PLx Pharma Inc. Reports First Quarter 2020 Results

May 15, 2020

-- Company to begin bioequivalence study of VAZALORE 325 mg dose --
-- sNDA submissions expected by year-end --

SPARTA, N.J., May 15, 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 ended March 31, 2020.

Highlights of, and certain events subsequent to, the first quarter of 2020 include:

- Net income attributable to common stockholders totaled $1.2 million, or $0.08 per basic and diluted share, compared to net loss of $23.7 million, or ($2.71) per basic and diluted share, for the first quarter of 2019. This includes a non-cash gain of $4.6 million, or $0.45 per share, compared to a 2019 non-cash charge of $7.7 million for a change in the fair value of warrant liability, or ($0.88) per share;
- Held Type-C meeting with the U.S. Food and Drug Administration ("FDA") on the bioequivalence study design to support the supplemental New Drug Application ("sNDA") for VAZALORE 325 mg dose strength and awaiting meeting minutes;
- Engaged a contract research organization to conduct the required bioequivalence study once study is finalized with FDA;
- Presented two original abstracts showcasing: first, VAZALORE's improved pharmacologic profile over enteric-coated aspirin, and second, VAZALORE's ability to largely mitigate the negative impact of increasing weight on antiplatelet efficacy at the virtual American College of Cardiology Annual Scientific Session;
- Announced an $8 million Series B Convertible Preferred Stock financing with Park West Asset Management, LLC and MSD Partners, L.P., providing a cash runway through the second quarter of 2021, subject to stockholder approval; and
- Targeting filing sNDA submissions for both VAZALORE 325 mg dose and VAZALORE 81 mg dose to the FDA by year-end 2020, provided no delays caused by COVID-19.

"We are pleased to be moving ahead with the bioequivalence study and look forward to completing the regulatory requirements to support our sNDA submissions. This additional study will serve to reinforce our application for approval and will proceed alongside the ongoing pre-launch commercial activities already under way. We are excited about VAZALORE's unique and innovative qualities and are eager to bring this critical new aspirin to millions of people with vascular disease," said Natasha Giordano, President and Chief Executive Officer of PLx.

First Quarter 2020 Financial Results

The Company recognized revenue of $2,523 for the three months ended March 31, 2020, compared to revenue of $317,560 for the three months ended March 31, 2019. Revenue in both the 2020 and 2019 periods is attributable to work performed under a federal grant from the National Institutes of Health which will be coming to an end in the second quarter of 2020.

Research and development expenses totaled $0.5 million in the three months ended March 31, 2020 and $1.0 million in the prior year period. The decrease reflects lower reimbursable grant expenses combined with reduced spending on manufacturing-related activities for VAZALORE.

General and administrative expenses totaled $2.5 million in the three months ended March 31, 2020, compared to $2.2 million in the prior year period. The increase is primarily due to pre-commercial related activities for VAZALORE and increased stock-based compensation.

Other income (expense), net, totaled $4.5 million of net other income in the three months ended March 31, 2020, compared to $7.9 million of net other expense in the prior year period. The 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 ($4.6 million of other income in the three months ended March 31, 2020, compared to $7.7 million of other expense in the comparable 2019 period).

Net income attributable to common stockholders for the first quarter of 2020 was $1.2 million, or $0.08 per basic and diluted share, compared to net loss of $23.7 million, or ($2.71) per share, for the first quarter of 2019. The first quarter of 2020 includes a non-cash gain of $4.6 million, or $0.45 per share compared to a non-cash loss of $7.7 million, or ($0.88) per share in the first quarter of 2019, related to the change in warrant liability. The first quarter of 2020 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. 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.

As of March 31, 2020, cash and cash equivalents were $9.3 million. The $8 million Series B Preferred Stock financing should provide a cash runway until the second quarter of 2021. The Company will need additional financing upon submission of the sNDAs. The timing of submissions and the amount of 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 first quarter 2020 conference call as follows:

Date:	Friday, May 15, 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.

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.

FINANCIAL TABLES FOLLOW

PLx Pharma Inc.
UNAUDITED CONSOLIDATED BALANCE SHEETS

	March 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 9,286,571	$ 14,001,304
Accounts receivable	2,523	18,683
Prepaid expenses and other current assets	248,597	263,268
Deferred financing costs	43,518	-
TOTAL CURRENT ASSETS	9,581,209	14,283,255
NON-CURRENT ASSETS		

Property and equipment, net	1,437,324	1,466,646
Right of use assets	548,089	618,158
Goodwill	2,061,022	2,061,022
Security deposit	73,665	73,665
TOTAL ASSETS	$ 13,701,309	$ 18,502,746
LIABILITIES, SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 761,588	$ 928,921
Accrued bonuses	317,634	1,166,821
Accrued interest	557,643	34,964
Current portion of term loan, net of discount and fees	3,377,855	3,658,121
Other current liabilities	319,835	304,603
TOTAL CURRENT LIABILITIES	5,334,555	6,093,430
NON-CURRENT LIABILITIES		
Accrued interest, net of current portion	-	501,826
Term loan, net of discount, fees and current portion	-	622,265
Warrant liability	3,648,426	8,247,679
Accrued dividends	1,378,788	1,058,498
Other liabilities	321,590	409,431
TOTAL LIABILITIES	10,683,359	16,933,129
Series A convertible preferred stock: $0.001 par value; liquidation value of $16,378,788 and $16,058,498, respectively; 45,000 shares designated, 15,000 shares issued and outstanding	13,661,578	13,661,578
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock; $0.001 par value; 955,000 shares authorized; none issued and outstanding	-	-
Common stock; $0.001 par value; 100,000,000 shares authorized; 9,156,260 shares issued and outstanding	9,156	9,156
Additional paid-in capital	74,789,293	74,837,046
Accumulated deficit	(85,442,077)	(86,938,163)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(10,643,628)	(12,091,961)
TOTAL LIABILITIES, SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 13,701,309	$ 18,502,746

PLx Pharma Inc.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2020	**2019**
REVENUES:		
Federal grant	$ 2,523	$ 317,560
TOTAL REVENUES	2,523	317,560
OPERATING EXPENSES:		
Research and development	513,914	992,704
General and administrative	2,493,251	2,244,160

TOTAL OPERATING EXPENSES	3,007,165	3,236,864
OPERATING LOSS	(3,004,642)	(2,919,304)
OTHER INCOME (EXPENSE):		
Interest income	47,303	82,350
Interest and other expense	(145,828)	(294,862)
Change in fair value of warrant liability	4,599,253	(7,726,935)
TOTAL OTHER INCOME (EXPENSE)	4,500,728	(7,939,447)
INCOME (LOSS) BEFORE INCOME TAXES	1,496,086	(10,858,751)
Income taxes	-	-
NET INCOME (LOSS)	$ 1,496,086	$ (10,858,751)
Preferred dividends and beneficial conversion feature	(320,290)	(12,820,526)
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ 1,175,796	$ (23,679,277)
Net income (loss) per common share - basic	$ 0.08	$ (2.71)
Net income (loss) per common share - diluted	$ 0.08	$ (2.71)
Weighted average shares of common shares - basic	9,156,260	8,750,543
Weighted average shares of common shares - diluted	9,216,667	8,750,543

Source: PLx Pharma Inc.