

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): March 11, 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 March 11, 2022, PLx Pharma Inc. (the “Company”) issued a press release announcing its financial results for its fourth quarter and full fiscal year ended December 31, 2021. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 11, 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: March 11, 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 March 11, 2022.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).

PLx Pharma Inc. Reports Fourth Quarter and Full Year 2021 Results and Provides Business Update

MOMENTUM BUILDING FOR NOVEL VAZALORE[®] LIQUID-FILLED ASPIRIN CAPSULES

- Total Net Sales of \$8.2 Million in Last Five Months of 2021
- Net Sales of \$1.6 Million in the Fourth Quarter 2021, Reflecting Timing of Trade Re-Orders Following Strong Initial Sales Distribution of VAZALORE in the Third Quarter 2021
- Key Performance Measures Are Positive and Trending Higher; Company on Track and Well-Positioned to Grow Sales Substantially in 2022
- GAAP Net Loss of (\$0.73) Per Diluted Share in Fourth Quarter 2021; Adjusted Non-GAAP Net Loss Per Diluted Share of (\$0.73)
- Cash & Cash Equivalent Balance of \$69.4 Million at Year-End 2021

Sparta, New Jersey, March 11, 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 and 12 months ended December 31, 2021.

“The VAZALORE launch strategy is on track as planned. We are excited that VAZALORE is now the number three brand in the Aspirin Heart Health segment, within six months after introduction,” said Natasha Giordano, PLx’s President & CEO. “We are pleased with our progress and our agility in managing the various market dynamics at play when establishing a new brand. Across several key performance measures, VAZALORE is building momentum and the results are positive and trending higher, with growth rates as we expected for this initial period. We are well positioned for sales growth and market share expansion in 2022.”

Select Business Highlights of Full Year 2021 and Recent Key Accomplishments

- The Company is executing a fully integrated, multi-channel commercial strategy for VAZALORE, including a three-pronged approach focused on healthcare professionals, retailers, and consumers. The combined efforts of its cardiovascular care specialists, medical communications, product display support, and national media campaign are yielding favorable results across several measures including:
 - o Retail consumption: VAZALORE continues to gain momentum, with strong unit and dollar growth over the last several consecutive four-week periods¹.
 - o Number three brand: VAZALORE has gone from having zero brand awareness among consumers less than six months ago, to becoming the number three brand in the Aspirin Heart Health Segment, on a dollar-share basis².
 - o Advertising effectiveness: Through mid-January 2022, the Company’s national media campaign for VAZALORE had delivered more than 500 million impressions, reaching more than 90% of its target audience, or nearly 15 million consumers, with high frequency.³
 - o Field force effectiveness: The Company’s cardiovascular care specialists, coupled with medical communications support, are effectively targeting healthcare professionals (“HCPs”), affiliated with the top 100 heart/stroke hospitals in the U.S., and reaching 98% of their top group practices.⁴ The field force is also expanding its coverage within existing territories to include surrounding practices.
-

- The Company has been engaging and building advocacy with more than 100 regional and national cardiovascular thought leaders across the U.S. through various medical communications programs. Important scientific data supporting VAZALORE's pharmacokinetic and pharmacodynamic profile has also been presented.
- The Company has been supporting Heart Health Awareness and the benefits of aspirin therapy in secondary prevention of heart attack or clot-related stroke.
- The Company has implemented the National Advertising Division's ("NAD") recommendations associated with the VAZALORE television commercial and online advertising to health care professionals and consumers.
 - The NAD closed its compliance proceeding for PLx on January 27, 2022, and the Federal Trade Commission subsequently determined not to take additional action.

Fourth Quarter 2021 Financial Highlights

Total revenues for the fourth quarter of 2021 were \$1.6 million, compared to no revenue in the fourth quarter of 2020, reflecting the timing of trade re-orders following the strong initial sales distribution of VAZALORE into U.S. retail channels in the third quarter of 2021. Net sales of the 81 mg dose (consisting of a 12 count and 30 count SKU), represented approximately 86% of total net sales in the fourth quarter of 2021.

