Proteon Therapeutics Announces Second Quarter 2019 Financial Results

August 7, 2019

WALTHAM, Mass., Aug. 07, 2019 (GLOBE NEWSWIRE) -- Proteon Therapeutics, Inc. (Nasdaq: PRTO), a company that has historically focused on the development of novel, first-in-class pharmaceuticals to address the medical needs of patients with kidney and vascular disease, today announced its financial results for the quarter ended June 30, 2019, and recent events.

Recent Events

Engaged H.C. Wainwright to Assist in Strategic Review. On April 15, 2019, Proteon announced it had engaged H.C. Wainwright & Co., LLC as its financial advisor to assist in the strategic review process. Potential strategic alternatives that may be explored or evaluated as part of this review include, but are not limited to, an acquisition, merger, business combination or other strategic transaction involving Proteon. There is no defined timeline for completion of the review process.

PATENCY-2 Trial Misses Statistical Significance on Both Co-Primary Endpoints. On March 28, 2019, the Company announced top-line results from PATENCY-2, its Phase 3 clinical trial of investigational vonapanitase in patients with chronic kidney disease, or CKD, undergoing creation of a radiocephalic fistula for hemodialysis. The PATENCY-2 clinical trial had two co-primary endpoints (i) fistula use for hemodialysis and (ii) secondary patency, or time from surgical creation of the fistula to its abandonment. Neither endpoint reached statistical significance in PATENCY-2. The PATENCY-2 clinical trial was the second of two randomized, double-blind Phase 3 trials, comparing investigational vonapanitase to placebo. As to safety in the PATENCY-2 trial, the proportions of patients experiencing adverse events were comparable between the vonapanitase and placebo arms of the study. The most common adverse events were consistent with medical events experienced by patients with CKD undergoing creation of a radiocephalic fistula.

Reduction in Headcount and Discontinuation of Substantially all R&D Activities. We initiated a plan in April 2019 to reduce personnel and expenses to preserve capital and further reduce our operations consistent with our decision to discontinue substantially all research and development activities. We expect to devote significant time and resources to identifying and evaluating strategic alternatives, however, there can be no assurance that such activities will result in any agreements or transactions that will enhance shareholder value.

Second Quarter 2019 Financial Results

Cash, cash equivalents and available-for-sale investments totaled $10.8 million as of June 30, 2019, compared to $16.8 million as of March 31, 2019. The decrease was primarily driven by operational costs for the three-month period ending June 30, 2019.

R&D expenses: Research and development expenses for the second quarter of 2019 were $2.1 million as compared to $2.8 million for the second quarter of 2018. The decrease in R&D expenses was due primarily to decreased external research and development expenses in the second quarter of 2019 as compared to the second quarter of 2018.

G&A expenses: General and administrative expenses for the second quarter of 2019 were $3.3 million as compared to $2.2 million for the second quarter of 2018. The increase in G&A expenses was due primarily to increased expenses related to our reduction in force and associated severance expenses in the second quarter of 2019 as compared to the second quarter of 2018.

Net loss: Net loss for the second quarter of 2019 was $5.3 million as compared to $4.9 million for the second quarter of 2018. Net loss included stock-based compensation expense of $0.1 million for the second quarter of 2019 and $0.9 million for the second quarter of 2018.

Financial guidance: The Company expects that its cash, cash equivalents and available-for-sale investments will be sufficient to fund its operations into 2020, based on the Company's current operating plan.

About Proteon Therapeutics

Proteon Therapeutics is focused on 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 announced in March 2019 top-line results from PATENCY-2, a Phase 3 clinical trial evaluating vonapanitase in patients with chronic kidney disease undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. The PATENCY-2 trial did not reach statistical significance on either of the co-primary endpoints of fistula use for hemodialysis and secondary patency. Proteon has also evaluated investigational vonapanitase in Phase 1 clinical trials in patients with peripheral artery disease, or 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," their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements, including the whether and when the Company may complete a strategic review process or related transaction, 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, 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)

	June 30, 2019	December 31, 2018
Cash, cash equivalents and available-for-sale investments	$ 10,813	$ 21,867
Prepaid expenses and other current assets	682	1,369
Property and equipment, net and other non-current assets	105	285
Total assets	**$ 11,600**	**$ 23,521**
Accounts payable, accrued expenses and other current liabilities	$ 2,123	$ 3,078
Preferred Stock, common stock and additional paid-in-capital	231,789	230,908
Accumulated deficit and accumulated other comprehensive income	(222,312)	(210,465)
Total liabilities and stockholders' deficit	**$ 11,600**	**$ 23,521**

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,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 2,120	$ 2,760	$ 6,168	$ 6,831
General and administrative	3,266	2,240	5,855	4,534
Total operating expenses	5,386	5,000	12,023	11,365
Loss from operations	(5,386)	(5,000)	(12,023)	(11,365)
Other income (expense):				
Investment income	73	106	178	198
Other income (expense), net	(2)	15	(1)	207
Total other (expense) income	71	121	177	405
Net loss	$ (5,315)	$ (4,879)	$ (11,846)	$ (10,960)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.27)	$ (0.28)	$ (0.61)	$ (0.62)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	19,585,394	17,674,729	19,421,131	17,674,729

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	$ 4	$ 312	$ 259	$ 579
General and administrative	97	610	622	1,164

Total	$ 101	$ 922	$ 881	$ 1,743

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Source: Proteon Therapeutics, Inc.