Proteon Therapeutics Announces Fourth Quarter and Full-Year 2018 Financial Results

March 13, 2019

WALTHAM, Mass., March 13, 2019 (GLOBE NEWSWIRE) -- Proteon Therapeutics, Inc. (Nasdaq: PRTO), a company developing novel, first-in-class pharmaceuticals to address the medical needs of patients with kidney and vascular diseases, today announced its financial results for the year ended December 31, 2018, and recent business highlights.

“We are looking forward to the expected release this month of top-line results from PATENCY-2, our second Phase 3 clinical trial of investigational vonapanitase,” said Timothy Noyes, President and Chief Executive Officer of Proteon. “We are now focused on preparing for a potential BLA filing in the fourth quarter of 2019. It is a very exciting time for all of us at Proteon.”

2018 Highlights and Recent Events

Expect to release top-line results this month for 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. As previously disclosed, Proteon has received written confirmation from the U.S. Food and Drug Administration (FDA) that, if PATENCY-2 is successful in showing statistical significance ($p \leq 0.05$) on each of the co-primary endpoints, the PATENCY-2 trial together with data from previously completed studies would provide the basis for a Biologics License Application (BLA) submission. If PATENCY-2 is successful in showing statistical significance ($p \leq 0.05$) on each of the co-primary endpoints, Proteon expects to submit a BLA to the FDA in the fourth quarter of 2019.

Received scientific advice and pediatric waiver from the European Medicines Agency (EMA) in 2018. Based on the EMA scientific advice, Proteon expects to submit a Marketing Authorization Application (MAA) to the EMA in the first half of 2020 if PATENCY-2 is successful. In addition, Proteon filed a pediatric investigational plan with EMA in 2018 and received a pediatric waiver from conducting pediatric trials prior to EMA approval.

Executed an amendment to the supply agreement with Lonza. Proteon signed an amendment to the supply agreement with Lonza in 2018, securing a potential long-term commercial supply of active pharmaceutical ingredient (API) for vonapanitase. Lonza has manufactured API for Proteon at its microbial manufacturing facility in Visp, Switzerland, since 2009. The amendment extends the term of the supply agreement until 2029.

Raised $3 million through Proteon’s “at-the-market” (ATM) program. New Leaf Venture Partners LLC purchased approximately 1.5 million shares of common stock in September 2018. With this additional funding, Proteon has sufficient capital to operate into Q1 2020, or almost a year past the expected release of top-line data from the PATENCY-2 trial, based on the Company’s current operating plan.

Continuing enrollment in a Phase 1 clinical trial of vonapanitase in patients with peripheral artery disease (PAD). Proteon ended 2018 having enrolled and treated 24 patients in the Phase 1, multicenter, randomized, double-blind, placebo-controlled, dose escalation trial designed to evaluate the safety and technical feasibility of a single administration of vonapanitase as an adjunct to angioplasty for patients with PAD below the knee. Proteon expects to enroll up to 16 additional patients in this study before the end of 2019, for a maximum of up to 40 patients, and to follow each of these patients for a period of up to seven months.

Key Milestones

- Release top-line results from PATENCY-2 in March 2019.
- Complete enrollment of up to 16 additional patients in the Phase 1 PAD trial before the end of 2019.

Upcoming Events

- Presentation of top-line results from PATENCY-2 at the 11th Congress of the Vascular Access SocietyApril 12th in Rotterdam, by C. Keith Ozaki, M.D., John A. Mannick Professor of Surgery, Brigham and Women's Hospital and Harvard Medical School.
- Presentation of top-line results from PATENCY-2 at the Charing Cross International Symposium Vascular Access Masterclass April 17th in London, by Paul Gibbs, M.D., Renal Transplant and Vascular Access Surgeon, Care Group Director of General Surgery, Queen Alexandra Hospital, Portsmouth Hospitals NHS Trust.
- Presentation at the JMP Securities Life Science ConferenceJune 19-20 in New York, NY.

