

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 6, 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.)

8285 El Rio Street, Ste. 130, Houston, Texas
(Address of Principal Executive Offices)

77054
(Zip Code)

Registrant's Telephone Number, Including Area Code: (713) 842-1249

(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))

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 8, 2019, PLx Pharma Inc. (the “*Company*”) issued a press release announcing its financial results for its fourth quarter and full fiscal year ended December 31, 2018. 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On March 6, 2019, the holders of the Company’s Series A Convertible Preferred Stock (the “*Series A Preferred Stock*”) notified the Company that they appointed Tony Bartsh as a member of the Company’s Board of Directors pursuant to the Company’s Amended and Restated Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock, which gives the holders of the Series A Preferred Stock the exclusive right, voting separately as a class, to elect one (1) director to the Board of Directors, for so long as Park West Asset Management LLC and its affiliates hold at least twenty-five percent (25%) of the issued and outstanding Series A Preferred Stock. Mr. Bartsh will not at present serve on any of our Board committees.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 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: March 8, 2019

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

For Immediate Release

PLx Pharma Inc. Reports Fourth Quarter 2018 Results

– Company Completes Successful \$15 Million Financing –

Houston, Texas, March 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 twelve-month periods ended December 31, 2018.

Highlights of, and certain events subsequent to, the fourth quarter of 2018 include:

- Net income totaled \$2.9 million, or \$0.34 per share, compared to net loss of \$7.9 million, or (\$0.90) per share, for the fourth quarter of 2017. This includes a non-cash gain of \$5.7 million for a change in the fair value of warrant liability, or \$0.65 per share;
- Successfully completed development scale batches to enable generation of data to be submitted in the briefing package for the U.S. Food and Drug Administration (FDA) Type C meeting;
- Completed a \$15 million financing with the Company’s largest shareholder, Park West Asset Management, LLC (Park West) and welcomed Tony Bartsh, Portfolio Manager at Park West, to the Board of Directors;
- Pleased to announce that Mark J. Alberts, MD, FAHA, Physician-in-Chief at the Ayer Neuroscience Institute at Hartford Healthcare and Chief of Neurology at Hartford Hospital, has joined PLx’s esteemed Scientific Advisory Board;
- Presented at the Cardiovascular Clinical Trialists (CVCT) conference and attended the American Heart Association (AHA) conference to continue to engage with thought leaders in the field and build awareness about the benefits of Vazalore in the treatment of atherosclerotic cardiovascular disease (ASCVD);
- Continued to advance the Company’s commercialization plans, including discussions with key retailers; and
- Remain on track for mid-2020 launch of Vazalore.

“We continue to advance commercialization plans by creating awareness among healthcare professionals through key cardiology and neurology conferences. We held our second Scientific Advisory Board meeting, where our commercialization plans to position Vazalore as the new standard of care were enthusiastically endorsed. We are pleased to welcome Dr. Mark Alberts, a renowned national leader in stroke care, who adds valuable neurologist’s perspective to our Scientific Advisory Board.

“We have successfully completed our development scale batches and are preparing for our next meeting with the FDA. Our recent \$15 million financing serves as validation of our business strategy and our commitment to addressing a large unmet need among the more than 43 million patients with ASCVD and diabetes. We are delighted to welcome Tony Bartsh to our Board of Directors, and we look forward to working with him. We appreciate Park West’s confidence in Vazalore’s potential to impact so many patients’ lives,” said Natasha Giordano, President and Chief Executive Officer of PLx Pharma.

“Park West is excited to provide the capital necessary to advance Vazalore. We believe Vazalore offers many compelling clinical benefits and has the potential to become a best-in-class aspirin therapy. The PLx team has a proven track record of successfully launching products and we look forward to working with them as they advance toward commercialization,” said Tony Bartsh.

Fourth Quarter 2018 Financial Results

The Company recognized revenue of \$0.3 million in the fourth quarter of 2018, compared to revenue of \$0.3 million for the three months ended December 31, 2017. All the revenue recognized in 2018 and \$0.1 million of the revenue recognized in 2017 is attributable to work performed under an award of a National Institutes of Health grant. 2017 also included \$0.2 million of deferred revenue recognized upon the completion of effort of a licensing agreement.

Research and development expenses were \$0.9 million for the fourth quarter of 2018, compared to \$2.4 million in the fourth quarter of 2017, a decrease of \$1.6 million, which reflects timing of continued product development and manufacturing activities for Vazalore.

General and administrative expense remained roughly flat at \$1.9 million in the fourth quarter of 2018, compared to the fourth quarter of 2017, as lower stock-based compensation of \$0.2 million was offset by higher prelaunch marketing spend of \$0.2 million.

In the fourth quarter of 2017, operating expenses also included a non-cash impairment charge of \$2.3 million, or (\$0.26) per share, related to the impairment of its intangible assets (trademarks and in-process research and development) acquired from Dipexium in connection with a change in operational strategy related to its Locilex assets.

Other income (net of expense) totaled approximately \$5.5 million for the fourth quarter of 2018, compared to \$1.6 million of net other expense in the prior year period. The fluctuation is largely attributable to the change in fair value of warrant liability of \$5.7 million of other income versus \$1.4 million of other expense in the prior period.

Net income for the fourth quarter of 2018 was \$2.9 million, or \$0.34 per share, compared to a net loss of \$7.9 million, or (\$0.90) per share, for the fourth quarter of 2017.

Full Year 2018 Financial Results

For the year ended December 31, 2018, total revenues were \$0.8 million, as compared to \$0.8 million for the year ended December 31, 2017. All the revenue recognized in 2018 and \$0.6 million of the revenue recognized in 2017 is attributable to work performed under an award of a National Institutes of Health grant. 2017 also includes \$0.2 million of deferred revenue recognized upon the completion of effort of a licensing agreement.

