



## PLx Pharma Inc. Reports Third Quarter 2020 Results and Provides Business Update

November 16, 2020

--Announces \$18 million private placement--

--Submitted sNDAs for VAZALORE 325 mg and 81 mg doses to FDA end of October--

--On target for third quarter 2021 commercial launch of VAZALORE--

SPARTA, N.J., Nov. 16, 2020 (GLOBE NEWSWIRE) -- PLx Pharma Inc. (NASDAQ: PLXP) ("PLx" or the "Company"), a late-stage specialty pharmaceutical company focused on its clinically-validated and patent-protected PLxGuard™ drug delivery platform to provide more effective and safer products, with its lead products VAZALORE™ 325 mg and VAZALORE™ 81 mg (referred to together as "VAZALORE"), announced today certain financial and operational results for the three and nine months ended September 30, 2020.

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

- Entered into an \$18 million private placement with investors led by White Rock Capital Management, L.P. and Level One Partners, LLC;
- Submitted supplemental New Drug Applications ("sNDAs") for VAZALORE 325 mg and 81 mg doses to the U.S. Food and Drug Administration ("FDA") for regulatory approval at the end of October ahead of previously announced timeline; and
- Targeting commercial launch of both VAZALORE 325 mg and 81 mg doses for the third quarter of 2021, assuming FDA approval, adequate capital funding and no COVID-related delays.

"The submission of our two sNDAs marks a significant milestone for PLx in our efforts to bring VAZALORE, our novel aspirin therapy to market. While VAZALORE is under regulatory review, we will continue our precommercial activities focused on specialists treating vascular disease, retailers and consumers. Our upcoming priorities are to execute our commercial strategy for a successful product launch that will bring this much-needed aspirin alternative to the millions of at-risk patients," said Natasha Giordano, President and Chief Executive Officer of PLx.

### Private Placement

On November 16, 2020, the Company entered into a securities purchase agreement for the sale of units comprised of shares of common stock and a warrant to purchase shares of common stock in a private placement that will result in gross proceeds to the Company of approximately \$18 million, before deducting placement agent and other offering expenses, for the issuance of 4,755,373 shares of common stock and warrants to purchase up to an additional 5,230,910 shares of common stock for a per unit price of \$3.787. The private placement is expected to close on or prior to November 18, 2020. The warrants will become exercisable on the date of issuance, have an exercise price of \$4.31 per share and will expire five years from the date of issuance.

"We are pleased to be leading the financing in support of PLx and VAZALORE, as the Company advances its innovative aspirin product through the regulatory process and prepares for market entry. With management's extensive experience launching large, commercially successful products, we are confident in PLx's ability to execute its strategic plan and to take full advantage of the significant market opportunity for VAZALORE," stated Tom Barton, White Rock Capital Management, L.P.

### Third Quarter 2020 Financial Results

The Company recognized no revenue for the three months ended September 30, 2020, compared to revenue of \$41,106 for the three months ended September 30, 2019. Revenue in the 2019 period is attributable to work performed under a federal grant from the National Institutes of Health ("NIH"), which came to an end in the second quarter of 2020.

Research and development expense totaled \$1.2 million in the three months ended September 30, 2020 and 2019. The expense in the 2020 period includes clinical-related spending for the bioequivalence study combined with pre-validation manufacturing costs. The prior year period included manufacture and packaging costs for the VAZALORE registration batches.

General and administrative expenses totaled \$2.0 million in the three months ended September 30, 2020, compared to \$2.5 million in the prior year period. The decrease primarily reflects lower compensation-related expenses combined with reduced spending on conferences and related travel due to COVID-19 restrictions.

Other income (expense), net, totaled \$61,847 and \$5.4 million of net other income in the three months ended September 30, 2020 and 2019, respectively. The decrease 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, combined with lower net interest expense, which was impacted by a lower principal debt balance and lower interest rates.

Net loss attributable to common stockholders for the third quarter of 2020 was \$3.6 million, or (\$0.40) per basic and diluted share, compared to net income of \$1.4 million, or \$0.09 per share, for the third quarter of 2019. The third quarter of 2020 includes non-cash income of \$134,552, or \$0.01 per share, related to the change in fair value of warrant liability and \$0.5 million, or (\$0.05) per share, of Series A and Series B convertible preferred stock

dividends. The third quarter of 2019 included non-cash income of \$5.5 million, or \$0.55 per share, related to the change in the warrant liability and \$0.3 million, or (\$0.03) per share, for preferred stock dividends related to the Series A convertible preferred stock.

### **Nine Months Ended September 30, 2020 Financial Results**

For the nine months ended September 30, 2020, revenue was \$30,430 compared to \$541,571 in the comparable period in 2019. All the revenue recognized is attributable to work performed under an award of an NIH grant, which came to an end in the second quarter of 2020.

Research and development expense decreased to \$3.1 million for the nine months ended September 30, 2020, compared to \$3.8 million for the first nine months of 2019. The decrease is due to lower manufacturing-related activities for VAZALORE, as the prior year included the manufacture and packaging of the registration batches. The decrease also reflects lower reimbursable grant expenses, as the grant from the NIH came to an end in the second quarter 2020. Higher clinical-related spending, primarily for the bioequivalence study, partially offset this decrease.

General and administrative expense totaled \$6.7 million for the nine months ended September 30, 2020, compared to \$7.2 million in the comparable 2019 period. The decrease was due to compensation-related expense and reduced spending on conferences and related travel due to COVID-19 restrictions, offset somewhat by higher spending on pre-launch marketing activities and higher stock compensation expense.

Other income (expense), net was \$2.5 million of net other income for the first nine months of 2020, compared to \$8.1 million of net other expense for the first nine months of 2019. The difference 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, combined with lower net interest expense due to lower interest rates and a lower principal debt balance.