2018 Financial Results

Cash, cash equivalents and available-for-sale investments totaled $21.9 million as of December 31, 2018, compared to $42.1 million as of December 31, 2017. The decrease was primarily driven by operational costs for 2018 and offset by approximately $3 million of common stock sales.

R&D expenses: Research and development expenses for 2018 were $11.8 million as compared to $21.7 million for 2017. The decrease in R&D expenses was due primarily to decreased expenses for our manufacturing pre-validation and validation efforts and for our ongoing clinical trials.

MG&A expenses: Marketing, general and administrative expenses for 2018 were $9.5 million as compared to $8.7 million for 2017. The increase in MG&A expenses was due primarily to higher overhead and personnel expenses in 2018 as compared to 2017.

Net loss: Net loss for 2018 was $20.7 million as compared to $30.0 million for 2017. Net loss included stock-based compensation expense of $3.4 million for 2018 and $3.2 million for 2017.

Financial guidance: The Company expects that its cash, cash equivalents and available-for-sale investments will be sufficient to fund its operations into the first quarter of 2020, 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 Food and Drug Administration (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 has completed enrollment in PATENCY-2, a Phase 3 clinical trial evaluating vonapanitase in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. 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 or a Marketing Authorization Application (MAA) in the European Union, the potential long-term commercial supply of active pharmaceutical ingredient (API) for vonapanitase, 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 first quarter of 2020, 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, 2018, as filed with the Securities and Exchange Commission ("SEC") on March 13, 2019, 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, 2018	December 31, 2017
Cash, cash equivalents and available-for-sale investments	$ 21,867	$ 42,141
Prepaid expenses and other current assets	1,369	1,339
Property and equipment, net and other non-current assets	285	499
Total assets	**$ 23,521**	**$ 43,979**
Accounts payable and accrued expenses	$ 3,078	$ 9,240

Preferred stock, common stock and additional paid-in-capital	230,908	224,494
Accumulated deficit and accumulated other comprehensive income	(210,465)	(189,755)
Total liabilities and stockholders' deficit	**$ 23,521**	**$ 43,979**

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

	Three Months Ended December 31, (Unaudited)		Year Ended December 31, (Audited)	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development (1)	$ 2,663	$ 3,213	$ 11,848	$ 21,686
General and administrative (1)	2,722	2,377	9,524	8,676
Total operating expenses	5,385	5,590	21,372	30,362
Loss from operations	(5,385)	(5,590)	(21,372)	(30,362)
Other income:				
Investment income	125	98	436	259
Other income (expense), net	1	(59)	207	139
Total other income	126	39	643	398
Net loss	$ (5,259)	$ (5,551)	$ (20,729)	$ (29,964)
Foreign currency translation adjustment	-	6	(1)	6
Unrealized gain (loss) on available-for-sale investments	1	(13)	20	(20)
Comprehensive loss	(5,258)	(5,558)	(20,710)	(29,978)
Reconciliation of net loss to net loss attributable to common stockholders:				
Net loss	$ (5,259)	$ (5,551)	$ (20,729)	$ (29,964)
Accretion of convertible preferred stock to redemption value	-	-	-	(6,747)
Net loss attributable to common stockholders	$ (5,259)	$ (5,551)	$ (20,729)	$ (36,711)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.27)	$ (0.32)	$ (1.15)	$ (2.13)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	19,221,292	17,619,418	18,102,219	17,274,326

(1) Included in operating expenses, above, are the following amounts for non-cash stock based compensation expense:

Research and development	$ 265	$ 268	$ 1,142	$ 1,109
General and administrative	517	500	2,287	2,118
Total	$ 782	$ 768	$ 3,429	$ 3,227

Investor Contact
George Eldridge, Proteon Therapeutics, Senior Vice President and Chief Financial Officer
781-890-0102
geldridge@proteontherapeutics.com

Media Contact
Ann Stanesa, Ten Bridge Communications
617-230-0347
proteon@tenbridgecommunications.com

Source: Proteon Therapeutics, Inc.