November 5, 2015

Vital Therapies Announces Third Quarter 2015 Financial Results and Provides Corporate Update

SAN DIEGO, Nov. 5, 2015 (GLOBE NEWSWIRE) -- Vital Therapies, Inc. (Nasdaq:VTL), a biotherapeutic company developing ELAD®, a cell-based therapy targeting the treatment of liver failure, today announced results for the third quarter ended September 30, 2015 and provided a corporate update.

"Since we announced in late August that our VTI-208 phase 3 clinical trial had failed to meet its primary and secondary endpoints, we have conducted extensive analyses of the VTI-208 data and now believe we have a better understanding of the appropriate patient population to target with the ELAD System," said Terry Winters, Ph.D., Chief Executive Officer and Co-Chairman of Vital Therapies. "We have used this to design a new phase 3 trial, VTL-308, and have started the process of seeking FDA approval of the trial design and statistical plan and commenced opening clinical sites that we anticipate will be mostly the high enrolling sites from VTI-208. We are excited about the path forward for ELAD."

Key Recent Developments

- Through extensive review of medically pertinent pre-specified and post-hoc subsets of the VTI-208 data discovered that reduced ELAD tolerability in subjects with higher Model of End-Stage Liver Disease, or MELD, scores, exacerbated in older subjects, contributed to the overall failure of the study. In particular, those subjects with kidney dysfunction and serious blood coagulation problems, both components of MELD score, had poorer outcomes. The adverse event profile was similar to that observed in previous ELAD studies in similar patient populations.

- Based on these findings, the Company has defined what it believes is the optimal target population for its next phase 3 trial, to be known as VTL-308, which will be conducted in patients suffering from alcohol-induced liver decompensation (AILD). VTL-308's proposed design excludes subjects aged 50 years or older and those with a MELD score of 30 or higher. Considering the three components of MELD, subjects are also excluded with creatinine of 1.3 mg/dL or above, which limits kidney dysfunction, and international normalized ratio (INR) above 2.5, which limits blood coagulopathy. The third MELD component, bilirubin, has been raised to a minimum of 16 mg/dL to ensure that liver dysfunction is a major contributor to MELD. A post-hoc analysis of the subset of the VTI-208 clinical trial matching these criteria included 60 subjects with overall survival through at least 91 days. Had it been pre-specified, this Kaplan Meier analysis would have been associated with a p-value of less than 0.01 and a hazard ratio of 0.28. The survival benefit appeared durable with survival at the end of 180 days of 89% for the ELAD group versus 48% in those treated only with standard ‑ of ‑ care (Pearson's Chi ‑ squared $p < 0.01$). More details regarding this post-hoc analysis can be found in the Company's October 16, 2015 press release. Although the result of this post hoc analysis showed statistical significance, it was not pre ‑ specified and there is no guarantee that the results of the planned VTL ‑ 308 phase 3 trial will replicate the results of this subset.

- Announced that a briefing document, including a draft trial protocol for VTL-308, was submitted to the Food and Drug Administration (FDA) for an upcoming Type C written response meeting. The Company expects feedback from the FDA by year-end. VTL-308 is designed to enroll approximately 150 subjects and to be conducted at approximately 40 sites in the U.S., U.K., Ireland, Germany and Spain that the Company anticipates will be comprised mostly of high enrolling sites from VTI-208. The Company expects to be allowed to proceed with the VTL-308 trial, although there is a possibility that FDA could have substantive comments on the trial design and statistical plan that could result in changes to the trial design and anticipated timeline. The Company expects the first subject to be enrolled in the first half of 2016.

- Announced that results of the VTI-208 trial will be the subject of an oral presentation at The Liver Meeting, the annual meeting of the American Association for the Study of Liver Disease (AASLD), in San Francisco, CA on Monday, November 16, 2015 at 3:00 p.m. Pacific.

- Also, during the AASLD meeting, will present a poster describing further work on ELAD's mechanism, of action titled "ELAD VTL C3A Cells May Impact Liver Regeneration Through Secreted Factors" on Tuesday, November 17 between 8:00 a.m. and 12:00 noon Pacific. This work builds on prior laboratory-based studies into the potential mechanisms by which the Company believes ELAD may contribute to improved outcomes in subjects with AILD. It should be noted that these findings have yet to be demonstrated in patients and correlated with clinical outcomes. The Company plans to release more details on this poster after it has been presented at AASLD.

