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): May 13, 2022

PLx Pharma Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-36351**	**46-4995704**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

9 Fishers Lane, Suite E, Sparta, New Jersey	**07871**
(Address of Principal Executive Offices)	(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 follow 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 May 13, 2022, PLx Pharma Inc. (the "Company") issued a press release announcing its financial results for its first quarter ended March 31, 2022. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated May 13, 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: May 13, 2022

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

EXHIBIT INDEX

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For Immediate Release

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

BUILDING A SOLID BASE OF VAZALORE® USERS

- *Total Net Sales of $2.1 Million in the First Quarter of 2022, an Increase of Approximately 31% from Fourth Quarter of 2021*
- *GAAP Net Loss of ($0.39) Per Diluted Share in the First Quarter 2022; Adjusted Non-GAAP Net Loss Per Diluted Share of ($0.66)*
- *Cash & Cash Equivalent Balance of $52.5 Million as of March 31, 2022*
- *Disciplined Spending to Support Strategic Growth*

Sparta, New Jersey, May 13, 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 March 31, 2022.

"Our solid base of VAZALORE users continues to grow, and feedback from consumers and healthcare professionals is overwhelmingly positive," said Natasha Giordano, PLx's President & CEO. "We continuously evaluate the feedback, along with market research and other data, and have refined our marketing efforts."

Giordano continued, "We are intensifying our focus to more strongly differentiate VAZALORE from the limitations of other aspirins. VAZALORE provides fast, predictable absorption and was designed to help protect the gastroduodenal lining. We are executing enhanced messaging and some unique programs to increase trial and conversion among a broader community of consumers and healthcare professionals."

Select Business Highlights of First Quarter 2022 and Recent Key Accomplishments

Progress in Building Brand Awareness and Trial of VAZALORE:

- Retail consumption data for the most recent 13-week period showed steady growth of VAZALORE in a declining Heart Health category.[1]
- Feedback from healthcare professionals (HCPs) and consumers is overwhelmingly positive.
  - HCPs recognize VAZALORE as an innovative aspirin therapy, and how important it is for their secondary prevention patients to achieve the antiplatelet benefit of aspirin in a reliable and consistent way every day.
  - Consumer sentiment of VAZALORE centers on the following themes: easy to swallow, did not upset my stomach, and effective for pain relief.
- The Company's cardiovascular care specialists are implementing new VAZALORE sampling and patient-use survey programs to drive physician adoption and consumer trial.
- A manuscript of recently reported pharmacokinetic/pharmacodynamic results on VAZALORE 81 mg has been submitted to a journal for publication and is under review.

- The study was led by Drs. Franchi and Angiolillo from the University of Florida titled, Pharmacokinetic and Pharmacodynamic Profile of PL-ASA, a Novel Phospholipid-Aspirin Complex Liquid Formulation, Compared to Enteric-coated Aspirin at an 81 mg Dose – Results from a Prospective, Randomized Crossover Study, was a randomized, open-label, crossover pharmacokinetic and pharmacodynamic study in healthy volunteers.
- As expected and consistent with earlier studies at 325 mg, compared to enteric-coated aspirin VAZALORE 81 mg provided faster and more complete absorption after a single dose, with earlier and more potent inhibition of platelet aggregation.

· Cardiovascular thought leaders held a virtual town hall meeting on March 28, 2022, titled "Aspirin in 2022: A New Aspirin for a New Chapter" as a public health service to help clarify aspirin therapy in secondary prevention of cardiac events and dual anti-platelet therapy (DAPT) for the practicing clinician.

First Quarter 2022 Financial Highlights

Total revenues for the first quarter of 2022 were $2.1 million, compared to no revenue in the first quarter of 2021. On a sequential basis, net sales increased approximately 31% compared to the fourth quarter of 2021 and reflected shipments to retailers in conjunction with strong promotion and display support during National Heart Health month in February. Net sales of the 81 mg dose (consisting of a 12 count and 30 count SKU), represented approximately 79% of total net sales in the first quarter of 2022.

Gross margin of 44% was in-line sequentially with the fourth quarter of 2021 and reflected a favorable product mix consisting of higher sales of VAZALORE 81 mg.

Total operating expenses were $19.1 million during the first quarter of 2022, compared to operating expenses of $3.6 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, first quarter operating expenses declined 11% compared to the fourth quarter of 2021, primarily due to a strategic reduction in spending on the Company's national television advertising campaign.

Research and development expenses declined approximately 32% to $0.7 million in the first quarter of 2022, compared to approximately $1 million in first quarter of 2021. The decrease reflected the non-recurrence of the prior year costs for pre-commercial manufacturing-related activities such as validation and optimization work for VAZALORE.

