



PLx Pharma Inc. Reports Second Quarter 2019 Results

August 9, 2019

--Company completes manufacture of registration batches; remains on track for sNDA submission by year-end--

SPARTA, N.J., Aug. 09, 2019 (GLOBE NEWSWIRE) -- 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 six-month periods ended June 30, 2019.

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

- Net loss attributable to common shareholders totaled \$9.6 million, or (\$1.10) per share, compared to net loss of \$3.6 million, or (\$0.41) per share, for the second quarter of 2018. This includes a non-cash charge of \$5.4 million, or (\$0.61) per share compared to \$1.0 million, or (\$0.11) per share in 2018, related to the change in warrant liability;
- Conducted a Type C meeting with the U.S. Food and Drug Administration ("FDA"), in a written response only format, regarding its April briefing package submission for VAZALORE;
- Completed the manufacture of registration batches to provide data to be included in the Company's planned year-end sNDA submission for VAZALORE;
- Signed a Manufacturing Services Agreement with Thermo Fisher Scientific's Pharma Services business, a leading global contract development and manufacturing organization, providing PLx the capabilities to bring VAZALORE to market;
- Continued productive dialogues and planning with key retailers, who have indicated strong interest in VAZALORE;
- Presented two abstracts on VAZALORE's value proposition at the ISPOR Conference, the leading global conference for health economics and outcomes research, and participated in the EuroPCR conference, the leading annual forum on interventional cardiology, to broaden understanding and awareness within the clinical community of VAZALORE's unique benefits;
- Relocated its corporate headquarters from Houston, Texas, to Sparta, New Jersey; and
- Remains on track for the commercial launch of VAZALORE in mid-2020.

"During the quarter, we continued to advance VAZALORE through the regulatory process and are planning for the commercial launch, once approved, next year. With our registration batches now complete, we are gathering stability data to support our sNDA submission to the FDA later this year. We are encouraged by the medical community and retail trade's growing appreciation of VAZALORE's innovative attributes and its potential to transform the aspirin market and the current standard of care in the secondary prevention of cardiovascular disease," said Natasha Giordano, President and Chief Executive Officer of PLx Pharma. "As we continue to position ourselves for commercial success, we are pleased to have completed the relocation of our corporate headquarters to New Jersey, further aligning our organization as we transition the company from development to commercialization," added Giordano.

Second Quarter 2019 Financial Results

The Company recognized revenue of approximately \$0.2 million in the second quarter of 2019 and 2018. All the revenue recognized is attributable to work performed under an award of a National Institutes of Health grant.

Research and development expenses were approximately \$1.6 million for the second quarter of 2019, compared to \$0.7 million in the second quarter of 2018. The expenses in both periods include continued development and manufacturing activities for VAZALORE. This increase from 2018 is due to the manufacturing of the registration batches to provide data for the sNDA submission.

General and administrative expense totaled \$2.4 million in the second quarter of 2019, compared to \$1.8 million in the second quarter of 2018. This increase is due to commercial related activities to support the upcoming launch of \$0.4 million and a payment to the University of Texas associated with the patent license agreement of \$0.2 million.

Other income (expense), net was \$5.5 million of net other expense in the second quarter of 2019, compared to \$1.2 million of net other expense in the second 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.

Net loss attributable to common shareholders for the second quarter of 2019 was \$9.6 million, or (\$1.10) per share, compared to net loss attributable

to common shareholders of \$3.6 million, or (\$0.41) per share, for the second quarter of 2018. The second quarter of 2019 included a non-cash charge of \$5.4 million, or (\$0.61) per share compared to \$1.0 million or (\$0.11) per share in 2018, as a result of a change in the fair value of the warrant liability. The second quarter of 2019 also included \$0.3 million, or (\$0.03) per share, for preferred stock dividends related to the Series A \$15 million convertible preferred stock financing completed in February 2019.

First Half 2019 Financial Results

For the six months ended June 30, 2019, net revenue was \$0.5 million compared to \$0.2 million 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 \$2.6 million for the six months ended June 30, 2019, compared to \$1.8 million for the first six months of 2018, reflecting continued product development and manufacturing activities for VAZALORE. This increase was due to the manufacture of the registration batches, which provide data to be submitted in our sNDA filing.

General and administrative expense increased to \$4.7 million for the six months ended June 30, 2019 from \$4.1 million for the first six months of 2018. This increase is due to commercial-related activities to support the upcoming launch of \$0.4 million and a payment to the University of Texas associated with the patent license agreement of \$0.2 million.

Other income (expense), net was \$13.4 million of net other expense for the first half of 2019, compared to \$7.0 million of net other income for the first six 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 (\$13.1 million of net other expense in the six months ended June 30, 2019 as compared to \$7.4 million of other income in the comparable 2018 period).

Net loss attributable to common shareholders for the six months ended June 30, 2019 was \$33.3 million or (\$3.80) per share compared to net income attributable to common shareholders of \$1.4 million, or \$0.16 per share, for the first half of 2018. The first half of 2019 included \$13.1 million or (\$1.49) per share, for the beneficial conversion feature and preferred stock dividends related to the Series A \$15 million convertible preferred stock financing completed in February 2019. The first half of 2019 also included a non-cash charge of \$13.1 million, or (\$1.49) per share as a result of a change in the fair value of the warrant liability as compared to income of \$7.4 million or \$0.85 per share in the first half of 2018.

