PLx Pharma Inc. Reports Fourth Quarter 2019 Results and Provides Regulatory Update on VAZALORE

March 13, 2020

-- Planning a Bioequivalence Study to Support VAZALORE 325 mg sNDA --
-- Announces $8 Million Convertible Preferred Stock Financing with Park West and MSD Partners --

SPARTA, New Jersey, March 13, 2020 (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 and full year ended December 31, 2019, and provided a regulatory update on VAZALORE.

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

- Net loss attributable to common stockholders totaled $2.3 million, or ($0.25) per basic and diluted share, compared to net income of $2.9 million, or $0.34 per basic and diluted share, for the fourth quarter of 2018. Q4 2019 includes a non-cash gain of $1.9 million, or $0.20 per share, compared to a 2018 non-cash gain of $5.7 million for a change in the fair value of warrant liability, or $0.65 per share;

- Plan to initiate a bioequivalence study to support the supplemental New Drug Application ("sNDA") for VAZALORE 325 mg dose strength which will impact the previously announced timeline. The Company will announce an updated timeline once aligned with the U.S. Food and Drug Administration ("FDA") on the study design;

- Announces an $8 million Series B Convertible Preferred Stock ("Series B Preferred Stock") financing with funds affiliated with Park West Asset Management, LLC ("Park West"), the Company's largest stockholder, and an affiliate of MSD Partners, L.P. ("MSD Partners"), a new investor to PLx, subject to stockholder approval;

- Continued pre-commercial activities, including the presentation of abstracts at large medical conferences and the publication of study results in scientific journals, to build awareness of VAZALORE among health care professionals; and

- Received FDA approval for the updated labeling for VAZALORE 325 mg strength, which will be applied to the 81 mg dose.

Regulatory Update

The Company's discussions with the FDA have centered on data requirements for the approval of the new formulation of VAZALORE 325 mg. In accordance with the FDA's guidance, the Company will conduct a bioequivalence study for VAZALORE 325 mg to support approval of the sNDA which will impact the timeline previously announced. The Company currently has a meeting with the FDA scheduled for the end of April and will provide an updated timeline once details of the study design are confirmed. As previously announced, the sNDA for VAZALORE 81 mg will follow the submission of the VAZALORE 325 mg dose strength.

"Our discussions with the FDA over the past few months have led to a clearer understanding of the data requirements for our upcoming sNDA submissions, and we look forward to confirming the bioequivalence study design. We remain confident about the regulatory path forward for VAZALORE," said Natasha Giordano, President and Chief Executive Officer of PLx.

Convertible Preferred Stock Financing

PLx announced today that it has entered into a purchase agreement with Park West and MSD Partners pursuant to which the Company has agreed to issue 8,000 shares of Series B Preferred Stock for gross proceeds of $8 million. The Company intends to use the proceeds to advance VAZALORE to market readiness and for working capital and general purposes.

Subject to approval of the Company's stockholders and the satisfaction of certain customary closing conditions, the Series B Preferred Stock transaction is expected to close in the second quarter of 2020. The Company intends to set a date for a stockholder meeting to approve the transaction. Once a meeting date has been determined, the Company will send a notice and definitive proxy statement.

The Series B Preferred Stock will be issued at $1,000 per share and will be convertible into common shares at a conversion price of $3.10 per share. Holders of the Series B Preferred Stock will be entitled to an initial dividend rate of 8% per annum, which will stop accruing on the date of the FDA approval of the sNDAs of VAZALORE. The dividends are compounded quarterly and payable in cash or preferred stock at the Company's option.

"We are pleased that our largest stockholder, Park West, and new investor MSD Partners have committed $8 million of capital which will help support bringing VAZALORE to market. We continue to execute on our publication strategy to disseminate the scientific information to the clinical community, as well as to ensure that retailers and consumers understand the unique safety and efficacy profile of VAZALORE. In addition, the FDA's approval of the labeling for VAZALORE 325 mg is an important milestone on our way to commercialization," concluded Giordano.

Please refer to the Company's Form 8-K to be filed with the U.S. Securities and Exchange Commission for the complete terms of the Series B Preferred Stock transaction.

