

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 14, 2020

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 (see General Instruction A.2. below):

- 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(s)	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 14, 2020, PLx Pharma Inc. (the “*Company*”) issued a press release announcing its financial results for its second quarter ended June 30, 2020. 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 (the “*Securities Act*”), or the Exchange Act, regardless of any general incorporation language in such filing.

Item 5.08 Shareholder Director Nominations.

The Company expects to hold its 2020 annual meeting of stockholders (the “*Annual Meeting*”) on November 10, 2020. The time and location of the Annual Meeting will be as set forth in the Company’s definitive proxy statement for the Annual Meeting to be filed with the Securities and Exchange Commission (“*SEC*”). Pursuant to the Company’s amended and restated bylaws (the “*Bylaws*”), stockholders seeking to bring business before the Annual Meeting or to nominate candidates for election as directors at the Annual Meeting must deliver such proposals or nominations to the principal executive offices of the Company, at 9 Fishers Lane, Suite E, Sparta, New Jersey 07871, Attention: Secretary, not later than August 24, 2020. Any stockholder proposal or director nomination must also comply with the requirements of Delaware law, the rules and regulations promulgated by the SEC and the Bylaws, as applicable.

Item 7.01 Regulation FD Disclosure.

On August 14, 2020, the Company announced in its press release that it is targeting a launch of both VAZALORE 325 mg and 81 mg dose strengths during the third quarter of 2021, assuming FDA approval, adequate capital funding and no COVID-related delays. This update to the Company’s proposed launch timeline is included in the Company’s updated Corporate Presentation, available on the Company’s website under the Investor Relations tab.

The information furnished by the Company pursuant to this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of 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 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 August 14, 2020.

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 14, 2020

By: /s/ Natasha Giordano

Name: Natasha Giordano

Title: President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.

Description

[99.1](#)

[Press Release, dated August 14, 2020.](#)

PLx Pharma Inc. Reports Second Quarter 2020 Results and Provides Business Update

--Bioequivalence study of VAZALORE 325 mg on track with top-line data demonstrating bioequivalence to immediate release aspirin--

--Shifting the date of sNDA filings for VAZALORE 325 mg and 81 mg doses earlier to mid-November 2020--

--Targeting launch of VAZALORE 325 mg and 81 mg for third quarter 2021--

Sparta, New Jersey, August 14, 2020 — PLx Pharma Inc. (NASDAQ: PLXP) (“PLx” or the “Company”), a late-stage specialty pharmaceutical company focused on developing its clinically- validated and patent-protected PLxGuard™ delivery system to provide more effective and safer products, VAZALORE™ 325 mg and VAZALORE™ 81 mg (referred to together as “VAZALORE”™), announced today certain financial and operational results for the three and six months ended June 30, 2020.

Highlights of, and certain events subsequent to, the second quarter of 2020 include:

- Net loss attributable to common stockholders totaled \$6.0 million, or (\$0.66) per basic and diluted share, compared to net loss of \$9.6 million, or (\$1.10) per basic and diluted share, for the second quarter of 2019. This includes a non-cash charge related to the change in warrant liability of \$1.9 million, or (\$0.21) per share, compared to a non-cash charge of \$5.4 million, or (\$0.61) per share in the second quarter of 2019;
 - Confirmed the design of the VAZALORE 325 mg bioequivalence study with the U.S. Food and Drug Administration (“FDA”) in writing after the April Type C meeting;
 - Bioequivalence study with VAZALORE 325 mg on track with top-line data demonstrating bioequivalence to immediate release aspirin further supporting the change in formulation;
 - Finalizing supplemental New Drug Application (“sNDA”) filings for VAZALORE 325 mg and VAZALORE 81 mg dose strengths to be submitted to the FDA mid-November, ahead of the previously committed timeline of the end of the year;
 - Targeting launch of both VAZALORE 325 mg and 81 mg dose strengths for third quarter of 2021, assuming FDA approval, adequate capital funding and no COVID-related delays; and
 - Completed \$8 million Series B convertible preferred stock financing by investment funds affiliated with Park West Asset Management LLC and MSD Partners, L.P. (“Series B”).
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“We are pleased with the top-line data from the bioequivalence study and eager to complete the remaining steps to submit our sNDAs to bring this innovative therapy to market next year. We are also building out our pre-commercialization plans and engaging with the medical and retail communities about VAZALORE’s potential to help the millions of vascular patients who can benefit from a novel aspirin therapy,” said Natasha Giordano, President and Chief Executive Officer of PLx.

Second Quarter 2020 Financial Results

The Company recognized revenue of \$27,907 for the three months ended June 30, 2020, compared to revenue of \$182,905 for the three months ended June 30, 2019. Revenue in both the 2020 and 2019 periods is attributable to work performed under a federal grant from the National Institutes of Health (“NIH”), which came to an end in the second quarter of 2020.

