



PLx Pharma Inc. Reports Fourth Quarter and Full Year 2020 Results and Provides Business Update

March 12, 2021

- Received FDA approval of sNDAs for both VAZALORE 325 mg and 81 mg, the first-ever novel, liquid-filled aspirin capsule --
- U.S. commercial launch of VAZALORE planned for third quarter 2021 --
- Secured \$63 million of gross proceeds in an underwritten public offering of common stock for the launch of VAZALORE --

SPARTA, N.J., March 12, 2021 (GLOBE NEWSWIRE) -- PLx Pharma Inc. (NASDAQ: PLXP) ("PLx" or the "Company"), a 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 months and full year ended December 31, 2020.

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

- Received U.S. Food and Drug Administration ("FDA") approval of its supplemental new drug applications ("sNDAs") for its lead products, VAZALORE 325 mg and VAZALORE 81 mg, the first-ever liquid-filled aspirin capsules;
- Completed a \$63 million financing of 7,875,000 shares of common stock, offered at a price of \$8.00 for the launch of VAZALORE;
- Entered into an \$18 million private placement in November 2020; and
- VAZALORE commercial launch planned for the third quarter 2021.

"We are delighted to receive FDA approval of the sNDAs for both dose strengths and are excited to launch this breakthrough product to the medical community and to patients who can benefit from a reliable and predictable antiplatelet therapy," stated Natasha Giordano, President and Chief Executive Officer of PLx.

"The successful \$63 million financing provides the capital needed to commercialize VAZALORE. Our experienced leadership team is well prepared to execute our strategy, and this funding will enable us to launch the product successfully," concluded Giordano.

Public Offering

On March 5, 2021, the Company completed an underwritten public offering in which PLx issued and sold 7,875,000 shares of its common stock at a price to the public of \$8.00 per share. The gross proceeds to the Company from this offering were \$63 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Fourth Quarter 2020 Financial Results

The Company recognized no revenue for the fourth quarter of 2020 compared to \$24,000 for the fourth quarter of 2019. All the revenue recognized in 2019 was attributable to work performed under an award of a National Institutes of Health ("NIH") grant, which came to an end in the second quarter of 2020.

Research and development expenses were \$1.2 million for the fourth quarter of 2020, compared to \$0.9 million in the fourth quarter of 2019. This increase reflected the expiration of raw materials combined with higher regulatory costs supporting the filing of the supplemental new drug applications in October 2020.

General and administrative expense totaled \$2.5 million in the fourth quarter of 2020 compared to \$2.8 million in the fourth quarter of 2019. This decrease was due to lower pre-launch marketing costs combined with lower conference and related travel costs due to COVID-19 restrictions.

Other (expense) income totaled \$4.3 million of other expense and \$1.8 million of net other income in the three months ended December 31, 2020 and 2019, respectively. The decrease was 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 fourth quarter of 2020 was \$8.5 million, or (\$0.87) per basic and diluted share, compared to net loss of \$2.3 million, or (\$0.25) per share, for the fourth quarter of 2019. The fourth quarter of 2020 included a non-cash loss of \$4.2 million, or (\$0.44) 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 fourth quarter of 2019 included a non-cash gain of \$1.9 million, or \$0.20 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.

Full Year 2020 Financial Results

For the year ended December 31, 2020, total revenues were \$0.03 million, compared with \$0.6 million for the prior year. All the revenue recognized in

2020 and 2019 was attributable to work performed under a federal grant from the NIH, which came to an end in the second quarter of 2020.

Research and development expenses totaled \$4.3 million for the year ended December 31, 2020, compared to \$4.7 million in the prior year, reflecting continued product development and manufacturing activities for VAZALORE. This decrease was due to 2020 activities, which included the bioequivalence study to provide data for the sNDA filing, stability and validation work, compared to manufacture, packaging, stability, and analytical costs related to the registration batches in 2019.

General and administrative expenses totaled \$9.2 million for the year ended December 31, 2020, compared to \$10.0 million in the prior year. The decrease was due to lower compensation-related expenses combined with savings from COVID-19 restrictions on conference and travel costs.

Other (expense) income totaled \$1.8 million of other expense for the year ended December 31, 2020, compared to \$6.3 million of other expense in the prior year. The 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, combined with lower net interest expense due to lower interest rates and lower principal debt balance.

Net loss attributable to common stockholders for the year ended December 31, 2020 was \$16.9 million or (\$1.74) per basic and diluted share compared to net loss of \$34.3 million, or (\$3.84) per share for the prior year. Full year 2020 included non-cash expense of \$1.4 million, or (\$0.15) per share, as a result of a change in the fair value of the warrant liability and \$1.7 million, or (\$0.18) per share, of Series A and Series B convertible preferred stock dividends. 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 expense of \$5.7 million, or (\$0.64) per share as a result of a change in the fair value of the warrant liability.

