Proteon Therapeutics Announces Fourth Quarter and Full-Year 2017 Financial Results

March 14, 2018

WALTHAM, Mass., March 14, 2018 (GLOBE NEWSWIRE) -- Proteon Therapeutics, Inc. (Nasdaq:PRTO), a company developing novel, first-in-class therapeutics to address the medical needs of patients with kidney and vascular diseases, today announced its financial results for the year ended December 31, 2017, and recent business highlights.

"With enrollment completed on schedule in PATENCY-2, our second Phase 3 clinical trial of investigational vonapanitase, we are now focused on study follow-up and preparing for a potential BLA filing in the fourth quarter of 2019," said Timothy Noyes, President and Chief Executive Officer of Proteon. "Also, with sufficient capital to fund the Company's operations into the fourth quarter of 2019, we continue devoting resources to developing our market access strategy and preparing for commercialization of vonapanitase."

2017 Highlights and Recent Events

Enrollment completed in PATENCY-2, the second Phase 3 clinical trial of investigational vonapanitase. PATENCY-2 is a multicenter, randomized, double-blind, placebo-controlled trial that treated 603 patients in the United States and Canada with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. The study's co-primary endpoints are fistula use for hemodialysis and secondary patency (i.e., time to fistula abandonment), each of which demonstrated improvements in PATENCY-1 using the same definitions as in PATENCY-2. The Company expects to report top-line data from PATENCY-2 in April 2019. Additionally, if PATENCY-2 is successful in showing statistical significance ($p \leq 0.05$) on each of the co-primary endpoints, Proteon expects to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2019.

In the second quarter of 2017, vonapanitase received Breakthrough Therapy designation from the FDA for increasing arteriovenous fistula use for hemodialysis and secondary patency in patients on or expected to initiate hemodialysis. The FDA awards Breakthrough Therapy designations to expedite the development and review of investigational drugs that are intended to treat serious or life-threatening conditions and have demonstrated preliminary clinical evidence that the treatment may offer a substantial improvement over currently available therapies on one or more clinically significant endpoints.

In the third quarter of 2017, completed $22.0 million financing transaction. The transaction was led by an affiliate of Deerfield Management and included participation by Abingworth, Fairmount Funds, Perceptive Advisors, Pharmstandard, RA Capital, Skyline Ventures and TVM Capital. The financing extends the Company's cash runway into the fourth quarter of 2019, which allows the Company to operate for more than six months beyond the expected release of top-line data from the PATENCY-2 trial based on the Company's current operating plan.

Board of Directors Strengthened with leadership and industry expertise. Proteon strengthened its Board of Directors with the appointment of Jonathan Leff, a Partner at Deerfield Management, to the Board of Directors. Mr. Leff brings extensive industry experience to the board room having been a director at multiple publicly-traded biotechnology and pharmaceutical companies. He is also active in public policy discussions related to healthcare and medical innovations.

Enrollment continues in a Phase 1 clinical trial of vonapanitase in patients with peripheral artery disease (PAD). The multicenter, randomized, double-blind, placebo-controlled Phase 1 dose escalation trial is expected to enroll 24 symptomatic PAD patients being treated with balloon angioplasty of an artery below the knee and to follow each patient for up to seven months. Immediately following successful angioplasty, vonapanitase or placebo is delivered to the arterial wall using the Mercator MedSystems Bullfrog® Micro-Infusion Catheter. The primary outcome measure of the trial is safety and the secondary outcome measure is technical feasibility of study drug delivery via the catheter.

Key Milestones

- Completed enrollment of 603 treated patients in PATENCY-2 in March 2018.
- Complete enrollment of 24 patients in the PAD Phase 1 trial by the fourth quarter of 2018.
- Release top-line data from PATENCY-2 in March 2019.

Upcoming Events

- Presentation at the Cowen 38th Annual Health Care ConferenceMarch 12th in Boston, MA.
- Presentation at the Oppenheimer's 28 th Annual Healthcare Conference March 21st in New York, NY.

2017 Financial Results

Cash, cash equivalents and available-for-sale investments totaled $42.1 million as of December 31, 2017, compared to $41.3 million as of December 31, 2016. The increase was primarily driven by the $22.0 million preferred stock financing closed in August 2017 and offset by operational costs for 2017.

R&D expenses: Research and development expenses for 2017 were $21.7 million as compared to $18.9 million for 2016. The increase in R&D expenses was due primarily to higher manufacturing pre-validation and validation expenses in 2017.

MG&A expenses: Marketing, general and administrative expenses for 2017 were $8.7 million as compared to $9.8 million for 2016. The decrease in MG&A expenses was due primarily to decreased overhead and personnel expenses in 2017 as compared to 2016.

Net loss: Net loss for 2017 was $30.0 million as compared to $28.5 million for 2016. Net loss included stock-based compensation expense of $3.2 million for 2017 and $3.3 million for 2016.

Financial guidance: The Company expects that its cash, cash equivalents and available-for-sale investments will be sufficient to fund its operations into the fourth quarter of 2019, based on the Company's current operating plan.