- Strengthened the financial condition of the Company through an underwritten public offering in October. The Company sold 6,272,727 shares at $5.50 per share in an underwritten public offering that closed on October 28 resulting in

proceeds of $32.4 million, net of underwriting discounts and commissions. The Company had previously announced a workforce reduction and other cost cutting measures. Based on the Company's current forecast, these actions, combined with existing cash, are anticipated to fund the Company until mid-2018, which may or may not include the release of topline data from VTL-308.

Third Quarter 2015 Financial Results

Cash Position

Cash and cash equivalents at September 30, 2015, totaled $59.8 million compared to $102.2 million at December 31, 2014.

Results of Operations

Three Months Ended September 30, 2015

The Company reported a net loss of $12.3 million for the quarter ended September 30, 2015, which compared with a net loss of $12.8 million for the same prior year period. This resulted in a net loss attributable to common stockholders of $0.51 per share for the three months ended September 30, 2015, as compared to a net loss of $0.59 per share for the corresponding period in 2014, on both a basic and diluted basis. These per share figures are based on weighted-average common shares outstanding of 24,052,481 shares and 21,759,061 shares, respectively, with the increase in common shares outstanding in 2014 resulting from the Company's follow-on offering in the fourth quarter of 2014.

Total operating expenses for the three months ended September 30, 2015 were $12.3 million as compared to $12.8 million for the comparable period of 2014. Research and development expenses decreased to $9.6 million during the three months ended September 30, 2015 as compared to $10.2 million in the three months ended September 30, 2014. This was primarily due to a reduction in clinical trial activity in comparison to the prior year period. General and administrative expenses were $2.7 million for the three months ended September 30, 2015, up from $2.6 million for the comparable period of 2014.

Upcoming Investor Presentation

Additionally, the Company will be presenting at the 24th Annual Credit Suisse Healthcare Conference in Scottsdale, AZ on Tuesday, November 10, 2015 at 3:30 PM Mountain Time (5:30 PM ET).

Conference Call Details

Vital Therapies will host a conference call to discuss these results and provide a corporate update today, November 5, 2015, at 4:30 p.m. ET, which will be open to the public. The conference call dial-in numbers are (855) 765-5682 for domestic callers and (919) 825-3204 for international callers. The conference ID number for the call is 57542661. Participants may access the live webcast via a link on the Vital Therapies website in the Investor Relations section under "Events" at: http://ir.vitaltherapies.com/.

For those unable to dial in at the designated time, a conference call replay will be available for one week following the conference call, from approximately 7:30 p.m. ET on November 5, 2015 to 11:59 p.m. ET on November 12, 2015. The conference call replay numbers for domestic and international callers are (855) 859-2056 and (404) 537-3406, respectively. The conference ID number for the replay is 57542661. Additionally, an archive of the webcast will be available on the Company's website for 90 days.

About MELD Score

MELD (Model of End Stage Liver Disease) score was developed by clinicians at Mayo Clinic in Rochester, MN as an algorithm of three clinical laboratory measurements to yield a single uniformly accepted score to predict the probability of 90-day survival of chronic liver disease patients and thereby prioritize them for liver transplant. After rigorous empirical evaluation of hundreds of such patients, the clinicians concluded that no single laboratory measurement predicted survival in chronic liver disease, but that a complex algorithm of bilirubin, creatinine and INR gave a reliable estimate of survival probability.

MELD score has since been validated for predicting 90-day survival in other types of liver disease including acute alcoholic hepatitis. Details on MELD score can be found in a paper published in *Hepatology* (2005) titled "MELD Accurately Predicts Mortality in Patients With Alcoholic Hepatitis" (Winston Dunn, Laith H. Jamil, Larry S. Brown, Russell H. Wiesner, W. Ray Kim, K. V. Narayanan Menon, Michael Malinchoc, Patrick S. Kamath, and Vijay Shah). For reference, normal people with no liver disease have MELD scores of about 6 and the average MELD at liver transplant in the U.S. is about 24. High MELD scores are associated with high mortality. For example, at a MELD score of 26 (median MELD of the 60-subject post-hoc subset population targeted for VTL-308), the Dunn et al paper would predict that the patient has a 47% probability of death within 90 days. At a MELD score of 30, the upper limit in the proposed VTL-308 trial, the Dunn et al paper would predict that the patient has a 62% probability of death within 90 days.