Research and development expenses totaled approximately \$3.9 million in the year ended December 31, 2018, compared to \$4.2 million in the prior year, a decrease of approximately \$0.2 million. The expenses in both periods included continued product development and manufacturing activities for Vazalore.

General and administrative expenses totaled approximately \$7.8 million in the year ended December 31, 2018, compared to approximately \$10.2 million in the prior year. This decrease of approximately \$2.4 million was primarily attributable to public offering costs of \$1.5 million related to the June 2017 equity offering, lower compensation expense of \$1.1 million, lower professional fees of \$0.2 million, partially offset by prelaunch marketing spend in the 2018 period of \$0.4 million.

For the full year 2017, operating expenses also included a non-cash charge of \$2.3 million, or (\$0.26) per share, related to the impairment of its intangible assets (trademarks and in-process research and development) acquired from Dipexium, in connection with a change in operational strategy related to its Locilex assets.

Other income (expense), net totaled approximately \$11.9 million of net income for the year ended December 31, 2018, compared to \$0.4 million of net expense in the prior year. The fluctuation is largely attributable to the change in fair value of warrant liability of \$12.1 million of other income.

Net income for the twelve months ended December 31, 2018, was \$0.9 million, or \$0.10 per basic and diluted share, compared with a net loss of \$15.3 million, or (\$2.19) per basic and diluted share in the prior year period.

As of December 31, 2018, the Company had \$14.3 million in cash and cash equivalents.

Conference Call

As previously announced, PLx management will host its fourth quarter and full year 2018 conference call as follows:

Date	Friday, March 8, 2019
Time	8:30 a.m. EDT
Toll free (U.S.)	(866) 394-2901
International	(616) 548-5567
Webcast (live and replay)	www.plxpharma.com under the 'Investor Relations' section.

A replay of the conference call will be available for two weeks after the call's completion by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (International). The conference ID for the replay is 8166135. 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 atherosclerotic cardiovascular disease and diabetes 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:**

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Source: PLx Pharma Inc.

FINANCIAL TABLES FOLLOW

PLx Pharma Inc.
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 14,250,267	\$ 24,404,368
Accounts receivable	18,234	19,384
Inventory, net	—	246,374
Vendor and security deposits	12,564	719,667
Prepaid expenses	409,369	300,169
Deferred financing costs	174,976	—
TOTAL CURRENT ASSETS	14,865,410	25,689,962
NON-CURRENT ASSETS		
Property and equipment, net	1,394,230	1,029,875
Goodwill	2,061,022	2,061,022
Security deposit	67,714	67,714
TOTAL ASSETS	\$ 18,388,376	\$ 28,848,573
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 653,049	\$ 852,155
Accrued bonus and severance	1,048,393	849,703
Accrued interest	60,366	54,219
Current portion of term loan, net of discount and fees	2,909,709	—
Other current liabilities	61,143	59,614
TOTAL CURRENT LIABILITIES	4,732,660	1,815,691
NON-CURRENT LIABILITIES		
Accrued interest, net of current portion	309,440	89,717
Term loan, net of discount and fees	4,280,385	6,942,151
Warrant liability	2,537,317	15,242,915
Other liabilities	84,281	141,707
TOTAL LIABILITIES	11,944,083	24,232,181
STOCKHOLDERS' EQUITY		
Common stock; \$0.001 par value; 100,000,000 shares authorized; 8,743,950 and 8,722,823 shares issued and outstanding	8,744	8,723
Additional paid-in capital	72,871,317	71,939,917
Accumulated deficit	(66,435,768)	(67,332,248)
TOTAL STOCKHOLDERS' EQUITY	6,444,293	4,616,392
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 18,388,376	\$ 28,848,573

PLx Pharma Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Twelve months ended December 31,	
	2018	2017	2018	2017
REVENUES:				
Federal grant	\$ 287,662	\$ 140,447	\$ 753,108	\$ 578,657
License revenue	—	200,000	—	200,000
TOTAL REVENUES	287,662	340,447	753,108	778,657
OPERATING EXPENSES:				
Research and development	890,239	2,444,564	3,922,665	4,157,454
General and administrative	1,920,855	1,911,978	7,791,600	10,174,997
Impairment of intangible assets	—	2,294,048	—	2,294,048
TOTAL OPERATING EXPENSES	2,811,094	6,650,590	11,714,265	16,626,499
OPERATING LOSS	(2,523,432)	(6,310,143)	(10,961,157)	(15,847,842)
OTHER INCOME (EXPENSE)				
Interest income	78,426	64,295	297,800	112,377
Interest expense	(296,304)	(273,062)	(1,145,761)	(1,164,897)
Change in fair value of warrant liability	5,687,675	(1,365,247)	12,705,598	633,631
TOTAL OTHER INCOME (EXPENSE)	5,469,797	(1,574,014)	11,857,637	(418,889)
INCOME (LOSS) BEFORE INCOME TAX BENEFIT	2,946,365	(7,884,157)	896,480	(16,266,731)
Income tax benefit	—	—	—	920,000
NET INCOME (LOSS)	\$ 2,946,365	\$ (7,884,157)	\$ 896,480	\$ (15,346,731)
Net income (loss) per common share - basic	\$ 0.34	\$ (0.90)	\$ 0.10	\$ (2.19)
Net income (loss) per common share - diluted	\$ 0.34	\$ (0.90)	\$ 0.10	\$ (2.19)
Weighted average shares of common shares - basic	8,741,994	8,721,765	8,733,220	7,020,479
Weighted average shares of common shares - diluted	8,741,994	8,721,765	8,733,220	7,020,479