

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): August 12, 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 August 12, 2022, PLx Pharma Inc. (the “Company”) issued a press release announcing its financial results for its second quarter ended June 30, 2022 and other business updates. The Company’s press release is attached hereto as Exhibit 99.1 and the information set forth therein is incorporated herein by reference and constitutes a part of this report.

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 8.01 Other Events.

On August 12, 2022, the Company issued a press release providing business updates, including the Company’s recent engagement of a financial advisor to commence a formal process to evaluate strategic alternatives to enhance stockholder value. The Company’s press release is attached hereto as Exhibit 99.1 and the information set forth therein is incorporated herein by reference and constitutes a part of this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated August 12, 2022.
104	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: August 12, 2022

By: /s/ Natasha Giordano
Name: Natasha Giordano
Title: President and Chief Executive Officer

EXHIBIT INDEX

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

- Initiates Evaluation of Strategic Alternatives to Enhance Stockholder Value

- Reports Positive Results of VAZALORE® 81 mg Patient Experience Survey

- Streamlines Sales & Marketing Plan

- Total Net Sales of \$0.5 Million, Including \$0.4 Million of Unfavorable Adjustments for Additional Trade Allowances and Incremental Sales Returns Reserves in Second Quarter of 2022
- Total Operating Expenses Were Lower by \$4.9 Million in Second Quarter of 2022 vs. Q1 2022
- GAAP Net Loss of (\$0.43) Per Diluted Share in Second Quarter of 2022; Adjusted Non-GAAP Net Loss Per Diluted Share of (\$0.52)
- Cash & Cash Equivalent Balance of \$35.7 Million as of June 30, 2022

Sparta, New Jersey, August 12, 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 June 30, 2022, and provided other business updates.

“A key priority for us in the second quarter was implementing our refined marketing plan, putting greater emphasis on more cost efficient nonpersonal promotion, such as virtual and digital communications,” said PLx’s President & CEO Natasha Giordano. “We, like many companies, experienced a tough inflationary environment this quarter, marked by a shift in consumer spending and higher retail inventories. These macro elements put pressure on the rate of acceptance of our product in the marketplace and on our commercial resources. We have moved quickly to further streamline our sales and marketing plan, including significantly reducing our Cardiovascular Care Specialist team.”

Giordano added, “Despite these challenges, we remain as confident as ever in VAZALORE’s potential to transform the standard of aspirin therapy for secondary prevention of cardiovascular events and to reinvent aspirin for pain relief. Our product has been well received by early adopters and findings from those adopters, along with online reviews and results from our recent Patient Experience Survey, further validate its market acceptance. However, given the current market dynamics, we believe the uptake of VAZALORE could be maximized through a larger commercial organization with resources to drive a more robust commercial plan. We believe this product is too important for the patients we serve not to be given the best chance to succeed.”

Executive Chairman of the Board, Michael Valentino, said, “Another strategic priority of the quarter was evaluating options to bring in new sources of non-dilutive capital, including business development activities. After initial discussions with several major companies, external interest broadened, and management, with full support from the Board, engaged a financial advisor to commence a formal process to evaluate strategic alternatives to enhance stockholder value.”

