Proteon Therapeutics Announces Second Quarter 2017 Financial Results

August 7, 2017

WALTHAM, Mass., Aug. 07, 2017 (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 financial results for the quarter ended June 30, 2017, and recent business highlights.

“Our productive dialogue with the FDA has created a clear path forward for vonapanitase, and we believe the decision by the FDA to grant vonapanitase a Breakthrough Therapy designation speaks to the clinical importance of fistula survival and use for hemodialysis to patients with chronic kidney disease,” said Timothy Noyes, President and Chief Executive Officer of Proteon. “In addition, we are pleased to have closed earlier this month on our previously announced $22.0 million financing. We expect this transaction will allow the Company to operate for more than six months beyond the expected release of topline data from the PATENCY-2 Phase 3 clinical trial.”

Recent Highlights for 2017

In May, vonapanitase received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for increasing arteriovenous fistula secondary patency (i.e., survival of the fistula without abandonment) and use for hemodialysis in patients on or expected to initiate hemodialysis. Secondary patency and use for hemodialysis are the co-primary endpoints in PATENCY-2, Proteon’s ongoing pivotal Phase 3 clinical trial evaluating investigational vonapanitase in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for 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.

Closed on $22.0 million financing transaction. This month, Proteon raised gross proceeds of $22.0 million. The transaction was led by an affiliate of Deerfield Management and other participants in the financing included Abingworth, Fairmount Funds, Perceptive Advisors, Pharmstandard, RA Capital, Skyline Ventures, TVM Capital and certain other stockholders who invested prior to the Company’s initial public offering. The Company intends to use the proceeds from the transaction to complete the ongoing PATENCY-2 trial and fund continued market access activities. The financing also extends the Company’s cash runway from the third quarter of 2018 into the fourth quarter of 2019, which allows the Company to operate for more than six months beyond the expected release of topline 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.

PATENCY-2 enrollment on track for completion in Q1 2018. PATENCY-2 is a multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial expected to enroll 600 patients with CKD in the United States and Canada undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. PATENCY-2’s co-primary endpoints are secondary patency and fistula use for hemodialysis, each of which demonstrated improvements in the Company’s first Phase 3 clinical trial, PATENCY-1, using the same definitions as in PATENCY-2. Enrollment of 600 patients is expected in the first quarter of 2018 and Proteon expects to report top-line data in the first quarter of 2019.

Phase 3 PATENCY-1 clinical results were presented in Q2 at the (i) 10th Congress of the Vascular Access Society in Ljubljana, Slovenia, (ii) National Kidney Foundation 2017 Spring Clinical Meetings in Orlando, FL, and (iii) Charing Cross Symposium (CX 2017) in London, England.

The Company continues enrollment in a Phase 1 clinical study of vonapanitase in patients with peripheral artery disease (PAD). The multicenter, randomized, double-blind, placebo-controlled Phase 1 dose escalation study is expected to enroll this year 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 study is safety and the secondary outcome measure is technical feasibility of study drug delivery via the catheter.

Upcoming Key Milestones

- Enroll 24 patients in the PAD Phase 1 trial before the end of 2017.
- Complete enrollment of 600 patients in PATENCY-2 in the first quarter of 2018.

Upcoming Events

- Presentations at the Baird 2017 Global Healthcare Conference September 6-7 in New York City, NY.
- Presentation of PATENCY-1 results at the Vascular Access Society of Britain and Ireland Conference September 28-29 in Belfast, Northern Ireland.
- Presentation by Barry Browne, M.D. at the CIDA on Controversies in Dialysis Access on November 9th in San Diego.
- Presentation by Keith Ozaki, M.D. at the 44th Annual VEITH Symposium on November 18th in New York City.

Second Quarter 2017 Financial Results

Cash, cash equivalents and available-for-sale investments totaled $31.7 million as of June 30, 2017, compared to $41.3 million as of December 31, 2016. The decrease was driven by operational costs for the first six-month period of 2017. On August 2, 2017, we closed on the $22.0 million preferred stock financing announced on June 22, 2017.

R&D expenses: Research and development expenses for the second quarter of 2017 were $3.9 million as compared to $5.2 million for the second quarter of 2016. The decrease in R&D expenses was due primarily to a decrease in our manufacturing pre-validation and validation expenses in the second quarter of 2017 as compared to the second quarter of 2016.

G&A expenses: General and administrative expenses for the second quarter of 2017 were $2.1 million as compared to $2.6 million for the second quarter of 2016. The decrease in G&A expenses was due primarily to decreased overhead and personnel expenses in the second quarter of 2017 than in the second quarter of 2016.

Net loss: Net loss for the second quarter of 2017 was $5.6 million as compared to $7.9 million for the second quarter of 2016. Net loss included stock-based compensation expense of $0.9 million for the second quarter of 2017 and $0.9 million for the second quarter of 2016.

Financial guidance: When including the $22.0 million preferred stock financing that closed on August 2, 2017, 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 program 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 currently enrolling patients 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 clinical trials of vonapanitase, when the Company expects to report top-line data from the PATENCY-2 trial, the effect or benefit of vonapanitase in patients with CKD, whether vonapanitase improves fistula patency or use for hemodialysis, 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, 2016, as filed with the Securities and Exchange Commission ("SEC") on March 16, 2017, 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)

	June 30, 2017	December 31, 2016
Cash, cash equivalents and available-for-sale investments	$ 31,742	$ 41,317
Prepaid expenses and other current assets	1,280	1,438

Property and equipment, net and other non-current assets	609	765
Total assets	**$ 33,631**	**$ 43,520**
Accounts payable and accrued expenses	$ 4,137	$ 5,079
Other liabilities	-	-
Preferred Stock, common stock and additional paid-in-capital	201,384	198,218
Accumulated deficit and accumulated other comprehensive income	(171,890)	(159,777)
Total liabilities and stockholders' deficit	**$ 33,631**	**$ 43,520**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Operating expenses:				
Research and development	$ 3,891	$ 5,241	$ 8,137	$ 9,590
General and administrative	2,095	2,613	4,329	5,083
Total operating expenses	5,986	7,854	12,466	14,673
Loss from operations	(5,986)	(7,854)	(12,466)	(14,673)
Other income (expense):				
Investment income	46	53	78	109
Other (expense) income, net	332	(104)	282	107
Total other (expense) income	378	(51)	360	216
Net loss	$ (5,608)	$ (7,905)	$ (12,106)	$ (14,457)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.33)	$ (0.48)	$ (0.72)	$ (0.87)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	17,207,672	16,561,239	16,923,515	16,534,413

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	$ 308	$ 321	$ 606	$ 629
General and administrative	559	625	1,106	1,183
Total	$ 867	$ 946	$ 1,712	$ 1,812

Included in other expense, above, are the following amounts from forward foreign currency contracts:

Realized (losses) gains from forward foreign currency contracts	$ -	$ (10)	$ -	$ (4)
Unrealized (losses) gains from forward foreign currency contracts	-	(53)	-	125
Total	$ -	$ (63)	$ -	$ 121

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

Primary Logo

Proteon Therapeutics, Inc.