Gross margin of 44% reflected a slight sequential improvement from the third quarter of 2021, due to favorable product mix consisting of higher sales of VAZALORE 81mg. Cost of goods in the fourth quarter of 2021 primarily reflected outsourced manufacturing and packaging costs, combined with costs related to shipping, quality assurance and royalty payments.

Total operating expenses were \$21.6 million during the fourth quarter of 2021, compared to operating expenses of \$3.7 million for the prior year period, reflecting increased promotional activities and expenses associated with the commercial launch of VAZALORE during the third quarter of 2021.

Research and development expenses declined approximately 43% to \$0.7 million in the fourth quarter of 2021, and included costs associated with the VAZALORE 81 mg clinical study and scale-up of manufacturing activities. In the prior year period, research and development expenses were \$1.2 million, and included costs associated with manufacturing and validation work to support the sNDA filings for VAZALORE.

Selling, marketing and administrative expenses totaled \$20.9 million in the fourth quarter of 2021, compared to \$2.5 million in the prior year period, primarily due to higher sales and marketing expenses associated with the commercial launch of VAZALORE and increased non-cash stock-based compensation. 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.

Other income (expense), net totaled \$24.4 million of other income during the fourth quarter of 2021, compared to other expense of \$4.2 million in the fourth quarter of 2020. 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.

Net income attributable to common stockholders for the fourth quarter of 2021 was \$3.6 million, or a loss of (\$0.73) per diluted share, compared to a net loss of \$8.5 million, or (\$0.87) per diluted share in the prior year period.

Adjusted non-GAAP net loss per diluted share was (\$0.73) in the fourth quarter of 2021, compared to an adjusted net loss of (\$0.38) per diluted share in the fourth quarter of 2020.

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

Full Year 2021 Financial Highlights

For the full year ended December 31, 2021, total revenue was \$8.2 million, compared with total revenue of \$30,000 in 2020, reflecting initial sales of VAZALORE following the strong initial sales distribution of VAZALORE into U.S. retail channels in the third quarter of 2021. Net sales of the 81 mg dose represented approximately 68% of total net sales for the full year 2021. Revenue in the prior year period was attributable to work performed under an award of a federal grant from the National Institutes of Health, which came to an end in the second quarter of 2020.

Gross margin of 41% for the full year 2021 includes outsourced manufacturing and packaging costs combined with costs related to shipping, quality assurance and royalty payments. Gross profit from the VAZALORE 325 mg dose is lower due to proportionally higher raw materials and smaller batch sizes although with a list price equal to the 81 mg 30 count bottle.

Total operating expenses were \$44.2 million for full year 2021, compared to operating expenses of \$13.5 million for the prior year period, reflecting increased promotional activities and expenses associated with the commercial launch of VAZALORE during the third quarter of 2021.

Net loss attributable to common stockholders for the year ended December 31, 2021 was \$48.6 million or (\$2.06) per diluted share compared to a net loss of \$16.9 million, or (\$1.74) per diluted share for 2020.

Adjusted non-GAAP net loss per diluted share was (\$1.72) for full year 2021, compared to an adjusted net loss of (\$1.42) per diluted share in the prior year period.

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

Liquidity

As of December 31, 2021, the Company had cash and cash equivalents of \$69.4 million, and \$0.6 million in accounts receivable. The Company has zero debt on its balance sheet.

¹ Nielsen, Single entity Heart Health Aspirin xAOC; 4-week periods ended 11/6/21, 12/4/21, 1/1/22, 1/29/22 and 2/26/22.

² Nielsen, Heart Health Aspirin Total xAOC; 26-week period ended 2/26/22.

³ Nielsen, week of 8/23/21 through week of 1/17/22.

⁴ Internal data.

