

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 8, 2022

PLx Pharma Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or other Jurisdiction of Incorporation)

001-36351

(Commission File Number)

46-4995704

(IRS Employer Identification No.)

9 Fishers Lane, Suite E, Sparta, New Jersey

(Address of Principal Executive Offices)

07871

(Zip Code)

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

(Former name or former address if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition.

On November 10, 2022, PLx Pharma, Inc. (the “Company”) issued a press release announcing its financial results for its third quarter ended September 30, 2022. The Company’s press release is attached hereto as Exhibit 99.1.

The information furnished by the Company pursuant to this Item 2.02, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be deemed to be incorporated by reference into any Company filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 8, 2022, Anthony Bartsh, a member of the Board of Directors of the Company (the “Board”) appointed by the Series A Preferred Stock holders, resigned from the Board, effective immediately after the completion of the Company’s 2022 annual meeting of stockholders (the “Annual Meeting”), which was held on November 8, 2022. Mr. Bartsh’s resignation is not the result of any disagreement with the Company.

Item 5.07 Submission of Matters to a Vote of Security Holders.

On November 8, 2022, the Company held its Annual Meeting. At the Annual Meeting, the Company’s stockholders were asked to vote upon the following:

1. The election of each of Gary Balkema, Kirk Calhoun, Robert Casale, John Hadden II, Michael Valentino and Natasha Giordano to serve as directors until the Company’s 2023 annual meeting of stockholders and until their successors are duly elected and qualify;
2. The approval of an advisory vote on the compensation of our named executive officers as disclosed in the proxy statement; and
3. The ratification of the appointment of Marcum LLP as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2022.

The results of the matters voted on at the Annual Meeting, based on the presence in person or by proxy of holders of record of 19,852,946 of the 29,137,692 shares of the Company’s common stock entitled to vote, were as follows:

1. The election of each of Gary Balkema, Kirk Calhoun, Robert Casale, John Hadden II, Michael Valentino and Natasha Giordano to serve as directors until the Company’s 2023 annual meeting of stockholders and until their successors are duly elected and qualify was approved as follows:

	For	Withheld	Broker Non-Votes
Gary Balkema	7,691,361	984,771	11,176,814
Kirk Calhoun	7,800,810	875,322	11,176,814
Robert Casale	7,814,421	861,711	11,176,814
John Hadden II	7,829,325	846,807	11,176,814
Michael Valentino	8,019,932	656,200	11,176,814
Natasha Giordano	7,910,002	766,130	11,176,814

2. The approval of an advisory vote on the compensation of our named executive officers as disclosed in the proxy statement. The voting results were as follows:

For	Against	Abstain	Broker Non-Votes
5,688,936	2,880,295	106,901	11,176,814

3. The stockholders ratified the appointment of Marcum LLP as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2022. The voting results were as follows:

For	Against	Abstain	Broker Non-Votes
19,286,848	344,660	221,438	—

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.

Description

99.1

[Press Release, dated November 10, 2022.](#)

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Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).

SIGNATURES

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

PLX PHARMA INC.

Dated: November 10, 2022

By: /s/ Natasha Giordano

Name: Natasha Giordano

Title: President and Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 10, 2022.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).

PLx Pharma Inc. Reports Third Quarter 2022 Results and Provides Business Update

- Significant Reduction in Operating Expenses

- Strategic Alternatives Process Ongoing

- Total Net Sales of \$0.4 Million, Including \$0.3 Million of Unfavorable Adjustments for Additional Trade Allowances and Incremental Sales Returns Reserves in Q3 2022
- Total Operating Expenses Significantly Lower by \$2.8 Million, or 22%, in Q3 2022 vs. Q3 2021; \$4.4 Million or 31% Lower Sequentially vs Q2 2022
- GAAP Net Loss of (\$0.30) Per Diluted Share in Q3 2022; Adjusted Non-GAAP Net Loss Per Diluted Share of (\$0.37)
- Cash & Cash Equivalent Balance of \$25.8 Million as of September 30, 2022

Sparta, New Jersey, Nov. 10, 2022 — PLx Pharma Inc. (NASDAQ: PLXP) (“PLx” or the “Company”), is a commercial-stage drug delivery platform technology company focused on its clinically-validated and patent-protected PLxGuard™ that has the potential to improve the absorption of many drugs currently on the market and to reduce the risk of stomach injury associated with certain drugs. The Company, with its lead products VAZALORE 81 mg and VAZALORE 325 mg liquid-filled aspirin capsules (referred to together as “VAZALORE®”), announced today certain financial and operational results for the three months ended September 30, 2022, and provided other business updates.