Selling, marketing and administrative expenses totaled $18.5 million in the first quarter of 2022, compared to $2.6 million in the prior year period, primarily due to higher sales and marketing expenses associated with the commercial launch of VAZALORE. The higher year-over-year expense also included a new cardiovascular specialty field force and national media television campaign, which were launched during the third quarter of 2021. Non-cash stock-based compensation was $1.1 million, compared to $0.6 million in the first quarter of 2021.

Other income (expense), net totaled $7.4 million of other income during the first quarter of 2022, compared to other expense of $7.9 million in the first 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 first quarter of 2022 was $10.8 million, or a loss of ($0.39) per diluted share, compared to a net loss of $11.9 million, or ($0.73) per diluted share in the prior year period.

Adjusted non-GAAP net loss per diluted share was ($0.66) in the first quarter of 2022, compared to an adjusted net loss of ($0.22) per diluted share in the first quarter of 2021.

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

Liquidity
As of March 31, 2022, the Company had $52.5 million in cash and cash equivalents, $0.7 million in accounts receivable and zero debt on its balance sheet.

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[1] Nielsen, Single entity Heart Health Aspirin xAOC; 13-week period ended 3/26/22 versus 13-week period ended 1/1/22.

2022 First Quarter Conference Call
The Company's 2022 first quarter conference call with analysts and investors will be held today at 8:30am ET and may be accessed by dialing 1-866-394-2901, or if international, 1-616-548-5567, using Conference ID number 4037188. A live audio webcast of the conference call, along with the earnings press release and supplemental financial disclosures, will also be available on the Investor Relations section of the Company's website at https://ir.plxpharma.com/investor-relations. The webcast will be available for replay after the call for a period of at least 30 days.

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.

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.

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; and risks that PLx may lack the financial resources and access to capital to fund proposed operations. 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 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)

	March 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 52,499	$ 69,392
Accounts receivable	698	634
Inventory, net	3,839	2,458
Prepaid expenses and other current assets	712	992
TOTAL CURRENT ASSETS	57,748	73,476
NON-CURRENT ASSETS		
Property and equipment, net	828	858
Right of use assets	204	230
Goodwill	2,061	2,061
Security deposit	17	17
TOTAL ASSETS	$ 60,858	$ 76,642
LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 12,716	$ 10,600
Accrued bonuses	394	1,163
Other current liabilities	120	116
TOTAL CURRENT LIABILITIES	13,230	11,879
NON-CURRENT LIABILITIES		
Warrant liability	5,410	12,818
Accrued dividends	129	129
Other liabilities	106	136
TOTAL LIABILITIES	18,875	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 March 31, 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 March 31, 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; 27,539,229 shares issued and outstanding at March 31, 2022 and December 31, 2021	28	28
Additional paid-in capital	185,000	183,912
Accumulated deficit	(159,059)	(148,274)
TOTAL STOCKHOLDERS' EQUITY	25,969	35,666
TOTAL LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY	$ 60,858	$ 76,642

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

	Three Months Ended March 31,	
	2022	**2021**
REVENUES:		
Net sales	$ 2,083	$ —
TOTAL REVENUES	2,083	—
Cost of sales	1,169	—
GROSS PROFIT	914	—
OPERATING EXPENSES:		
Research and development	654	959
Selling, marketing and administrative	18,456	2,636
TOTAL OPERATING EXPENSES	19,110	3,595
OPERATING LOSS	(18,196)	(3,595)
OTHER INCOME (EXPENSE):		
Interest income (expense), net	3	(10)
Change in fair value of warrant liability	7,408	(7,935)
TOTAL OTHER INCOME (EXPENSE)	7,411	(7,945)
LOSS BEFORE INCOME TAXES	(10,785)	(11,540)
Income taxes	—	—
NET LOSS	(10,785)	(11,540)
Preferred dividends	—	(322)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (10,785)	$ (11,862)
Net loss per common share - basic and diluted	$ (0.39)	$ (0.73)
Weighted average shares of common shares - basic and diluted	27,539,229	16,361,583

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 March 31,	
	2022	**2021**
Net loss attributable to common stockholders - GAAP	$ (10,785)	$ (11,862)
Adjustments:		
Change in fair value of warrant liability	(7,408)	7,935
Preferred dividends	—	322
Adjusted non-GAAP net loss attributable to common stockholders	$ (18,193)	$ (3,605)
Adjusted non-GAAP net loss per common share - basic and diluted	$ (0.66)	$ (0.22)
Weighted average shares of common shares - basic and diluted	27,539,229	16,361,583