2021 Fourth Quarter Conference Call

The Company's 2021 fourth 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 2664996. 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, 2020, filed with the SEC on March 12, 2021, as amended on April 30, 2021, 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.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 69,392	\$ 22,449
Accounts receivable	634	—
Inventory	2,458	143
Prepaid expenses and other current assets	992	394
TOTAL CURRENT ASSETS	73,476	22,986
NON-CURRENT ASSETS		
Property and equipment, net	858	1,226
Right of use assets	230	327
Goodwill	2,061	2,061
Security deposit	17	17
TOTAL ASSETS	\$ 76,642	\$ 26,617
LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 10,600	\$ 863
Accrued bonuses	1,163	1,185
Accrued interest	—	597
Term loan, net of discount and fees	—	622
Other current liabilities	116	275
TOTAL CURRENT LIABILITIES	11,879	3,542
NON-CURRENT LIABILITIES		
Warrant liability	12,818	9,692
Accrued dividends	129	2,796
Other liabilities	136	134
TOTAL LIABILITIES	24,962	16,164
Series A convertible preferred stock: \$0.001 par value; liquidation value of \$12,642,000; 45,000 shares authorized, 12,642 and 15,000 issued and outstanding, respectively	13,708	13,662
Series B convertible preferred stock: \$0.001 par value; liquidation value of \$2,492,722; 25,000 shares authorized, 2,364 and 8,000 issued and outstanding, respectively	2,306	7,723
STOCKHOLDERS' EQUITY (DEFICIT)		
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; 27,539,022 and 13,911,633 shares issued and outstanding, respectively	28	14
Additional paid-in capital	183,912	91,203
Accumulated deficit	(148,274)	(102,149)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	35,666	(10,932)
TOTAL LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 76,642	\$ 26,617

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
REVENUES:				
Net sales	\$ 1,592	\$ —	\$ 8,208	\$ —
Federal grant revenue	—	—	—	30
TOTAL REVENUES	1,592	—	8,208	30
Cost of sales	892	—	4,805	—
GROSS PROFIT	700	—	3,403	30
OPERATING EXPENSES:				
Research and development	688	1,223	4,182	4,339
Selling, marketing and administrative	20,863	2,469	40,011	9,150
TOTAL OPERATING EXPENSES	21,551	3,692	44,193	13,489
OPERATING LOSS	(20,852)	(3,692)	(40,790)	(13,459)
OTHER INCOME (EXPENSE):				
Interest income (expense), net	3	(41)	1	(308)
Change in fair value of warrant liability	24,411	(4,249)	(5,336)	(1,444)
TOTAL OTHER INCOME (EXPENSE)	24,414	(4,289)	(5,335)	(1,752)
INCOME (LOSS) BEFORE INCOME TAXES	3,562	(7,981)	(46,125)	(15,211)
Income taxes	—	—	—	—
NET INCOME (LOSS)	3,562	(7,981)	(46,125)	(15,211)
Preferred dividends and beneficial conversion feature	—	(510)	(2,525)	(1,737)
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ 3,562	\$ (8,491)	\$ (48,650)	\$ (16,948)
Net income (loss) per common share - basic	\$ 0.10	\$ (0.87)	\$ (2.06)	\$ (1.74)
Net loss per common share - diluted	\$ (0.73)	\$ (0.87)	\$ (2.06)	\$ (1.74)
Weighted average shares of common shares - basic	27,531,566	9,714,951	23,650,457	9,714,951
Weighted average shares of common shares - diluted	28,416,696	9,714,951	23,650,457	9,714,951

PLx Pharma Inc.

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

(in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Net income (loss) attributable to common stockholders - GAAP	\$ 3,562	\$ (8,491)	\$ (48,650)	\$ (16,948)
Adjustments:				
Change in fair value of warrant liability	(24,411)	4,249	5,336	1,444
Preferred dividends and beneficial conversion feature	—	510	2,525	1,737
Adjusted non-GAAP net loss attributable to common stockholders	<u>\$ (20,848)</u>	<u>\$ (3,733)</u>	<u>\$ (40,789)</u>	<u>\$ (13,767)</u>
Adjusted non-GAAP net loss per common share -diluted	<u>\$ (0.73)</u>	<u>\$ (0.38)</u>	<u>\$ (1.72)</u>	<u>\$ (1.42)</u>
Weighted average shares of common shares - diluted	<u>28,416,696</u>	<u>9,714,951</u>	<u>23,650,457</u>	<u>9,714,951</u>