“During the first year of VAZALORE launch, we have invested in building a base of awareness among consumers and healthcare professionals,” said PLx’s President & CEO Natasha Giordano. “Since market acceptance and sales have taken longer than anticipated to develop, we have streamlined our investments, with the goal of maintaining our base consumption levels. We also recently initiated a formal process to evaluate strategic alternatives, to ensure that VAZALORE can remain available for the millions of patients who need it.”

Highlights of Third Quarter and Other Recent Events

- Partnered with two large healthcare systems to incorporate VAZALORE into their “Meds to Beds” cardiovascular discharge programs. The goal is to replicate these programs in other healthcare systems nationwide.
 - Expanded reach efficiently to both heart health and pain relief consumer audiences with introduction of VAZALORE ads on Facebook; ads featuring professional baseball legend John Smoltz’s personal experience with VAZALORE 325 mg for fast, effective pain relief were well received and delivered high engagement levels, beating industry benchmarks by four-times.
 - Expanded non-personal promotional efforts to over 3,000 cardiologists and neurologists nationwide who opted-in to receive VAZALORE educational materials; materials included clinical study results for healthcare professionals and samples, education brochures and coupons for patients; program slated to run through 1Q 2023.
 - Executed targeted digital campaign to over 500,000 healthcare professionals (HCPs), to include cardiologists, pharmacists, and advanced practice providers; message focused on VAZALORE benefits compared with other formulations as key reason to recommend; open rates across all target audiences performed above industry benchmarks.
 - Distributed VAZALORE samples and patient education materials to more than 1,000 HCPs who have adopted and are actively recommending VAZALORE in their practices.
 - Completed final stage of broad reach consumer email campaign; communication focused on how VAZALORE is different from other aspirin formulations; engagement level exceeded benchmark.
 - Published (Aug. 29, 2022) online by the *Journal of Thrombosis and Thrombolysis*: “Pharmacokinetic and Pharmacodynamic profiles of Novel Phospholipid-Aspirin Complex Liquid Formulation and Low Dose Enteric-Coated Aspirin: Results from a Prospective, Randomized, Crossover Study.”
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Third Quarter 2022 Financial Highlights

Total revenues for the third quarter of 2022 were \$0.4 million and 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. Sales in the prior year period of \$6.6 million benefitted from the commercial launch and initial distribution of VAZALORE to US retail channels. The VAZALORE 81 mg dose (consisting of two SKUs) represented 58% of the current period net sales versus 67% of net sales in the prior year period.

Cost of sales for the third quarter of 2022 were \$1.5 million and reflected costs related to outsourced manufacturing and packaging, shipping, quality assurance and royalties. Cost of sales 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.

Total operating expenses were \$9.8 million for the third quarter of 2022, a decline of approximately 22%, compared to \$12.6 million in the prior year period. The significant cost savings reflected the non-recurrence of prior year costs associated with the commercial launch of VAZALORE, coupled with the Company's disciplined spending approach, including reductions in sales and marketing expenses.

Research and development (R&D) expenses declined approximately 60% to \$0.6 million in the third quarter of 2022, compared to approximately \$1.6 million in the third quarter of 2021. The decrease primarily reflected the non-recurrence of prior year costs for pre-commercial manufacturing-related activities, such as validation and optimization work for VAZALORE. R&D expense in the current period included scale up manufacturing activities to increase capacity and lower cost of inventory.

Selling, marketing and administrative (SM&A) expenses of \$9.1 million declined approximately 17% in the third quarter of 2022, compared to \$11.0 million in the third quarter of 2021. The prior year period included higher costs associated with extensive VAZALORE launch activities, including deployment of a cardiovascular specialty field force and a national media television campaign. Sequentially, SM&A expenses declined approximately 33%, compared to the second quarter of 2022, due to lower media spending, the significant reduction in the Company's Cardiovascular Care Specialist team and a shift to more cost efficient nonpersonal promotional activities, such as virtual and digital communications. Non-cash stock-based compensation was \$1.1 million, compared to \$0.7 million in the third quarter of 2021.

Other income (expense), net totaled \$2.3 million of other income during the third quarter of 2022, compared to other expense of \$11.8 million in the third quarter of 2021. The increase 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.