Fourth Quarter 2019 Financial Results

The Company recognized revenue of approximately $24,000 for the fourth quarter of 2019 compared to $0.3 million for the fourth quarter of 2018. All the revenue recognized is attributable to work performed under an award of a National Institutes of Health grant, which is nearing completion.

Research and development expenses were approximately $0.9 million for the fourth quarter of 2019, roughly flat compared to the fourth quarter of 2018. The expenses in both periods include continued development and manufacturing activities for VAZALORE.

General and administrative expense totaled $2.8 million for the fourth quarter of 2019, compared to $1.9 million for the fourth quarter of 2018. This increase is due to commercial-related activities to support the upcoming launch of VAZALORE, as well as a non-cash increase in stock-based compensation of $0.2 million.

Other income (expense), net was down $3.7 million to $1.8 million of net other income for the fourth quarter of 2019, primarily attributable to $3.8 million of lower non-cash income from the change in fair value of the warrant liability primarily due to the fluctuation of the Company's common stock price.

Net loss attributable to common stockholders for the fourth quarter of 2019 was $2.3 million, or ($0.25) per basic and diluted share, compared to net income of $2.9 million, or $0.34 per share, for the fourth quarter of 2018. The fourth quarter of 2019 includes a non-cash gain of $1.9 million, or $0.20 per share compared to a gain of $5.7 million, or $0.65 per share in the fourth quarter of 2018, related to the change in warrant liability. The fourth 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.

Full Year 2019 Financial Results

For the year ended December 31, 2019, total revenues were approximately $0.6 million, compared to $0.8 million for the year ended December 31, 2018. All the revenue recognized is attributable to work performed under an award of a National Institutes of Health grant, which is nearing completion.

Research and development expense increased to $4.7 million for the year ended December 31, 2019, compared to $3.9 million in the prior year, 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 the Company's sNDA filings.

General and administrative expense increased to $10.0 million for the year ended December 31, 2019 compared to approximately $7.8 million in the prior year. This increase is due to commercial-related activities to support the upcoming launch of $1.9 million and payments to the University of Texas associated with the patent license agreement of $0.3 million.

Other income (expense), net was $6.3 million of net other expense for the year ended December 31, 2019, compared to $11.9 million of net other income in the prior year. This change is primarily 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 ($5.7 million of other expense for the year ended December 31, 2019, as compared to $12.7 million of other income in the prior year).

Net loss attributable to common stockholders for the year ended December 31, 2019 was $34.3 million or ($3.84) per basic and diluted share compared to net income of $0.9 million, or $0.10 per share for the prior year. Full year 2019 included $13.7 million or ($1.54) 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. Full year 2019 also included a non-cash charge of $5.7 million, or ($0.64) per share as a result of a change in the fair value of the warrant liability as compared to income of $12.7 million or $1.45 per share in the prior year.

As of December 31, 2019, the Company had cash and cash equivalents of $14.0 million. The $8 million Series B Preferred Stock financing should provide a cash runway until the end of the first quarter of 2021. The Company will need additional financing upon submission of the sNDAs. The timing of submissions and the amount of additional capital raised will determine the level of pre-launch marketing spending and commercial inventory build prior to approval of VAZALORE.

Conference Call

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

Date:	Friday, March 13, 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.

Important Additional Information Will Be Filed With the SEC

PLx plans to file with the SEC and mail to its stockholders a proxy statement in connection with the Series B Preferred Stock transaction. The proxy statement will contain important information about PLx, the transaction and related matters. Investors and security holders are urged to read the proxy statement carefully when it is available. Investors and security holders will be able to obtain free copies of the proxy statement and other documents filed with the SEC by PLx through the SEC's website at www.sec.gov. In addition, investors and security holders will be able to obtain free copies of the proxy statement from PLx by contacting the Corporate Secretary at (973) 409-6541.

PLx and its directors and executive officers may be deemed to be participants in the solicitation of proxies with respect to the transactions

contemplated by the Series B preferred stock purchase agreement. Additional information regarding interests of such participants is included in PLx's definitive proxy statement filed with the SEC on July 2, 2019, available free of charge as indicated above.

