PLx Pharma Inc. Reports Third Quarter 2018 Results

November 9, 2018

PLx has identified the alternate supply of a key ingredient for Vazalore

HOUSTON, Nov. 09, 2018 (GLOBE NEWSWIRE) -- PLx Pharma Inc. (NASDAQ: PLXP) ("PLx" or the "Company"), a late-stage specialty pharmaceutical company focused on commercializing two patent-protected 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-month periods ended September 30, 2018.

Highlights of, and certain events subsequent to, the third quarter of 2018 include:

- Net loss totaled $3.4 million, or ($0.39) per share, compared with a net loss of $3.8 million, or ($0.44) per share, for the third quarter of 2017;
- Identified alternate supply of a key ingredient in Vazalore to ensure the highest quality product, achieving consistent, successful dissolution and stability results in initial tests;
- Attended the European Society of Cardiology and Transcatheter Cardiovascular Therapeutics conferences to raise awareness around the unmet need for a better aspirin formulation and articulate the clinical value proposition of Vazalore with global cardiovascular disease and interventional cardiology key opinion leaders;
- Continue partnering discussions with major retailers to ensure a successful launch of Vazalore; and
- Remain on target for mid-2020 launch of Vazalore.

"We are very pleased with the progress we've made during the third quarter. Most importantly, we have identified the alternate supply of a key ingredient to achieve the optimal formulation of Vazalore, which will help to advance our program to obtain approval and bring Vazalore to market. Stability and dissolution testing is ongoing, and the initial results have been successful. As we continue to optimize our manufacturing process, our goal remains to provide the highest quality product in Vazalore," said Natasha Giordano, President and Chief Executive Officer of PLx Pharma.

"We remain excited about the progress we have made toward these very important milestones in our manufacturing process and on our path to commercialization with an expected launch in mid-2020. We also continue to gain visibility within the medical community through global conferences and ongoing engagement with retailers. We are confident that Vazalore, as the first-ever FDA-approved liquid-filled aspirin capsule, has the potential to become the new standard of care aspirin for physicians treating patients at risk of having a cardiovascular or cerebrovascular event," concluded Giordano.

Third Quarter 2018 Financial Results
The Company recognized revenue of $0.2 million in the third quarter of 2018 compared to revenue of $0.1 million for the three months ended September 30, 2017. Revenue in both the 2018 and 2017 periods is attributable to work performed under an award from the National Institutes of Health (NIH) federal grant received in 2017.

Research and development expenses were $1.2 million for the third quarter of 2018, compared to $1.0 million in the third quarter of 2017. The expense in both periods reflects continued product development and manufacturing activities for Vazalore.

General and administrative expense totaled $1.8 million in the third quarter of 2018 compared to $3.0 million in the third quarter of 2017. This decrease primarily reflects lower compensation expense.

Other income (expense), net totaled approximately $0.6 million of net other expense for the third quarter of 2018, compared to $0.1 million of net other income 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 ($0.4 million of net other expense in the third quarter of 2018, as compared to $0.3 million of net other income in the comparable 2017 period), along with approximately $0.1 million of additional interest expense in the 2018 period.

Net loss for the third quarter of 2018 was $3.4 million, or ($0.39) per share, compared to a net loss of $3.8 million, or ($0.44) per share, for the third quarter of 2017.

Nine MonthsEndedSeptember 30, 2018 and 2017 FinancialResults

For the nine months ended September 30, 2018, net revenue was $0.5 million, compared to $0.4 million in 2017, due to a federal grant received in the prior year.

Research and development expense increased to $3.0 million for the nine months ended September 30, 2018, compared to $1.7 million for the first nine months of 2017, reflecting continued product development and manufacturing activities for Vazalore.

General and administrative expense decreased $2.4 million to $5.9 million for the nine months ended September 30, 2018 from $8.3 million in the prior year period. This decrease was due primarily to public offering costs of $1.3 million related to the June 2017 equity offering, lower compensation

expense of $1.0 million and lower professional fees of $0.4 million, partially offset by pre-launch marketing spend in 2018 of $0.3 million.

Other income (expense), net totaled approximately $6.4 million of net other income in the nine months ended September 30, 2018, compared to $1.2 million of net other income 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 ($7.0 million of net other income in the nine months ended September 30, 2018, as compared to $2.0 million of net other income in the comparable 2017 period), partially offset by approximately $0.2 million of additional interest income earned in the 2018 period.