Highlights of Second Quarter and Other Recent Events

- Recently engaged Raymond James & Associates, Inc. as financial advisor to explore and evaluate strategic alternatives to enhance stockholder value.
- Reported positive results from initial VAZALORE 81 mg Patient Experience Survey. [Click here to read press release.](#)
 - o Highlights of results from 130 respondents through August 3, 2022:
 - § 97% felt “they are doing all they can to help support their heart health.”
 - § 96% felt “no issues with their stomach when taking, either with or without food.”
 - § 90% indicated their intent to purchase VAZALORE.
- Streamlined sales and marketing plan to include more nonpersonal programs, such as email campaigns, medical education programs, and social media advertising, in promoting VAZALORE’s benefits in both Heart Health and Pain to a broader audience of healthcare professionals (HCPs) and consumers. In August 2022, the Company significantly reduced its Cardiovascular Care Specialist team.
- Expanded email campaign target audience to more than 500,000 HCPs, to include Advanced Practice Providers, largely Nurse Practitioners and Physician Assistants. Email open rates across all target audiences performed at more than three-times industry benchmarks on average.
- Initiated a broad-reaching email program targeting approximately 10 million consumers, to highlight benefits of VAZALORE and provide high-value savings coupon, which resulted in more than two-times the normal website activity on VAZALORE.com.
- Launched PLx social media channels (Facebook, Twitter, LinkedIn) in July 2022, with VAZALORE-sponsored advertising on Facebook, targeting Heart Health and Pain Relief audiences.
- Developed feature story published under the titles, “Aspirin 101: What You Need To Know About This Foundational Therapy” and “Benefits of Taking Aspirin and the Main Reasons People Take It” to inform and educate patients and providers on the benefits of aspirin therapy, common side effects and available formulations, including FDA-approved VAZALORE liquid-filled capsules. [Click here to read article.](#)
 - o To date, the article has earned more than 1,000 placements, including in the 10 largest media markets in the U.S., and the online audience exceeds 250 million.
- Received acceptance of the manuscript titled, “Pharmacokinetic and Pharmacodynamic profiles of Novel Phospholipid-Aspirin Complex Liquid Formulation and Low Dose Enteric-Coated Aspirin: Results from a Prospective, Randomized, Crossover Study,” for publication by the “Journal of Thrombosis and Thrombolysis.”
- A series of educational webinars in June 2022 was led by interventional cardiologist and thought leader C. Michael Gibson, MS, MD, consultant at Boston Clinical Research Institute, titled, “Secondary Prevention with Aspirin – Learn about the Latest FDA Approved Aspirin Formulation.” [Click here to access webcast replay.](#)
 - o These virtual programs provided HCPs, and others, a forum to learn about the differences in available aspirin formulations, including VAZALORE liquid-filled aspirin capsules, and the importance of tailoring aspirin therapy to an individual patient profile.

Second Quarter 2022 Financial Highlights

Total revenues for the second quarter of 2022 were \$0.5 million, compared to no revenue in the second quarter of 2021, and included unfavorable adjustments totaling \$0.4 million for additional trade allowances and incremental sales returns reserves. The increased trade allowances related to retailer pricing programs initiated in the second quarter to promote sell through of existing retail inventory. The VAZALORE 81 mg (consisting of two SKUs) dose represented about half of the current period net sales.

Cost of sales for the second quarter of 2022 were \$0.8 million and reflected costs related to outsourced manufacturing and packaging, shipping, quality assurance and royalties. Cost of sales also included \$0.4 million of incremental costs related to expired packaging materials, higher shipping costs, including fuel surcharges, 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 \$14.2 million during the second quarter of 2022, compared to operating expenses of \$6.5 million for the prior year period, and reflected increased promotional activities and expenses associated with the commercial launch of VAZALORE during the third quarter of 2021. On a sequential basis, second quarter operating expenses declined \$4.9 million, or approximately 26% compared to the first quarter of 2022, primarily due to a disciplined spending approach, including a refined, more streamlined marketing plan.

Research and development expenses declined approximately 43% to \$0.6 million in the second quarter of 2022, compared to approximately \$1.0 million in the second quarter of 2021. The decrease reflected the non-recurrence of prior year costs for pre-commercial manufacturing-related activities, such as validation and optimization work for VAZALORE.

Selling, marketing and administrative expenses totaled \$13.6 million in the second quarter of 2022, compared to \$5.5 million in the prior year period, primarily due to higher sales and marketing expenses associated with increasing awareness of VAZALORE amongst HCPs and consumers. Non-cash stock-based compensation was \$1.1 million, compared to \$0.6 million in the second quarter of 2021.

Other income (expense), net totaled \$2.7 million of other income during the second quarter of 2022, compared to other expense of \$10.0 million in the second 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 second quarter of 2022 was \$11.9 million, or a loss of (\$0.43) per diluted share, compared to a net loss of \$18.7 million, or (\$0.79) per diluted share in the prior year period.

Adjusted non-GAAP net loss per diluted share was (\$0.52) in the second quarter of 2022, compared to an adjusted net loss of (\$0.27) per diluted share in the second quarter of 2021.