This release does not constitute an offer to sell or the solicitation of an offer to buy any security. The shares offered have not been registered under the Securities Act of 1933, as amended, or applicable state securities laws and may not be offered or sold in the United States or any state thereof absent registration under the securities act and applicable state securities laws or an applicable exemption from registration requirements.

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 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 collecting the data 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, 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, the proposed Series B Preferred Stock and the expected timetable for completing such transaction, 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, PLx's ability to obtain stockholder approval of the Series B Preferred Stock transaction, and the possibility that such transaction will not close or that the closing will be delayed. 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.

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Source: PLx Pharma Inc.

PLx Pharma Inc.
CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 14,001,304	$ 14,250,267
Accounts receivable	18,683	18,234
Prepaid expenses and other current assets	263,268	421,933
Deferred financing costs	-	174,976
TOTAL CURRENT ASSETS	14,283,255	14,865,410
NON-CURRENT ASSETS		
Property and equipment, net	1,466,646	1,394,230
Right of use assets	618,158	-

Goodwill	2,061,022	2,061,022
Security deposit	73,665	67,714
TOTAL ASSETS	$ 18,502,746	$ 18,388,376
LIABILITIES, SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 928,921	$ 687,257
Accrued bonuses	1,166,821	1,048,393
Accrued interest	34,964	60,366
Current portion of term loan, net of discount and fees	3,658,121	2,909,709
Other current liabilities	304,603	26,935
TOTAL CURRENT LIABILITIES	6,093,430	4,732,660
NON-CURRENT LIABILITIES		
Accrued interest, net of current portion	501,826	309,440
Term loan, net of discount, fees and current portion	622,265	4,280,385
Warrant liability	8,247,679	2,537,317
Accrued dividends	1,058,498	-
Other liabilities	409,431	84,281
TOTAL LIABILITIES	16,933,129	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; 9,156,260 and 8,743,950 shares		
issued and outstanding	9,156	8,744
Additional paid-in capital	74,837,046	72,871,317
Accumulated deficit	(86,938,163)	(66,435,768)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(12,091,961)	6,444,293
TOTAL LIABILITIES, SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 18,502,746	$ 18,388,376

PLx Pharma Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
REVENUES:				
Federal grant	$ 23,893	$ 287,662	$ 565,464	$ 753,108
TOTAL REVENUES	23,893	287,662	565,464	753,108
OPERATING EXPENSES:				
Research and development	935,513	890,239	4,741,130	3,922,665
General and administrative	2,845,953	1,920,855	10,026,627	7,791,600
TOTAL OPERATING EXPENSES	3,781,466	2,811,094	14,767,757	11,714,265
OPERATING LOSS	(3,757,573)	(2,523,432)	(14,202,293)	(10,961,157)

OTHER INCOME (EXPENSE):				
Interest income	76,176	78,426	405,239	297,800
Interest and other expense	(189,832)	(296,304)	(994,979)	(1,145,761)
Change in fair value of warrant liability	1,871,159	5,687,675	(5,710,362)	12,705,598
TOTAL OTHER INCOME (EXPENSE)	1,757,503	5,469,797	(6,300,102)	11,857,637
INCOME (LOSS) BEFORE INCOME TAXES	(2,000,070)	2,946,365	(20,502,395)	896,480
Income taxes	-	-	-	-
NET INCOME (LOSS)	$ (2,000,070)	$ 2,946,365	$ (20,502,395)	$ 896,480
Preferred dividends and beneficial conversion feature	(317,409)	-	(13,750,806)	-
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (2,317,479)	$ 2,946,365	$ (34,253,201)	$ 896,480
Net income (loss) per common share - basic	$ (0.25)	$ 0.34	$ (3.84)	$ 0.10
Net income (loss) per common share - diluted	$ (0.25)	$ 0.34	$ (3.84)	$ 0.10
Weighted average shares of common shares - basic	9,129,854	8,741,994	8,916,190	8,733,220
Weighted average shares of common shares - diluted	9,129,854	8,741,994	8,916,190	8,733,220

Source: PLx Pharma Inc.