Research and development expenses totaled \$1.4 million in the three months ended June 30, 2020 and \$1.6 million in the prior year period. The decrease is due to lower manufacturing-related activities for VAZALORE, as the prior year period included the manufacture of the registration batches. The decrease also reflected lower reimbursable grant expenses as the completion of the grant from the NIH came to an end in second quarter. Higher clinical-related spending, primarily the bioequivalence study partially offset this decrease.

General and administrative expenses totaled \$2.2 million in the three months ended June 30, 2020, compared to \$2.4 million in the prior year period. The decrease primarily reflects lower compensation related expenses, combined with reduced spending on conferences and related travel due to COVID restrictions. These decreases were partially offset by higher pre-launch activities for VAZALORE.

Other income (expense), net, totaled \$2.0 million and \$5.5 million of net other expense in the three months ended June 30, 2020 and 2019, respectively. The decrease 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 2020 was \$6.0 million, or (\$0.66) per basic and diluted share, compared to a net loss of \$9.6 million, or (\$1.10) per share, for the second quarter of 2019. The second quarter of 2020 includes a non-cash charge of \$1.9 million, or (\$0.21) per share related to the change in fair value of warrant liability and \$0.4 million, or (\$0.04) per share, for dividends on the Series A and Series B convertible preferred stock. The second quarter of 2019 included a charge of \$5.4 million, or (\$0.61) per share, related to the change in the warrant liability and \$0.3 million, or (\$0.03) per share, for preferred stock dividends related to the Series A convertible preferred stock.

First Half 2020 Financial Results

For the six months ended June 30, 2020, net revenue was \$30,430 compared to \$500,465 in the comparable period in 2019. All the revenue recognized is attributable to work performed under an award of a NIH grant, which came to an end in the second quarter of 2020.

Research and development expense decreased to \$1.9 million for the six months ended June 30, 2020, compared to \$2.6 million for the first six months of 2019. The decrease is due to lower manufacturing-related activities for VAZALORE, as the prior year included the manufacture of the registration batches. The decrease also reflected lower reimbursable grant expenses as the grant from the NIH came to an end in the second quarter 2020. Higher clinical-related spending primarily for the bioequivalence study partially offset this decrease.

General and administrative expense remained flat at \$4.7 million for the six months ended June 30, 2020 and 2019 as lower expenses for compensation and reduced spending on conferences and related travel due to COVID restrictions, were offset by higher spending on pre-launch activities.

Other income (expense), net was \$2.5 million of net other income for the first half of 2020, compared to \$13.4 million of net other expense for the first six months of 2019. This difference 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 six months ended June 30, 2020 was \$4.8 million or (\$0.53) per share compared to net loss attributable to common stockholders of \$33.3 million, or (\$3.80) per share, for the first half of 2019. The first half of 2020 included non-cash income of \$2.7 million, or \$0.29 per share, as a result of a change in the fair value of the warrant liability and \$0.7 million, or (\$0.08) per share, for preferred stock dividends related to Series A and Series B convertible preferred stock. The first half of 2019 included a charge of \$13.1 million or (\$1.49) per share related to the change in the warrant liability and a charge of \$13.1 million or (\$1.49) per share, for the beneficial conversion feature and dividends related to the Series A convertible preferred stock financing.

As of June 30, 2020, cash and cash equivalents were \$13.3 million. The Company plans to obtain additional financing upon submission of the sNDAs to fund pre-launch marketing spending and commercial inventory build prior to approval of VAZALORE.

Conference Call

As previously announced, PLx management will host its second quarter 2020 conference call as follows:

Date:	Friday, August 14, 2020
Time:	8:30 a.m. ET
Toll free (U.S.):	(866) 394-2901
International:	(616) 548-5567
Webcast (live and replay):	www.plxpharma.com under the 'Investor Relations' section.

The archived webcast will be available for 30 days via the aforementioned URL.

About VAZALORE

VAZALORE 325 mg is an FDA-approved liquid-filled aspirin capsule that provides patients with vascular disease and diabetic patients who are candidates for aspirin therapy with faster, reliable and more predictable platelet inhibition as compared to enteric-coated aspirin, while also reducing the risk of stomach erosions and ulcers, as compared to immediate-release aspirin, common in an acute setting. PLx is focused on collecting the data, including results from a bioequivalence study, required for post-approval manufacturing changes, which will be included in the sNDA filing for VAZALORE 325 mg and to support approval of low dose VAZALORE 81 mg.

About PLx Pharma Inc.

PLx Pharma Inc. is a late-stage specialty pharmaceutical company focused on developing its clinically-validated and patent-protected PLxGuard™ delivery system to provide more effective and safer products. The PLxGuard delivery system works by targeting delivery of active pharmaceutical ingredients to various portions of the gastrointestinal (GI) tract. PLx believes this has the potential to improve the absorption of many drugs currently on the market or in development, and to reduce the risk of stomach erosions and ulcers associated with aspirin and ibuprofen, and potentially other 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 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, 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 conditions 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, 2019 filed with the SEC on March 13, 2020, and in other filings that PLx has made or will make going forward. The 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.

