

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, 2019

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 November 8, 2019, PLx Pharma Inc. (the “*Company*”) issued a press release announcing its financial results for its third quarter ended September 30, 2019. 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 November 8, 2019.

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 8, 2019

By: /s/ Natasha Giordano

Name: Natasha Giordano

Title: President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.

Description

[99.1](#)

[Press Release, dated November 8, 2019.](#)

PLx Pharma Inc. Reports Third Quarter 2019 Results

--Company on track for sNDA submission to the FDA by year-end--

Sparta, New Jersey, November 8, 2019 — PLx Pharma Inc. (NASDAQ: PLXP) (“PLx” or the “Company”), a late-stage specialty pharmaceutical company initially 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 nine-month periods ended September 30, 2019.

Highlights of, and certain events subsequent to, the third quarter of 2019 include:

- Net income attributable to common shareholders totaled \$1.4 million, or \$0.09 per basic and diluted share, compared to net loss of \$3.4 million, or (\$0.39) per basic and diluted share, for the third quarter of 2018. 2019 includes a non-cash gain of \$5.5 million, or \$0.55 per share compared to a charge of \$0.4 million, or (\$0.05) per share in 2018, related to the change in warrant liability;
 - Presented an abstract entitled *Pharmacokinetic and pharmacodynamic assessment of a lipid-based aspirin formulation: results of a prospective, randomized, crossover study* at the European Society of Cardiology (ESC) Congress and published the study in the *Journal of Thrombosis and Thrombolysis*;
 - Expanding our medical education effort by sponsoring a Continuing Medical Education (CME) symposium on aspirin in partnership with the Cardiovascular Research Foundation at the annual Transcatheter Cardiovascular Therapeutics (TCT) conference addressing the critical role of aspirin therapy in the treatment of vascular disease;
 - Continued to collect stability data on the manufactured registration batches to be included in the Company’s supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) planned for the end of this year;
 - Initiating commercial planning with several large retailers that have indicated strong interest in VAZALORE;
 - Developing consumer-focused educational marketing campaigns; and
 - Tracking on all significant milestones, with the goal of launching VAZALORE in mid-2020.
-

“Aspirin therapy has received a significant amount of attention recently and is a topic of interest in every cardiology conference we attended this year. It is clear the market is in need of a better aspirin. VAZALORE’s better anti-platelet efficacy and improved GI safety profile offers the opportunity to become the new standard of care. As specialists learn more about the unique benefits for patients who require life-long aspirin therapy, VAZALORE is garnering a great deal of enthusiasm among clinicians.”

"This is an exciting time for PLx as we progress toward obtaining regulatory approval for VAZALORE and moving our commercialization efforts forward to bring our innovative product to market" said Natasha Giordano, President and Chief Executive Officer of PLx Pharma.

Third Quarter 2019 Financial Results

The Company recognized revenue of approximately \$41,000 in the third quarter of 2019 compared to \$0.2 million in the third quarter of 2018. All the revenue recognized is attributable to work performed under an award of a National Institutes of Health grant which is approaching completion.

Research and development expenses were approximately \$1.2 million for the third quarter of 2019 and 2018. The expenses in both periods include continued development and manufacturing activities for VAZALORE.

General and administrative expense totaled \$2.5 million in the third quarter of 2019, compared to \$1.8 million in the third quarter of 2018. This increase is due to commercial related activities to support the upcoming launch of VAZALORE.

Other income (expense), net was \$5.4 million of net other income in the third quarter of 2019, compared to \$0.6 million of net other expense in the third quarter of 2018. This change 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 (\$5.5 million of other income in the three months ended September 30, 2019, compared to \$0.4 million of other expense in the comparable 2018 period).

Net income attributable to common shareholders for the third quarter of 2019 was \$1.4 million, or \$0.09 per basic and diluted share, compared to net loss attributable to common shareholders of \$3.4 million, or (\$0.39) per basic and diluted share, for the third quarter of 2018. This includes a non-cash gain of \$5.5 million, or \$0.55 per share compared to a charge of \$0.4 million, or (\$0.05) per share in 2018, related to the change in warrant liability. The third quarter of 2019 also included \$0.3 million, or (\$0.03) per share, for preferred stock dividends related to the \$15 million Series A convertible preferred stock financing completed in February 2019.

Nine Months Ended September 30, 2019 Financial Results

For the nine months ended September 30, 2019, net revenue was approximately \$0.5 million, roughly unchanged from the same period in 2018. All the revenue recognized is attributable to work performed under an award of a National Institutes of Health grant.

Research and development expense increased to \$3.8 million for the nine months ended September 30, 2019, compared to \$3.0 million for the first nine months of 2018, reflecting continued product development and manufacturing activities for VAZALORE. This increase was due to the manufacture, packaging, stability and analytical costs related to the registration batches, which provide data to be submitted in our sNDA filing.

General and administrative expense increased to \$7.2 million for the nine months ended September 30, 2019 from \$5.9 million for the first nine months of 2018. This increase is due to commercial-related activities to support the upcoming launch of \$1.1 million and a payment to the University of Texas associated with the patent license agreement of \$0.2 million.

Other income (expense), net was \$8.1 million of net other expense for the nine months ended September 30, 2019, compared to \$6.4 million of net other income for the first nine months of 2018. This change 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 (\$7.6 million of other expense in the nine months ended September 30, 2019, as compared to \$7.0 million of other income in the comparable 2018 period).