Net loss attributable to common stockholders for the nine months ended September 30, 2020 was \$8.5 million, or (\$0.92) per share, compared to net loss attributable to common stockholders of \$31.9 million, or (\$3.60) per share, for the first nine months of 2019. The first nine months of 2020 included non-cash income of \$2.8 million, or \$0.31 per share, as a result of a change in the fair value of the warrant liability and \$1.2 million of Series A and Series B convertible preferred stock dividends. The first nine months of 2019 included a charge of \$13.4 million, or (\$1.52) per share, for the beneficial conversion feature and dividends related to the Series A convertible preferred stock. The first nine months of 2019 also included a non-cash charge of \$7.6 million, or (\$0.86) per share, as a result of a change in the fair value of the warrant liability.

As of September 30, 2020, cash and cash equivalents were \$9.1 million.

### **Conference Call**

As previously announced, PLx management will host its third quarter 2020 conference call as follows:

Date: Monday, November 16, 2020

Time: 4:30 p.m. ET

Toll free (866) 394-2901  
(U.S.):

International: (616) 548-5567

Webcast (live [www.plxpharma.com](http://www.plxpharma.com) under the 'Investor Relations' section and replay):

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 faster, reliable and more predictable platelet inhibition as compared to enteric-coated aspirin, while also reducing the risk of stomach erosions and ulcers, as compared to immediate-release aspirin, common in an acute setting. PLx's supplemental New Drug Applications for VAZALORE 325 mg and VAZALORE 81 mg doses, submitted in October 2020 to the FDA, are currently under regulatory review.

### **About PLx Pharma Inc.**

PLx Pharma Inc. is a late-stage specialty pharmaceutical company focused on its clinically-validated and patent-protected PLxGuard™ drug delivery platform to provide more effective and safer products. The PLxGuard drug delivery platform works by targeting the release 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 and ulcers 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, 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](http://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**

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 9,086,525	\$ 14,001,304
Accounts receivable	-	18,683
Inventory, net	143,380	-
Prepaid expenses and other current assets	<u>387,801</u>	<u>263,268</u>
<b>TOTAL CURRENT ASSETS</b>	<u>9,617,706</u>	<u>14,283,255</u>
<b>NON-CURRENT ASSETS</b>		
Property and equipment, net	1,252,434	1,466,646
Right of use assets	402,640	618,158
Goodwill	2,061,022	2,061,022
Security deposit	<u>17,035</u>	<u>73,665</u>
<b>TOTAL ASSETS</b>	<u>\$ 13,350,837</u>	<u>\$ 18,502,746</u>
<b>LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued liabilities	\$ 612,367	\$ 928,921
Accrued bonuses	718,092	1,166,821
Accrued interest	589,840	34,964
Current portion of term loan, net of discount and fees	1,548,865	3,658,121
Other current liabilities	<u>342,175</u>	<u>304,603</u>

TOTAL CURRENT LIABILITIES	3,811,339	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	5,442,717	8,247,679
Accrued dividends	2,285,920	1,058,498
Other liabilities	146,424	409,431
TOTAL LIABILITIES	11,686,400	16,933,129
Series A convertible preferred stock: \$0.001 par value; liquidation value of \$17,042,322; 45,000 shares authorized, 15,000 issued and outstanding	13,661,578	13,661,578
Series B convertible preferred stock: \$0.001 par value; liquidation value of \$8,243,598; 25,000 shares authorized, 8,000 and 0 issued and outstanding	7,723,312	-
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock; \$0.001 par value; 930,000 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	74,437,924	74,837,046
Accumulated deficit	(94,167,533)	(86,938,163)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(19,720,453)	(12,091,961)
TOTAL LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 13,350,837	\$ 18,502,746

**PLx Pharma Inc.**  
**UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
REVENUES:				
Federal grant	\$ -	\$ 41,106	\$ 30,430	\$ 541,571
TOTAL REVENUES	-	41,106	30,430	541,571
OPERATING EXPENSES:				
Research and development	1,207,302	1,214,029	3,116,097	3,805,617
General and administrative	1,981,037	2,503,314	6,681,452	7,180,674
TOTAL OPERATING EXPENSES	3,188,339	3,717,343	9,797,549	10,986,291
OPERATING LOSS	(3,188,339)	(3,676,237)	(9,767,119)	(10,444,720)
OTHER INCOME (EXPENSE):				
Interest and other expense, net	(72,705)	(118,432)	(267,213)	(476,084)

Change in fair value of warrant liability	134,552	5,498,391	2,804,962	(7,581,521)
TOTAL OTHER INCOME (EXPENSE)	61,847	5,379,959	2,537,749	(8,057,605)
(LOSS) INCOME BEFORE INCOME TAXES	(3,126,492)	1,703,722	(7,229,370)	(18,502,325)
Income taxes	-	-	-	-
NET (LOSS) INCOME	(3,126,492)	1,703,722	(7,229,370)	(18,502,325)
Preferred dividends and beneficial conversion feature	(499,797)	(311,136)	(1,227,422)	(13,433,397)
NET (LOSS) INCOME ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$(3,626,289)	\$ 1,392,586	\$(8,456,792)	\$(31,935,722)
Net (loss) income per common share - basic	\$ (0.40)	\$ 0.09	\$ (0.92)	\$ (3.60)
Net (loss) income per common share - diluted	\$ (0.40)	\$ 0.09	\$ (0.92)	\$ (3.60)
Weighted average shares of common shares - basic	9,156,260	8,921,345	9,156,260	8,860,168
Weighted average shares of common shares - diluted	9,156,260	8,936,255	9,156,260	8,860,168



Source: PLx Pharma Inc.