expenses also include costs for advertising (excluding the costs of cooperative advertising programs, which are reflected in net sales), contract field force, and consumer promotion costs (such as on-shelf advertisements and displays). SM&A costs are expensed as incurred.

SM&A expenses totaled $41.2 million for the nine months ended September 30, 2022, compared to $19.1 million for the nine months ended September 30, 2021. SM&A expenses included costs associated with extensive VAZALORE launch activities which commenced in the third quarter of 2021, including deployment of a cardiovascular specialty field force and a national media television campaign. Non-cash stock-based compensation was $3.2 million in the current period versus $1.9 million in the prior year period.

Other income (expense), net

Other income (expense), net totaled $12.4 million of other income and $29.7 million of other expense for the nine months ended September 30, 2022 and 2021, respectively. The variance 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.

LIQUIDITY AND GOING CONCERN

Financial Condition

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

	Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	$ (45,974)	$ (18,757)
Net cash provided by investing activities	$ -	$ 94
Net cash provided by financing activities	$ 2,416	$ 78,768

Net Cash Used in Operating Activities

Net cash used in operating activities of $46.0 million and $18.8 million for the nine months ended September 30, 2022 and 2021, respectively. Higher sales and marketing related spending to support the launch of VAZALORE in August of 2021 contributed to the increase.

Net Cash Provided by Investing Activities

Net cash provided by investing activities of $0.09 million for the nine months ended September 30, 2021 was generated from the disposal of various property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled $2.4 million during the nine months ended September 30, 2022 compared to $78.8 million during the nine months ended September 30, 2021. Financing activities included net proceeds from the ATM Offering of $2.4 million and $7.6 million for the nine months ended September 30, 2022 and 2021, respectively. The prior year period also included net proceeds of $66.9 million from the Offering (each as defined in Note 4 of the Notes to the Consolidated Financial Statements (unaudited)).

Future Liquidity and Going Concern

During the nine months ended September 30, 2022, the Company had a net loss of approximately $31.1 million and had used cash in operations of approximately $46.0 million. As of September 30, 2022, the Company had an accumulated deficit of approximately $179.4 million. Due to the difficult macroeconomic environment that has put pressure on the rate of acceptance of VAZALORE in the marketplace and on our commercial resources, combined with restrictive capital markets, the Company has recently engaged Raymond James to explore and evaluate strategic alternatives. There is no assurance that such activities will result in any agreements or transactions that will enhance stockholder value or provide additional capital. The rate of acceptance of VAZALORE in the marketplace, together with the uncertainty with regards to completing a transaction or the ability to raise additional capital, creates substantial doubt about the Company's ability to continue as a going concern for at least one year from the date that the accompanying financial statements are issued. In conjunction with the exploration of strategic alternatives, the Company has been streamlining its sales and marketing plan in order to preserve its capital and cash resources.

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 unaudited consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty.

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, 2022 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, 2022 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that many of our employees are working remotely. We are continually monitoring and assessing the COVID-19 pandemic situation on our internal controls to minimize the impact on their design and operating effectiveness.

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 GAAP. The Company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with 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
- 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

From time to time we are party 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, 2021, 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, except as set forth below.

Our activities to evaluate and pursue strategic alternatives may not be successful.

In August 2022, we announced that we have commenced a process of evaluating strategic alternatives to maximize stockholder value. We have engaged a financial advisory firm to help explore our available strategic alternatives, including a possible merger, business combination, or investment in the Company. We expect to devote significant time and resources to identifying and evaluating strategic transactions; however, there can be no assurance that such activities will result in any agreements or transactions that will enhance stockholder value. In addition, potential strategic transactions that require stockholder approval may not be approved by our stockholders or a counterparty's stockholders. Further, any strategic transaction that is completed ultimately may not deliver the anticipated benefits or enhance stockholder value.

If we do not successfully consummate a strategic transaction, our Board of Directors may need to consider other strategic alternatives, including ceasing operations and liquidating the Company. In such an event, the amount of cash available for distribution to our stockholders could be diminished after reserving for commitments and contingent liabilities.

