PLx Pharma Inc. Reports First Quarter 2019 Results

May 10, 2019

Company submits briefing package to U.S. Food and Drug Administration

HOUSTON, May 10, 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 months ended March 31, 2019.

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

- Net loss attributable to common shareholders totaled $23.7 million, or ($2.71) per share, compared to net income of $5.0 million, or $0.57 per share, for the first quarter of 2018. This includes a non-cash charge of $12.8 million, or ($1.47) per share, related to the $15 million convertible preferred stock financing and a non-cash charge of $7.7 million, or ($0.88) per share as a result of a change in the fair value of the warrant liability; whereas the first quarter of 2018 included income of $8.4 million, or $0.97 per share, related to the change in warrant liability;
- Submitted a meeting briefing package to the U.S. Food and Drug Administration (FDA) for Vazalore;
- Participated in the American College of Cardiology (ACC) and American Academy of Neurology (AAN) conferences to articulate the value proposition and build awareness with the clinical community around the unique benefits of Vazalore;
- Attended the annual National Association of Chain Drug Stores (NACDS) conference, a prestigious gathering of influential retail leaders, and met with key retailers to discuss the Vazalore opportunity; and
- Remain on schedule for the commercial launch of Vazalore in mid-2020.

"As we prepare for our commercial launch next year, we continue to focus on engaging with specialists in the cardiology and neurology communities and broadening awareness of Vazalore's unique efficacy, reliability and safety profile. Our market research among physicians and consumers is very encouraging, underscoring the need for a better aspirin therapy. We look forward to advancing our dialogue with the FDA and preparing for a successful launch in 2020," said Natasha Giordano, President and Chief Executive Officer of PLx Pharma.

First Quarter 2019 Financial Results

The Company recognized revenue of $0.3 million in the first quarter of 2019, compared to revenue of $0.08 million for the three months ended March 31, 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 $1.0 million for the first quarter of 2019, compared to $1.1 million in the first quarter of 2018. The expenses in both periods included continued development and manufacturing activities for Vazalore.

General and administrative expense totaled $2.2 million in the first quarter of 2019, roughly flat with the first quarter of 2018.

Other income (expense), net was $7.9 million of net other expense in the first quarter of 2019, compared to $8.2 million of net other income in the first 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 ($7.7 million of net other expense in the three months ended March 31, 2019 as compared to $8.4 million of other income in the comparable 2018 period.)

Net loss attributable to common shareholders for the first quarter of 2019 was $23.7 million, or ($2.71) per share, compared to net income attributable to common shareholders of $5.0 million, or $0.57 per share, for the first quarter of 2018. The first quarter of 2019 included $12.8 million, or ($1.47) 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 quarter of 2019 also included a non-cash charge of $7.7 million, or ($0.88) per share as a result of a change in the fair value of the warrant liability. The first quarter of 2018 included income of $8.4 million, or $0.97 per share, related to the change in the fair value of the warrant liability.

As of March 31, 2019, cash and cash equivalents were $24.3 million.

Conference Call

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

Date	Friday, May 10, 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 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:
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

	March 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 24,318,786	$ 14,250,267
Accounts receivable	15,959	18,234
Prepaid expenses and other current assets	307,800	421,933
Deferred financing costs	130,279	174,976
TOTAL CURRENT ASSETS	24,772,824	14,865,410
NON-CURRENT ASSETS		
Property and equipment, net	1,345,552	1,394,230
Leased assets	644,625	-
Goodwill	2,061,022	2,061,022

Security deposit	67,714	67,714
TOTAL ASSETS	$ 28,891,737	$ 18,388,376
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 702,015	$ 687,257
Accrued bonus and severance	473,797	1,048,393
Accrued interest	58,799	60,366
Current portion of term loan, net of discount and fees	3,563,098	2,909,709
Current lease liability	301,616	26,935
TOTAL CURRENT LIABILITIES	5,099,325	4,732,660
NON-CURRENT LIABILITIES		
Accrued interest, net of current portion	365,358	309,440
Term loan, net of discount, fees and current portion	3,377,871	4,280,385
Warrant liability	10,264,252	2,537,317
Accrued dividends	128,218	-
Other liabilities	449,079	84,281
TOTAL LIABILITIES	19,684,103	11,944,083
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; 8,752,178 and 8,743,950 shares issued and outstanding	8,752	8,744
Additional paid-in capital	72,831,823	72,871,317
Accumulated deficit	(77,294,519)	(66,435,768)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(4,453,944)	6,444,293
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 28,891,737	$ 18,388,376

PLx Pharma Inc.
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2019	**2018**
REVENUES:		
Federal grant	$ 317,560	$ 81,457
TOTAL REVENUES	317,560	81,457
OPERATING EXPENSES:		
Research and development	992,704	1,079,036
General and administrative	2,244,160	2,240,000
TOTAL OPERATING EXPENSES	3,236,864	3,319,036
OPERATING LOSS	(2,919,304)	(3,237,579)
OTHER INCOME (EXPENSE):		
Interest income	82,350	66,923

Interest expense	(294,862)	(275,399)
Change in fair value of warrant liability	(7,726,935)	8,424,647
TOTAL OTHER INCOME (EXPENSE)	(7,939,447)	8,216,171
INCOME (LOSS) BEFORE INCOME TAXES	(10,858,751)	4,978,592
Income taxes	-	-
NET INCOME (LOSS)	(10,858,751)	4,978,592
Preferred stock beneficial conversion feature and dividends	(12,820,526)	-
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (23,679,277)	$ 4,978,592
Net income (loss) per common share - basic	$ (2.71)	$ 0.57
Net income (loss) per common share - diluted	$ (2.71)	$ 0.57
Weighted average shares of common shares - basic	8,750,543	8,725,038
Weighted average shares of common shares - diluted	8,750,543	8,725,038

Source: PLx Pharma Inc.