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

Liquidity

As of June 30, 2022, the Company had \$35.7 million in cash and cash equivalents, approximately \$0.5 million in accounts receivable and zero debt on its balance sheet.

2022 Second Quarter Conference Call

The Company's 2022 second 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:

Janet M. Barth
Vice President, Investor Relations & Corporate Communications, PLx Pharma Inc.
(973) 409-6542
IR@PLxPharma.com

Lisa M. Wilson
Founder & President, In-Site Communications, Inc.
(212) 452-2793
lwilson@insitecony.com

Source: PLx Pharma Inc.

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

	June 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 35,730	\$ 69,392
Accounts receivable	490	634
Inventory, net	3,883	2,458
Prepaid expenses and other current assets	1,376	992
TOTAL CURRENT ASSETS	41,479	73,476
NON-CURRENT ASSETS		
Property and equipment, net	798	858
Goodwill	2,061	2,061
Other assets	202	247
TOTAL ASSETS	\$ 44,540	\$ 76,642
LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 8,212	\$ 10,600
Accrued bonuses	729	1,163
Other current liabilities	127	116
TOTAL CURRENT LIABILITIES	9,068	11,879
NON-CURRENT LIABILITIES		
Warrant liability	2,759	12,818
Accrued dividends	129	129
Other liabilities	79	136
TOTAL LIABILITIES	12,035	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 June 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 June 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; 28,172,468 and 27,539,229 shares issued and outstanding at June 30, 2022 and December 31, 2021	28	28
Additional paid-in capital	187,380	183,912
Accumulated deficit	(170,917)	(148,274)
TOTAL STOCKHOLDERS' EQUITY	16,491	35,666
TOTAL LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY	\$ 44,540	\$ 76,642

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
REVENUES:				
Net sales	\$ 483	\$ —	\$ 2,566	\$ —
TOTAL REVENUES	483	—	2,566	—
Cost of sales	820	—	1,989	—
GROSS PROFIT	(337)	—	577	—
OPERATING EXPENSES:				
Research and development	556	983	1,210	1,942
Selling, marketing and administrative	13,645	5,498	32,101	8,134
TOTAL OPERATING EXPENSES	14,201	6,481	33,311	10,076
OPERATING LOSS	(14,538)	(6,481)	(32,734)	(10,076)
OTHER INCOME (EXPENSE):				
Interest income (expense), net	29	4	32	(6)
Change in fair value of warrant liability	2,651	(10,028)	10,059	(17,963)
TOTAL OTHER INCOME (EXPENSE)	2,680	(10,024)	10,091	(17,969)
LOSS BEFORE INCOME TAXES	(11,858)	(16,505)	(22,643)	(28,045)
Income taxes	—	—	—	—
NET LOSS	(11,858)	(16,505)	(22,643)	(28,045)
Preferred dividends	—	(2,203)	—	(2,525)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (11,858)	\$ (18,708)	\$ (22,643)	\$ (30,570)
Net loss per common share - basic and diluted	\$ (0.43)	\$ (0.79)	\$ (0.82)	\$ (1.53)
Weighted average shares of common shares - basic and diluted	27,693,527	23,638,239	27,616,804	20,020,012

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss attributable to common stockholders - GAAP	\$ (11,858)	\$ (18,708)	\$ (22,643)	\$ (30,570)
Adjustments:				
Change in fair value of warrant liability	(2,651)	10,028	(10,059)	17,963
Preferred dividends	—	2,203	—	2,525
Adjusted non-GAAP net loss attributable to common stockholders	<u>\$ (14,509)</u>	<u>\$ (6,477)</u>	<u>\$ (32,702)</u>	<u>\$ (10,082)</u>
Adjusted non-GAAP net loss per common share - basic and diluted	<u>\$ (0.52)</u>	<u>\$ (0.27)</u>	<u>\$ (1.18)</u>	<u>\$ (0.50)</u>
Weighted average shares of common shares - basic and diluted	<u>27,693,527</u>	<u>23,638,239</u>	<u>27,616,804</u>	<u>20,020,012</u>