About VTI-208 and VTI-208E

VTI-208 was a phase 3 randomized, controlled, open-label trial, evaluating the ELAD System in subjects with AILD. The primary endpoint was overall survival through at least 91 days assessed using the Kaplan Meier statistical method, and the secondary endpoint was proportion of survivors at study days 28 and 91. The trial enrolled 203 subjects over 22 months with 96 subjects randomized to the treated group and 107 randomized to the control group. VTI-208E, an extension study, assesses subject outcomes for five years after enrollment in VTI-208. Results of the VTI-208 clinical trial, incorporating VTI-208E survival data through July 30, 2015, showed that the trial failed to reach its primary or secondary endpoints.

About Vital Therapies, Inc.

Vital Therapies, Inc. is a biotherapeutic company developing a cell-based therapy targeting the treatment of liver failure. The Company's ELAD System is an extracorporeal human allogeneic cellular liver therapy currently in phase 3 clinical trials. Vital Therapies, Inc. is based in San Diego, California. Vital Therapies® and ELAD® are trademarks of Vital Therapies, Inc.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements concerning or implying the timing and conduct of our clinical trials, including the number of patients and timing of patient enrollment, site openings, data release, accomplishment and timing of certain development goals including regulatory determinations and filings, possible mechanism of action for ELAD and our projected cash runway. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance and you are cautioned not to place undue reliance on these forward-looking statements. Risks and uncertainties include, but are not limited to, the success or failure of our clinical trials and development programs; whether a single phase 3 clinical trial will be sufficient to support FDA approval of a biologics license application or whether the FDA will require us to conduct additional clinical trials; difficulty obtaining regulatory approval in the United States or Europe, in particular for a combination product and open-label clinical trials; whether or when we begin building any significant commercial infrastructure; our limited experience in conducting pivotal clinical trials and significant issues regarding our clinical trials, including, but not limited to, the successful opening and the continued participation of clinical sites and their ongoing adherence to protocols, assumptions regarding enrollment rates, timing and availability of subjects meeting inclusion and exclusion criteria, changes to protocols or regulatory requirements, the ability to comply with and meet applicable laws and regulations, and unexpected adverse events or safety issues; and the sufficiency of funding. There can be no assurance that data from any of our clinical trials will be sufficient to support an application for marketing in any country or that any such application will ever be approved. These and other risks regarding our business are described in detail in our Securities and Exchange Commission filings, including in our Annual Report on Form 10-K for the year ended December 31, 2014 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015. Additional information will also be set forth in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 to be filed with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and Vital Therapies, Inc. disclaims any obligation to update these statements except as may be required by law.

Vital Therapies, Inc.

Condensed Consolidated Balance Sheets

(unaudited, in thousands)

	September 30, 2015	December 31, 2014
Cash and cash equivalents	$ 59,754	$ 102,238
Other current assets	2,855	2,578
Property and equipment, net	4,163	3,068
Other assets	171	198
Total assets	$ 66,943	$ 108,082
Accounts payable and other accrued liabilities	$ 8,119	$ 10,278
Long-term liabilities	146	241
Stockholders' equity	58,678	97,563

Total liabilities and stockholders' equity	$ 66,943	$ 108,082

Vital Therapies, Inc.

Condensed Consolidated Statements of Operations

(unaudited and in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Operating expenses:				
Research and development	$ 9,646	$ 10,244	$ 32,945	$ 28,589
General and administrative	2,689	2,566	9,286	7,736
Total operating expenses	12,335	12,810	42,231	36,325
Loss from operations	(12,335)	(12,810)	(42,231)	(36,325)
Revaluation of future purchase rights liabilities and other income (expense), net	35	12	67	2,613
Net loss	(12,300)	(12,798)	(42,164)	(33,712)
Accretion to redemption value and amortization of deemed dividend on preferred stock	—	—	—	(9,154)
Net loss attributable to common stockholders	$ (12,300)	$ (12,798)	$ (42,164)	$ (42,866)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.51)	$ (0.59)	$ (1.76)	$ (3.18)
Weighted-average common sharesoutstanding, basic and diluted	24,025,481	21,759,061	23,998,396	13,483,813

CONTACT: Vital Therapies, Inc.

Al Kildani

Vice President, Investor Relations and Business Development

858-673-6840

akildani@vitaltherapies.com