Net loss attributable to common shareholders for the nine months ended September 30, 2019 was \$31.9 million or (\$3.60) per basic and diluted share compared to net loss attributable to common shareholders of \$2.0 million, or (\$0.23) per basic and diluted share, for the first nine months of 2018. The first nine months of 2019 included \$13.4 million or (\$1.52) per share, for the beneficial conversion feature and preferred stock dividends related to the \$15 million Series A convertible preferred stock financing completed in February 2019. The first nine months of 2019 also included a non-cash charge of \$7.6 million, or (\$0.86) per share as a result of a change in the fair value of the warrant liability as compared to income of \$7.0 million or \$0.80 per share in the first nine months of 2018.

As of September 30, 2019, the Company had cash and cash equivalents of \$18.5 million.

Conference Call

As previously announced, PLx management will host its third quarter 2019 conference call as follows:

Date	Friday, November 8, 2019
Time	8:30 a.m. EST
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 aspirin product being developed to provide patients with vascular disease and diabetic patients who are candidates for aspirin therapy with more reliable and predictable antiplatelet efficacy as compared to enteric-coated aspirin, while also reducing the adverse gastric events common in an acute setting. PLx is focused on manufacturing, scale-up and label finalization for VAZALORE 325 mg aspirin dosage form and preparing an sNDA for VAZALORE 81 mg maintenance dose form. Our goal is to begin selling both products in the United States by mid-2020, subject to approval by the FDA.

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 (API) 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 GI side effects—including erosions, ulcers and bleeding—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 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 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, 2018 filed with the SEC on March 8, 2019, and in other filings that PLx 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.

T: 212-452-2793

E: lwilson@insitecony.com

Source: PLx Pharma Inc.

FINANCIAL TABLES FOLLOW

PLx Pharma Inc.
UNAUDITED CONSOLIDATED BALANCE SHEETS

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 18,509,487	\$ 14,250,267
Accounts receivable	—	18,234
Prepaid expenses and other current assets	250,363	421,933
Deferred financing costs	—	174,976
TOTAL CURRENT ASSETS	<u>18,759,850</u>	<u>14,865,410</u>
NON-CURRENT ASSETS		
Property and equipment, net	1,392,206	1,394,230
Lease assets	699,996	—
Goodwill	2,061,022	2,061,022
Security deposit	73,666	67,714
TOTAL ASSETS	<u>\$ 22,986,740</u>	<u>\$ 18,388,376</u>
LIABILITIES, SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 1,290,839	\$ 687,257
Accrued bonus and severance	907,130	1,048,393
Accrued interest	40,508	60,366
Current portion of term loan, net of discount and fees	3,626,168	2,909,709
Other current liabilities	309,239	26,935
TOTAL CURRENT LIABILITIES	<u>6,173,884</u>	<u>4,732,660</u>
NON-CURRENT LIABILITIES		
Accrued interest, net of current portion	462,708	309,440
Term loan, net of discount, fees and current portion	1,548,864	4,280,385
Warrant liability	10,118,838	2,537,317
Accrued dividends	741,089	—
Other liabilities	488,599	84,281
TOTAL LIABILITIES	<u>19,533,982</u>	<u>11,944,083</u>
Series A convertible preferred stock: \$0.001 par value; liquidation value of \$15,000,000; 45,000 shares designated, 15,000 and 0 shares issued and outstanding	13,661,578	—
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock; \$0.001 par value; 955,000 authorized, none issued and outstanding	—	—
Common stock; \$0.001 par value; 100,000,000 shares authorized; 9,122,990 and 8,743,950 shares issued and outstanding	9,123	8,744
Additional paid-in capital	74,720,150	72,871,317
Accumulated deficit	(84,938,093)	(66,435,768)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	<u>(10,208,820)</u>	<u>6,444,293</u>
TOTAL LIABILITIES, SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	<u>\$ 22,986,740</u>	<u>\$ 18,388,376</u>

PLx Pharma Inc.
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
REVENUES:				
Federal grant	\$ 41,106	\$ 216,530	\$ 541,571	\$ 465,446
TOTAL REVENUES	41,106	216,530	541,571	465,446
OPERATING EXPENSES:				
Research and development	1,214,029	1,219,144	3,805,617	3,032,426
General and administrative	2,503,314	1,800,159	7,180,674	5,870,745
TOTAL OPERATING EXPENSES	3,717,343	3,019,303	10,986,291	8,903,171
OPERATING LOSS	(3,676,237)	(2,802,773)	(10,444,720)	(8,437,725)
OTHER INCOME (EXPENSE):				
Interest income	111,621	77,276	329,063	219,374
Interest and other expense	(230,053)	(290,773)	(805,147)	(849,457)
Change in fair value of warrant liability	5,498,391	(408,803)	(7,581,521)	7,017,923
TOTAL OTHER INCOME (EXPENSE)	5,379,959	(622,300)	(8,057,605)	6,387,840
INCOME (LOSS) BEFORE INCOME TAXES	1,703,722	(3,425,073)	(18,502,325)	(2,049,885)
Income taxes	—	—	—	—
NET INCOME (LOSS)	\$ 1,703,722	\$ (3,425,073)	\$ (18,502,325)	\$ (2,049,885)
Preferred dividends and beneficial conversion feature	(311,136)	—	(13,433,397)	—
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$ 1,392,586	\$ (3,425,073)	\$ (31,935,722)	\$ (2,049,885)
Net income (loss) per common share - basic	\$ 0.09	\$ (0.39)	\$ (3.60)	\$ (0.23)
Net income (loss) per common share - diluted	\$ 0.09	\$ (0.39)	\$ (3.60)	\$ (0.23)
Weighted average shares of common shares - basic	8,921,345	8,735,790	8,860,168	8,730,303
Weighted average shares of common shares - diluted	8,936,255	8,735,790	8,860,168	8,730,303