PLx Pharma Inc. Reports Second Quarter 2018 Results

August 10, 2018

Announces that FDA has approved new name Vazalore for PLx's next generation, novel aspirin

HOUSTON, Aug. 10, 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 six-month periods ended June 30, 2018.

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

- Net loss totaled $3.6 million, or ($0.41) per share, compared to net loss of $2.2 million, or ($0.36) per share, for the second quarter of 2017;
- Making solid progress towards obtaining an alternate supply of material to achieve the optimal formulation of Vazalore and remain on track for launch by mid-2020;
- Pleased to announce the new name Vazalore was approved by the FDA for our next generation, novel aspirin;
- Attended the EuroPCR Conference, the official annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI) and the World-Leading Course in Interventional Cardiovascular Medicine, to continue to build awareness and articulate the clinical value proposition of Vazalore with key opinion leaders and top interventional cardiologists in the world; and,
- Expanded our global patent estate with 49 patents issued and two new notices of allowance received.

"During the quarter, we accomplished some key milestones in the lab, identified alternate suppliers and are in the process of analytical, dissolution and stability testing in order to achieve the highest-quality product in Vazalore, said Natasha Giordano, President and Chief Executive Officer of PLx Pharma.

"We also had the opportunity to submit a new name, Vazalore, to the U.S. Food and Drug Administration, one that captures the essence of our unique clinical advantages. We believe that Vazalore has the potential to change the standard of care in the treatment of coronary artery disease for patients at risk of having a cardiovascular or cerebrovascular event," continued Giordano.

"We continue to engage with key members of the medical community, including top interventional cardiologists and the retail trade to build awareness of Vazalore. We have received positive feedback from these important constituents as they learn more about the benefits of Vazalore, namely its more predictable and reliable antiplatelet efficacy than enteric-coated aspirin, and improved gastrointestinal safety over regular aspirin," concluded Giordano.

Second Quarter 2018 Financial Results

The Company recognized revenue of $0.2 million in the second quarter of 2018 compared to revenue of $0.4 million for the three months ended June 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 $0.7 million for the second quarter of 2018, compared to $0.6 million in the second 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 second quarter of 2018 compared to $4.0 million in the second quarter of 2017. The decrease was primarily due to public offering costs of approximately $1.3 million related to the June 2017 equity offering, decreased compensation expense of $0.5 million, as a result of a one-time discretionary bonus of $1.2 million issued to senior management due to the achievement of financing in 2017, partially offset by additional personnel in 2018, and decreased other professional fees totaling approximately $0.4 million.

Other income (net of expense), was $1.2 million of net other expense in the second quarter of 2018, compared to $1.1 million of net other income in the second quarter of 2017. This change is largely attributable to the non-cash change in fair value of a warrant liability of $1.0 million loss in 2018 as compared to a $1.7 million gain in the second quarter of 2017. Interest expense also decreased to $0.3 million in the second quarter of 2018 as compared to $0.6 million in the second quarter of 2017. The interest expense in 2018 related to the interest expense and debt discount amortization on the Company's term loan with Silicon Valley Bank. The interest expense in the second quarter of 2017 related to a beneficial conversion feature.

Net loss for the second quarter of 2018 was $3.6 million, or ($0.41) per share, compared to a net loss of $2.2 million, or ($0.36) per share, for the second quarter of 2017.

Six MonthsEndedJune 30, 2018 and 2017 FinancialResults

For the six months ended June 30, 2018, net revenue was $0.2 million compared to $0.4 million in 2017, due to a federal grant received in the prior year.

Research and development expense increased to $1.8 million for the six months ended June 30, 2018, compared to $0.8 million for the first six months of 2017, reflecting continued product development and manufacturing activities for Vazalore.

General and administrative expense decreased to $4.1 million for the six months ended June 30, 2018 from $5.2 million for the first six months of 2017. This decrease was primarily due to public offering costs of $1.3 million related to the June 2017 equity offering.

Net income for the six months ended June 30, 2017 was $1.4 million, or $0.16 per basic and diluted share, compared with a net loss of $3.7 million, or ($0.69) per basic and diluted share in the prior year period.

As of June 30, 2018, the Company had $17.9 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

	June 30, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 17,924,709	$ 24,404,368
Accounts receivable	127,588	19,384
Inventory, net	-	246,374
Vendor deposits	575,687	715,603
Prepaid expenses	584,973	300,169
Security deposit	4,064	4,064
TOTAL CURRENT ASSETS	19,217,021	25,689,962
NON-CURRENT ASSETS		
Property and equipment, net	1,516,594	1,029,875
Goodwill	2,061,022	2,061,022
Security deposit	67,714	67,714
TOTAL ASSETS	$ 22,862,351	$ 28,848,573
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 477,660	$ 852,155
Accrued bonus and severance	504,305	849,703
Accrued interest	55,574	54,219
Current portion of term loan, net of discount and fees	1,003,170	-
Other current liabilities	60,362	59,614
TOTAL CURRENT LIABILITIES	2,101,071	1,815,691
NON-CURRENT LIABILITIES		
Accrued interest	198,794	89,717
Term loan, net of discount and fees	6,061,864	6,942,151
Warrant liability	7,816,189	15,242,915
Other liabilities	130,253	141,707
TOTAL LIABILITIES	16,308,171	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; 8,731,756 and 8,722,823 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	8,732	8,723
Additional paid-in capital	72,502,508	71,939,917
Accumulated deficit	(65,957,060)	(67,332,248)
TOTAL STOCKHOLDERS' EQUITY	6,554,180	4,616,392
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 22,862,351	$ 28,848,573

PLx Pharma Inc.
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
REVENUES:				
Federal grant	$ 167,459	$ 375,951	$ 248,916	$ 375,951
TOTAL REVENUES	167,459	375,951	248,916	375,951
OPERATING EXPENSES:				
Research and development	734,246	626,296	1,813,282	754,635
General and administrative	1,830,586	4,024,658	4,070,586	5,241,729
TOTAL OPERATING EXPENSES	2,564,832	4,650,954	5,883,868	5,996,364
OPERATING LOSS	(2,397,373)	(4,275,003)	(5,634,952)	(5,620,413)

OTHER INCOME (EXPENSE)				
Interest income	75,175	14,482	142,098	14,482
Interest expense	(283,285)	(642,006)	(558,684)	(723,563)
Change in fair value of warrant liability	(997,921)	1,746,420	7,426,726	1,746,420
TOTAL OTHER INCOME (EXPENSE)	(1,206,031)	1,118,896	7,010,140	1,037,339
INCOME (LOSS) BEFORE INCOME TAX BENEFIT	(3,603,404)	(3,156,107)	1,375,188	(4,583,074)
Income tax benefit	-	920,000	-	920,000
NET INCOME (LOSS)	$ (3,603,404)	$ (2,236,107)	$ 1,375,188	$ (3,663,074)
Net income (loss) per common share - basic	$ (0.41)	$ (0.36)	$ 0.16	$ (0.69)
Net income (loss) per common share - diluted	$ (0.41)	$ (0.36)	$ 0.16	$ (0.69)
Weighted average shares of common shares - basic	8,729,962	6,157,970	8,727,514	5,275,603
Weighted average shares of common shares - diluted	8,729,962	6,157,970	8,727,514	5,275,603

Source: PLx Pharma Inc.