As of June 30, 2019, the Company had cash and cash equivalents of \$21.3 million.

Conference Call

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

Date	Friday, August 9, 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.

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](http://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: wilson@insitecony.com

Source: PLx Pharma Inc.

FINANCIAL TABLES FOLLOW

PLx Pharma Inc.
UNAUDITED CONSOLIDATED BALANCE SHEETS

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$21,256,643	\$14,250,267
Accounts receivable	193,732	18,234
Prepaid expenses and other current assets	266,542	421,933
Deferred financing costs	-	174,976
TOTAL CURRENT ASSETS	<u>21,716,917</u>	<u>14,865,410</u>
NON-CURRENT ASSETS		
Property and equipment, net	1,364,181	1,394,230
Lease assets	574,953	-
Goodwill	2,061,022	2,061,022
Security deposit	67,714	67,714
TOTAL ASSETS	<u><u>\$25,784,787</u></u>	<u><u>\$18,388,376</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$1,501,848	\$687,257
Accrued bonus and severance	711,937	1,048,393
Accrued interest	49,480	60,366
Current portion of term loan, net of discount and fees	3,594,495	2,909,709
Current lease liabilities	296,797	26,935
TOTAL CURRENT LIABILITIES	<u>6,154,557</u>	<u>4,732,660</u>
NON-CURRENT LIABILITIES		
Accrued interest, net of current portion	417,205	309,440
Term loan, net of discount, fees and current portion	2,467,370	4,280,385
Warrant liability	15,617,229	2,537,317
Accrued dividends	429,953	-
Other liabilities	377,963	84,281
TOTAL LIABILITIES	<u>25,464,277</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 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; 8,871,369 and 8,743,950 shares issued and outstanding	8,871	8,744
Additional paid-in capital	73,291,876	72,871,317
Accumulated deficit	(86,641,815)	(66,435,768)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	<u>(13,341,068)</u>	<u>6,444,293</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	<u><u>\$25,784,787</u></u>	<u><u>\$18,388,376</u></u>

PLx Pharma Inc.
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
REVENUES:				
Federal grant	\$182,905	\$167,459	\$500,465	\$248,916
TOTAL REVENUES	<u>182,905</u>	<u>167,459</u>	<u>500,465</u>	<u>248,916</u>
OPERATING EXPENSES:				
Research and development	1,598,884	734,246	2,591,588	1,813,282
General and administrative	2,433,200	1,830,586	4,677,360	4,070,586
TOTAL OPERATING EXPENSES	<u>4,032,084</u>	<u>2,564,832</u>	<u>7,268,948</u>	<u>5,883,868</u>
OPERATING LOSS	<u>(3,849,179)</u>	<u>(2,397,373)</u>	<u>(6,768,483)</u>	<u>(5,634,952)</u>
OTHER INCOME (EXPENSE)				
Interest income	135,092	75,175	217,442	142,098
Interest and other expense	(280,232)	(283,285)	(575,094)	(558,684)
Change in fair value of warrant liability	(5,352,977)	(997,921)	(13,079,912)	7,426,726
TOTAL OTHER INCOME (EXPENSE)	<u>(5,498,117)</u>	<u>(1,206,031)</u>	<u>(13,437,564)</u>	<u>7,010,140</u>
INCOME (LOSS) BEFORE INCOME TAXES	<u>(9,347,296)</u>	<u>(3,603,404)</u>	<u>(20,206,047)</u>	<u>1,375,188</u>
Income taxes	-	-	-	-
NET INCOME (LOSS)	<u><u>\$(9,347,296)</u></u>	<u><u>\$(3,603,404)</u></u>	<u><u>\$(20,206,047)</u></u>	<u><u>\$1,375,188</u></u>
Preferred dividends and beneficial conversion feature	(301,735)	-	(13,122,261)	-
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS	<u><u>\$(9,649,031)</u></u>	<u><u>\$(3,603,404)</u></u>	<u><u>\$(33,328,308)</u></u>	<u><u>\$1,375,188</u></u>
Net income (loss) per common share - basic	<u><u>\$(1.10)</u></u>	<u><u>\$(0.41)</u></u>	<u><u>\$(3.80)</u></u>	<u><u>\$0.16</u></u>
Net income (loss) per common share - diluted	<u><u>\$(1.10)</u></u>	<u><u>\$(0.41)</u></u>	<u><u>\$(3.80)</u></u>	<u><u>\$0.16</u></u>
Weighted average shares of common shares - basic	<u><u>8,779,909</u></u>	<u><u>8,729,962</u></u>	<u><u>8,779,096</u></u>	<u><u>8,727,514</u></u>
Weighted average shares of common shares - diluted	<u><u>8,779,909</u></u>	<u><u>8,729,962</u></u>	<u><u>8,779,096</u></u>	<u><u>8,727,514</u></u>



Source: PLx Pharma Inc.