Net loss attributable to common stockholders for the third quarter of 2022 was \$8.5 million, or a loss of (\$0.30) per diluted share, compared to a net loss of \$21.6 million, or (\$0.80) per diluted share in the prior year period.

Adjusted non-GAAP net loss per diluted share was (\$0.37) in the third quarter of 2022, compared to an adjusted net loss of (\$0.37) per diluted share in the third quarter of 2021.

See table for reconciliation of GAAP to adjusted non-GAAP net loss per diluted share.

Liquidity

As of September 30, 2022, the Company had \$25.8 million in cash and cash equivalents, approximately \$0.1 million in accounts receivable and zero debt on its balance sheet.

2022 Third Quarter Conference Call

The Company's 2022 third quarter conference call with analysts and investors will be held today at 8:30am ET. To participate in the conference call, please click here to obtain your dial in number and PIN. A live audio webcast of the call can be accessed in the Events & Presentations section of the Company's Investor Relations website <https://ir.plxpharma.com/events-presentations/events>. A replay of the audio webcast will be available under the same link immediately following the conclusion of the conference call and will be available for 30 days after the call.

About VAZALORE

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 is designed for targeted release of aspirin, limiting its direct contact with the stomach. VAZALORE delivers fast, reliable absorption for pain relief plus the lifesaving benefits of aspirin. To learn more about VAZALORE, please visit www.vazalore.com and follow us on Facebook.

About PLx Pharma Inc.

PLx Pharma 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. PLx believes 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. To learn more about PLx Pharma Inc. and its pipeline, please visit www.plxpharma.com and follow us on LinkedIn and Twitter.

Forward-Looking Statements

Any statements made in this press release relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, including without limitation, the prospects for commercializing or selling any products or drug candidates, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to PLx may identify forward-looking statements. PLx cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including risks relating to PLx's ability to successfully further commercialize its VAZALORE products; the failure by PLx to secure and maintain relationships with collaborators; risks relating to clinical trials; risks relating to the commercialization, if any, of PLx's proposed product candidates (such as marketing, regulatory, product liability, supply, competition, and other risks); dependence on the efforts of third parties; dependence on intellectual property; developments and projections relating to our competitors or our industry; risks that PLx may lack the financial resources and access to capital to fund proposed operations; the impact of difficult macroeconomic conditions, such as inflation and reductions in consumer spending, on the demand for PLx's products; and risks relating to PLx's ability to identify, evaluate and complete any strategic alternative that yields value for its stockholders. Further information on the factors and risks that could affect PLx's business, financial condition and results of operations are contained in PLx's filings with the U.S. Securities and Exchange Commission ("SEC"), which are available at www.sec.gov. Other risks and uncertainties are more fully described in PLx's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 11, 2022, and in other filings that PLx has made or will make going forward. These forward-looking statements represent PLx's estimate as of the date hereof only, and PLx specifically disclaims any duty or obligation to update forward-looking statements.

Non-GAAP Measures

PLx's management considers adjusted non-GAAP net loss and adjusted non-GAAP net loss per basic and diluted earnings per share to be important financial indicators of operating performance, providing investors and analysts with useful measures 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 and beneficial conversion features on our preferred stock. Management uses adjusted non-GAAP net loss and adjusted non-GAAP net loss per share when analyzing 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.

CONTACTS:

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Source: PLx Pharma Inc.

PLx Pharma Inc.
UNAUDITED CONSOLIDATED BALANCE SHEETS
(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
STOCKHOLDERS' EQUITY		
Preferred stock; \$0.001 par value; 930,000 shares authorized; none issued and outstanding	—	—
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

PLx Pharma Inc.
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS
(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
Cost 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

PLx Pharma Inc.

RECONCILIATION OF GAAP TO ADJUSTED NON-GAAP NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS AND
ADJUSTED NON-GAAP EARNINGS PER SHARE

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	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	<u>\$ (10,720)</u>	<u>\$ (9,858)</u>	<u>\$ (43,422)</u>	<u>\$ (19,940)</u>
Adjusted non-GAAP net loss per common share - basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.37)</u>	<u>\$ (1.55)</u>	<u>\$ (0.89)</u>
Weighted average shares of common shares - basic and diluted	<u>28,603,426</u>	<u>26,911,855</u>	<u>27,949,292</u>	<u>22,342,538</u>