Net loss for the nine months ended September 30, 2018, was $2.0 million, or ($0.23) per basic and diluted share, compared with a net loss of $7.5 million, or ($1.16) per basic and diluted share in the prior year period.

As of September 30, 2018, the Company had $16.5 million in cash and cash equivalents.

About Vazalore
Vazalore 325 mg is an FDA-approved aspirin product being developed to provide high-risk cardiovascular and stroke patients 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.

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 effective and safe aspirin 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 acute 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, 2017 filed with the SEC on March 23, 2018, 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.

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Source: PLx Pharma Inc.

FINANCIAL TABLES FOLLOW

PLx Pharma Inc.
UNAUDITED CONSOLIDATED BALANCE SHEETS

	September 30, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 16,537,259	$ 24,404,368
Accounts receivable	41,491	19,384
Inventory, net	-	246,374
Vendor deposits	86,250	715,603

Prepaid expenses	470,525	300,169
Security deposit	4,064	4,064
TOTAL CURRENT ASSETS	17,139,589	25,689,962
NON-CURRENT ASSETS		
Property and equipment, net	1,449,969	1,029,875
Goodwill	2,061,022	2,061,022
Security deposit	67,714	67,714
TOTAL ASSETS	$ 20,718,294	$ 28,848,573
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 750,502	$ 852,155
Accrued bonus and severance	755,074	849,703
Accrued interest	56,458	54,219
Current portion of term loan, net of discount and fees	1,952,258	-
Other current liabilities	26,545	59,614
TOTAL CURRENT LIABILITIES	3,540,837	1,815,691
NON-CURRENT LIABILITIES		
Accrued interest	253,920	89,717
Term loan, net of discount and fees	5,175,032	6,942,151
Warrant liability	8,224,992	15,242,915
Other liabilities	124,370	141,707
TOTAL LIABILITIES	17,319,151	24,232,181
STOCKHOLDERS' EQUITY		
Preferred stock; $0.001 par value; 10,000,000 shares authorized; none issued and outstanding	-	-
Common stock; $0.001 par value; 100,000,000 shares authorized; 8,738,163 and 8,722,823 shares issued and outstanding	8,739	8,723
Additional paid-in capital	72,772,537	71,939,917
Accumulated deficit	(69,382,133)	(67,332,248)
TOTAL STOCKHOLDERS' EQUITY	3,399,143	4,616,392
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 20,718,294	$ 28,848,573

PLx Pharma Inc.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
REVENUES:				
Federal grant	$ 216,530	$ 62,259	$ 465,446	$ 438,210
TOTAL REVENUES	216,530	62,259	465,446	438,210

OPERATING EXPENSES:				
Research and development	1,219,144	958,255	3,032,426	1,712,890
General and administrative	1,800,159	3,021,290	5,870,745	8,263,019
TOTAL OPERATING EXPENSES	3,019,303	3,979,545	8,903,171	9,975,909
OPERATING LOSS	(2,802,773)	(3,917,286)	(8,437,725)	(9,537,699)
OTHER INCOME (EXPENSE):				
Interest income	77,276	33,600	219,374	48,082
Interest and other expense	(290,773)	(168,272)	(849,457)	(891,835)
Change in fair value of warrant liability	(408,803)	252,458	7,017,923	1,998,878
TOTAL OTHER INCOME (EXPENSE)	(622,300)	117,786	6,387,840	1,155,125
LOSS BEFORE INCOME TAX BENEFIT	(3,425,073)	(3,799,500)	(2,049,885)	(8,382,574)
Income tax benefit	-	-	-	920,000
NET LOSS	$(3,425,073)	$(3,799,500)	$(2,049,885)	$(7,462,574)
Net loss per common share - basic	$ (0.39)	$ (0.44)	$ (0.23)	$ (1.16)
Net loss per common share - diluted	$ (0.39)	$ (0.44)	$ (0.23)	$ (1.16)
Weighted average common shares outstanding- basic	8,735,790	8,704,985	8,730,303	6,447,053
Weighted average common shares outstanding- diluted	8,735,790	8,704,985	8,730,303	6,447,053

Source: PLx Pharma Inc.