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 resulted 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 closed on November 18, 2020. The warrants 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.

As of December 31, 2020, the Company had cash and cash equivalents of \$22.4 million.

Conference Call

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

Date:	Friday, March 12, 2021
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 is an FDA-approved liquid-filled aspirin capsule that provides patients with vascular disease and diabetic patients who are candidates for aspirin therapy based on physician recommendation, with fast, reliable and predictable platelet inhibition as compared to enteric-coated aspirin. It also reduces the risk of stomach erosions and ulcers, as compared to immediate-release aspirin, common in an acute setting.

About PLx Pharma Inc.

PLx Pharma Inc. is a 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 platform 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 certain 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. Other risks and uncertainties are more fully described in PLx's Form 10-K for the year ended December 31, 2020 filed with the SEC on March 12, 2021, 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.
CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 22,448,651	\$ 14,001,304
Accounts receivable	-	18,683
Inventory, net	143,380	-
Prepaid expenses and other current assets	393,470	263,268
TOTAL CURRENT ASSETS	<u>22,985,501</u>	<u>14,283,255</u>
NON-CURRENT ASSETS		
Property and equipment, net	1,225,879	1,466,646
Right of use assets	327,161	618,158
Goodwill	2,061,022	2,061,022
Security deposit	17,036	73,665
TOTAL ASSETS	<u>\$ 26,616,599</u>	<u>\$ 18,502,746</u>
LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 862,568	\$ 928,921
Accrued bonuses	1,184,823	1,166,821
Accrued interest	597,411	34,964
Current portion of term loan, net of discount and fees	622,265	3,658,121
Other current liabilities	275,247	304,603
TOTAL CURRENT LIABILITIES	<u>3,542,314</u>	<u>6,093,430</u>
NON-CURRENT LIABILITIES		
Accrued interest, net of current portion	-	501,826
Term loan, net of discount, fees and current portion	-	622,265
Warrant liability	9,691,271	8,247,679
Accrued dividends	2,795,795	1,058,498
Other liabilities	134,184	409,431
TOTAL LIABILITIES	<u>16,163,564</u>	<u>16,933,129</u>
Series A convertible preferred stock: \$0.001 par value; liquidation value of \$17,385,970; 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 \$8,409,825; 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; 13,911,633 and 9,156,260 shares issued and outstanding	13,912	9,156
Additional paid-in capital	91,203,050	74,837,046
Accumulated deficit	(102,148,817)	(86,938,163)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	<u>(10,931,855)</u>	<u>(12,091,961)</u>
TOTAL LIABILITIES, SERIES A AND SERIES B CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	<u>\$ 26,616,599</u>	<u>\$ 18,502,746</u>

PLx Pharma Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS

Three Months Ended December 31,

Year Ended December 31,

	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
REVENUES:				
Federal grant	\$ -	\$ 23,893	\$ 30,430	\$ 565,464
TOTAL REVENUES	<u>-</u>	<u>23,893</u>	<u>30,430</u>	<u>565,464</u>
OPERATING EXPENSES:				
Research and development	1,222,877	935,513	4,338,974	4,741,130
General and administrative	2,469,116	2,845,953	9,150,568	10,026,627
TOTAL OPERATING EXPENSES	<u>3,691,993</u>	<u>3,781,466</u>	<u>13,489,542</u>	<u>14,767,757</u>
OPERATING LOSS	<u>(3,691,993)</u>	<u>(3,757,573)</u>	<u>(13,459,112)</u>	<u>(14,202,293)</u>
OTHER (EXPENSE) INCOME:				
Interest and other expense, net	(40,737)	(113,656)	(307,950)	(589,740)
Change in fair value of warrant liability	(4,248,554)	1,871,159	(1,443,592)	(5,710,362)
TOTAL OTHER (EXPENSE) INCOME	<u>(4,289,291)</u>	<u>1,757,503</u>	<u>(1,751,542)</u>	<u>(6,300,102)</u>
LOSS BEFORE INCOME TAXES	<u>(7,981,284)</u>	<u>(2,000,070)</u>	<u>(15,210,654)</u>	<u>(20,502,395)</u>
Income taxes	-	-	-	-
NET LOSS	<u>(7,981,284)</u>	<u>(2,000,070)</u>	<u>(15,210,654)</u>	<u>(20,502,395)</u>
Deemed dividends	-	-	-	(12,692,308)
Preferred dividends	<u>(509,875)</u>	<u>(317,409)</u>	<u>(1,737,297)</u>	<u>(1,058,498)</u>
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (8,491,159)	\$ (2,317,479)	\$ (16,947,951)	\$ (34,253,201)
Net loss per common share - basic and diluted	\$ (0.87)	\$ (0.25)	\$ (1.74)	\$ (3.84)
Weighted average shares of common shares - basic and diluted	9,714,951	9,129,854	9,714,951	8,916,190



Source: PLx Pharma Inc.