About Vonapanitase

Vonapanitase is an investigational drug intended to improve hemodialysis vascular access outcomes. Vonapanitase is applied in a single administration and is currently being studied in a Phase 3 clinical trial in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. Vonapanitase has received Breakthrough Therapy, Fast Track and Orphan Drug designations from the FDA, and Orphan Medicinal Product designation from the European Commission, for hemodialysis vascular access indications. In addition, vonapanitase may have other surgical and endovascular applications in diseases or conditions in which vessel injury leads to blockages in blood vessels and reduced blood flow. Proteon is currently conducting a Phase 1 clinical trial of vonapanitase in patients with peripheral artery disease (PAD).

About Proteon Therapeutics

Proteon Therapeutics is committed to improving the health of patients with kidney and vascular diseases through the development of novel, first-in-class therapeutics. Proteon's lead product candidate, vonapanitase, is an investigational drug intended to improve hemodialysis vascular access outcomes. Proteon is evaluating vonapanitase in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula. Proteon is also evaluating vonapanitase in a Phase 1 clinical trial in patients with PAD. For more information, please visit www.proteontx.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that are, or may be deemed to be, "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "estimates," "anticipates," "expects," "plans," "intends," "may," or "will," in each case, their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements, including the number of patients to be enrolled in and the timing of enrollment in the Company's ongoing Phase 1 clinical trial of vonapanitase in patients with peripheral artery disease (PAD), when the Company expects to release top-line data from the PATENCY-2 trial, whether and when the Company may submit a Biologics License Application (BLA) in the United States, the effect or benefit of vonapanitase in patients with CKD, whether vonapanitase improves fistula use for hemodialysis or secondary patency, the potential surgical and endovascular applications for vonapanitase, including PAD, the sufficiency of the Company's cash, cash-equivalents and available-for-sale investments to fund the Company's operations into the fourth quarter of 2019, and those relating to future events or our future financial performance or condition, involve substantial known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties and other factors, including whether our cash resources will be sufficient to fund the Company's operating expenses and capital expenditure requirements for the period anticipated; whether data from early nonclinical or clinical studies will be indicative of the data that will be obtained from future clinical trials; whether vonapanitase will advance through the clinical trial process on the anticipated timeline and warrant submission for regulatory approval; whether such a submission would receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies on a timely basis or at all; and whether the Company can successfully commercialize and market its product candidates, are described more fully in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission ("SEC") on March 14, 2018, and the Company's subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as filed with the SEC, particularly in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." In light of the significant uncertainties in the Company's forward-looking statements, no person should place undue reliance on these statements or regard these statements as a representation or warranty by the Company or any other person that the Company will achieve its objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this press release represent the Company's estimates and assumptions only as of the date of this press release and, except as required by law, the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this press release.

Proteon Therapeutics, Inc.
Consolidated Balance Sheet Data
(In thousands)

	December 31, 2017	2016
Cash, cash equivalents and available-for-sale investments	$ 42,141	$ 41,317
Prepaid expenses and other current assets	1,339	1,438
Property and equipment, net and other non-current assets	499	765
Total assets	**$ 43,979**	**$ 43,520**
Accounts payable and accrued expenses	$ 9,240	$ 5,079

Preferred Stock, common stock and additional paid-in-capital	224,494	198,218
Accumulated deficit and accumulated other comprehensive loss	(189,755)	(159,777)
Total liabilities and stockholders' deficit	**$ 43,979**	**$ 43,520**

Proteon Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,		
	2017	**2016**	**2015**
Revenue	$ -	$ -	$ -
Operating expenses:			
Research and development	$ 21,686	$ 18,869	$ 12,381
General and administrative	8,676	9,836	8,489
Total operating expenses	30,362	28,705	20,870
Loss from operations	(30,362)	(28,705)	(20,870)
Other income (expense):			
Investment income	259	193	144
Other (expense) income	139	(14)	(651)
Total other (expense) income	398	179	(507)
Net loss	$ (29,964)	$ (28,526)	$ (21,377)
Accretion of redeemable convertible preferred stock to redemption value	(6,747)	-	-
Net loss attributable to common stockholders	$ (36,711)	$ (28,526)	$ (21,377)
Net loss per share attributable to common stockholders - basic and diluted	$ (2.13)	$ (1.72)	$ (1.30)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	17,274,326	16,561,799	16,464,123

Supplemental disclosure of stock-based compensation expense and loss from currency forward contracts:

Included in operating expenses, above, are the following amounts for non-cash stock based compensation expense:			
Research and development	$ 1,109	$ 1,114	$ 650
General and administrative	2,118	2,229	1,514
Total	$ 3,227	$ 3,343	$ 2,164
Included in other expense, above, are the following amounts from forward foreign currency contracts:			
Realized losses from forward foreign currency contracts	$ -	$ (61)	$ (52)
Unrealized losses from forward foreign currency contracts	-	127	(537)
Total	$ -	$ 66	$ (589)

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Source: Proteon Therapeutics, Inc.