There can be no assurance that the process to identify a strategic transaction will result in a successfully consummated transaction. If no transaction is completed, our Board of Directors may need to consider other strategic alternatives, including ceasing operations and liquidating the Company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such alternative, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic alternatives. In addition, if our Board of Directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our Company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include, without limitation, obligations under our commercial agreements; obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our Company; and potential investigations or litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of the Company. If a dissolution and liquidation were pursued, our Board of Directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our Company.

Our failure to meet the continued listing requirements of the Nasdaq Stock Market could result in a delisting of our common stock.

On October 3, 2022, we received written notice from the Listing Qualifications Department of the Nasdaq Stock Market (“Nasdaq”) notifying us that, for a period of 30 consecutive business days, the bid price of our common stock closed below the minimum of $1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days, or until April 3, 2023, to regain compliance with the minimum bid price requirement. If, at any time during the 180-day grace period, the closing bid price of our common stock is at least $1.00 per share for a minimum of 10 consecutive business days, we will have regained compliance and Nasdaq will provide us with written confirmation of such.

If we fail to regain compliance before April 3, 2023, but meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for the Nasdaq Capital Market, we may be eligible for additional time to regain compliance with the minimum bid price requirement.

Our common stock will continue to be listed and traded on the Nasdaq Capital Market during the 180-day grace period, subject to our compliance with the other continued listing requirements of the Nasdaq Capital Market.

However, there can be no assurance that we will regain compliance before April 3, 2023. Even if we regain compliance, there can be no assurance that we will be able to continue to satisfy our continued listing requirements of the Nasdaq Capital Market going forward. Our failure to meet the continued listing requirements could result in a de-listing of our common stock. The delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, customers and employees and potential loss of business development opportunities. The delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock.

Thus, although we may take actions to regain our compliance with Nasdaq's listing requirements, we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, or prevent future non-compliance with Nasdaq's listing requirements.

Weak, or weakening of, economic or other negative conditions, including reductions in consumer spending, could have a material adverse effect on our business and financial results.

Difficult macroeconomic conditions, such as further decreases in per capita income and level of disposable income driven by increases to inflation, income (and other) taxes, the cost of living, increased and prolonged continued unemployment or a further decline in consumer confidence, in each case, as a result of the coronavirus pandemic or otherwise, could continue to have a material adverse effect on the demand for our products.

Unfavorable macroeconomic conditions, such as a recession or continued slowed economic growth could negatively affect consumer demand for our product which consequently, may negatively affect the results of operations. Under difficult economic conditions, consumers may seek to reduce spending by forgoing purchases of our products, negatively impacting our net sales and margins. Softer consumer demand for our products could reduce our profitability and could negatively affect our overall financial performance.

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

Number	Description
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of the Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of the Principal Executive Officer and Principal Financial and Accounting Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, formatted in Inline XBRL: (i) Consolidated Balance Sheets (unaudited), (ii) Consolidated Statements of Operations (unaudited), (iii) Consolidated Statements of Changes in Series A and Series B Convertible Preferred Stock and Stockholders' Equity (unaudited), (iv) Consolidated Statements of Cash Flows (unaudited), and (v) Notes to Consolidated Financial Statements (unaudited), tagged as blocks of text and including detailed tags.
104	Cover Page Interactive Data File (Embedded within the Inline XBRL and included in Exhibit 101).

*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.

PLX PHARMA INC.

Date: November 10, 2022

/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)

Exhibit 31.1

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

I, Natasha Giordano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PLx Pharma Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d– 15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: November 10, 2022

/s/ Natasha Giordano

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

Exhibit 31.2

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

I, Rita O'Connor, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PLx Pharma Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: November 10, 2022

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

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of PLx Pharma Inc. (the "Company") for the quarterly period ended September 30, 2022 (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 10, 2022

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

Dated: November 10, 2022

/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.