Contact

Investor Relations:

Lisa M. Wilson, In-Site Communications, Inc.

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Source: PLx Pharma Inc.

FINANCIAL TABLES FOLLOW

PLx Pharma Inc.
UNAUDITED CONSOLIDATED BALANCE SHEETS

	<u>June 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 13,257,204	\$ 14,001,304
Accounts receivable	—	18,683
Inventory, net	143,380	—
Prepaid expenses and other current assets	363,539	263,268
TOTAL CURRENT ASSETS	<u>13,764,123</u>	<u>14,283,255</u>
NON-CURRENT ASSETS		
Property and equipment, net	1,401,939	1,466,646
Right of use assets	476,268	618,158
Goodwill	2,061,022	2,061,022
Security deposit	73,665	73,665
TOTAL ASSETS	<u>\$ 17,777,017</u>	<u>\$ 18,502,746</u>
LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 1,299,611	\$ 928,921
Accrued bonuses	492,296	1,166,821
Accrued interest	575,822	34,964
Current portion of term loan, net of discount and fees	2,467,372	3,658,121
Other current liabilities	335,467	304,603
TOTAL CURRENT LIABILITIES	<u>5,170,568</u>	<u>6,093,430</u>
NON-CURRENT LIABILITIES		
Accrued interest, net of current portion	—	501,826
Term loan, net of discount, fees and current portion	—	622,265
Warrant liability	5,577,269	8,247,679
Accrued dividends	1,786,123	1,058,498
Other liabilities	230,449	409,431
TOTAL LIABILITIES	<u>12,764,409</u>	<u>16,933,129</u>
Series A convertible preferred stock: \$0.001 par value; liquidation value of \$16,705,466; 45,000 shares authorized, 15,000 issued and outstanding	13,661,578	13,661,578
Series B convertible preferred stock: \$0.001 par value; liquidation value of \$8,080,657; 25,000 shares authorized, 8,000 and 0 issued and outstanding	7,731,379	—
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; 9,156,260 shares issued and outstanding	9,156	9,156
Additional paid-in capital	74,651,536	74,837,046
Accumulated deficit	(91,041,041)	(86,938,163)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	<u>(16,380,349)</u>	<u>(12,091,961)</u>
TOTAL LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	<u>\$ 17,777,017</u>	<u>\$ 18,502,746</u>

PLx Pharma Inc.
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
REVENUES:				
Federal grant	\$ 27,907	\$ 182,905	\$ 30,430	\$ 500,465
TOTAL REVENUES	<u>27,907</u>	<u>182,905</u>	<u>30,430</u>	<u>500,465</u>
OPERATING EXPENSES:				
Research and development	1,394,881	1,598,884	1,908,795	2,591,588
General and administrative	2,207,164	2,433,200	4,700,415	4,677,360
TOTAL OPERATING EXPENSES	<u>3,602,045</u>	<u>4,032,084</u>	<u>6,609,210</u>	<u>7,268,948</u>
OPERATING LOSS	<u>(3,574,138)</u>	<u>(3,849,179)</u>	<u>(6,578,780)</u>	<u>(6,768,483)</u>
OTHER INCOME (EXPENSE):				
Interest income	8,688	135,092	55,991	217,442
Interest and other expense	(104,671)	(280,232)	(250,499)	(575,094)
Change in fair value of warrant liability	(1,928,843)	(5,352,977)	2,670,410	(13,079,912)
TOTAL OTHER INCOME (EXPENSE)	<u>(2,024,826)</u>	<u>(5,498,117)</u>	<u>2,475,902</u>	<u>(13,437,564)</u>
LOSS BEFORE INCOME TAXES	<u>(5,598,964)</u>	<u>(9,347,296)</u>	<u>(4,102,878)</u>	<u>(20,206,047)</u>
Income taxes	—	—	—	—
NET LOSS	<u>(5,598,964)</u>	<u>(9,347,296)</u>	<u>(4,102,878)</u>	<u>(20,206,047)</u>
Preferred dividends and beneficial conversion feature	(407,335)	(301,735)	(727,625)	(13,122,261)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (6,006,299)</u>	<u>\$ (9,649,031)</u>	<u>\$ (4,830,503)</u>	<u>\$ (33,328,308)</u>
Net loss per common share - basic	<u>\$ (0.66)</u>	<u>\$ (1.10)</u>	<u>\$ (0.53)</u>	<u>\$ (3.80)</u>
Net loss per common share - diluted	<u>\$ (0.66)</u>	<u>\$ (1.10)</u>	<u>\$ (0.53)</u>	<u>\$ (3.80)</u>
Weighted average shares of common shares - basic	<u>9,156,260</u>	<u>8,779,909</u>	<u>9,156,260</u>	<u>8,779,096</u>
Weighted average shares of common shares - diluted	<u>9,156,260</u>	<u>8,779,909</u>	<u>9,156,260</u>	<u>8,779,096</u>