

March 8, 2016

Vital Therapies Announces Fourth Quarter and Full Year 2015 Financial Results and Provides Corporate Update

SAN DIEGO, March 08, 2016 (GLOBE NEWSWIRE) -- Vital Therapies, Inc. (Nasdaq:VTL), a biotherapeutic company developing ELAD®, a cell-based therapy targeting the treatment of acute forms of liver failure, today announced results for the fourth quarter and full year ended December 31, 2015 and provided a corporate update.

"Since the FDA's response to our Type C submission on our proposed VTL-308 trial in November, we have started to open clinical trial sites and are preparing for the trial," said Terry Winters, Ph.D., Chief Executive Officer and Co-Chairman of Vital Therapies. "We look forward to enrolling the first subject in VTL-308 during the first half of this year."

Key Recent Developments

- | The initial database lock for VTI-208 was July 31, 2015. At that time the Company had a range of between six and 27 months of follow up data. The subjects are being followed in the VTI-208E extension study with periodic contacts to assess long term survival and the incidence of cancer, liver transplant and to assess quality of life. The Company has now updated the survival data as of December 31, 2015, providing an additional five months of follow up data. These additional data show:
 - | Three additional deaths in control subjects and one in ELAD-treated subjects. One additional subject withdrew consent and two were lost to follow-up.
 - | No significant changes to conclusions from the data as of July 31, 2015.
 - | The overall survival data for the primary end point of intent-to-treat Kaplan Meier analysis continued to show no difference between treated and control groups.
 - | Pre-specified and post-hoc subgroup analyses maintained the previously observed differences between the ELAD-treated and control groups.
 - | The Kaplan Meier analysis of the post hoc subset of 60 subjects that is the basis for the new VTL-308 trial maintained its p value of < 0.01 (p=0.006) and a hazard ratio of 0.28 and is shown in Figure 1. Survival at 180 days was 90% in ELAD-treated subjects and 48% in control subjects. There is no guarantee that these results can be replicated in the VTL-308 trial.
- | Received written responses from the FDA regarding the Type C briefing document that included a draft of the VTL-308 trial protocol. Subsequently, the final protocol was submitted to the FDA. The Company is proceeding with the trial and continues to anticipate that the first subject will be enrolled in the first half of 2016. Clinical sites are in the process of opening in the U.S. and should begin to open in the EU soon.
- | Presented posters and continued the laboratory R&D work to help characterize ELAD's mechanism of action:
 - | A poster presented at the annual meeting of the American Association for the Study of Liver Disease (AASLD) in November described eleven factors secreted by VTL C3A cells that have been associated with liver regeneration. This poster also described what the Company believes is a very exciting finding that the media from growing the VTL C3A cells reduces the rate of apoptosis, or cell death, of primary human hepatocytes in cell culture. This is significant because it could explain how ELAD stabilizes the liver and allows for its regeneration through preventing further hepatocyte cell death.
 - | A metabolomics study of samples from 8 ELAD-treated and 8 control subjects from the VTI-208 trial provided additional support that the ELAD C3A cells perform some of the metabolic processes that comprise liver function. These data will be presented at a future medical meeting.
 - | The findings from these and other studies on the hypothesized mechanism of action of ELAD have not yet been related to clinical outcomes. However, the Company believes the findings help to further elucidate the ELAD mechanism of action, and ongoing studies will continue to focus on the potential for ELAD to modulate inflammation, promote liver regeneration, produce key metabolites such as blood coagulation factors, and perform other liver-specific metabolism and detoxification functions.
- | Two key promotions were made in the Vital Therapies executive team:
 - | Duane Nash, M.D., J.D. has been promoted to the newly created role of President where he will work closely with Co-Chairman and CEO Terry Winters, whose role remains unchanged.
 - | Mike Swanson has been promoted to Executive Vice President and Chief Financial Officer.

- 1 Finished 2015 with \$83.4 million in cash and cash equivalents. The Company believes its cash position is sufficient to fund operations into the first quarter of 2018. This compares with the Company's previous cash runway estimate of mid-2018 with the difference attributable to the re-initiation of certain programs halted in the fall of 2015 following the announcement of VTI-208 trial results. The Company currently anticipates extending its cash runway by raising additional capital under its shelf registration statement, which includes an at-the-market (ATM) facility, over the next two years, or by reducing spending.

Figure 1. Kaplan Meier Curve for VTI-208/VTI-208E Overall Survival MELD < 30, Age < 50, INR ≤2.5, creatinine < 1.3mg/dL and bilirubin ≥16 mg/dL at December 31, 2015 (N=60, p-value=0.006, HR 0.278)

<http://resource.globenewswire.com/Resource/Download/ee7c9723-70c5-46ca-9d31-c1c0fcb97600?size=0>

Fourth Quarter 2015 Financial Results

Results of Operations

Three Months Ended December 31, 2015

The Company reported a net loss of \$9.9 million for the quarter ended December 31, 2015, which compared with a net loss of \$14.0 million for the same prior year period. This resulted in a net loss attributable to common stockholders of \$0.34 per share for the three months ended December 31, 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 28,578,955 shares and 23,689,613 shares, respectively, with the increase in common shares outstanding in 2015 resulting from the Company's follow-on offering in the fourth quarter of 2015.

Research and development expenses decreased to \$6.8 million during the three months ended December 31, 2015 as compared to \$10.9 million in the three months ended December 31, 2014. This was primarily due to a reduction in clinical trial and related costs in comparison to the prior year period. General and administrative expenses were \$3.1 million for both the three months ended December 31, 2015 and 2014.

Twelve Months Ended December 31, 2015

The Company reported a net loss of \$52.0 million for the year ended December 31, 2015, which compared with a net loss of \$47.7 million for the prior year. The net loss attributable to common stockholders was also \$52.0 million for the year ended December 31, 2015, which compared with a net loss attributable to common stockholders of \$56.8 million for the prior year. This resulted in a net loss attributable to common stockholders of \$2.07 per share for the year ended December 31, 2015, as compared to a net loss attributable to common stockholders of \$3.54 per share for 2014, on both a basic and diluted basis. These per share figures are based on weighted-average common shares outstanding of 25,152,948 shares and 16,054,452 shares, respectively, with the large increase in common shares outstanding resulting from the Company's initial public offering (IPO) in the second quarter of 2014, the conversion of preferred stock to common stock in conjunction with the IPO, and the Company's follow-on offerings in the fourth quarters of both 2014 and 2015.

Research and development expenses were \$39.8 million during the year ended December 31, 2015 as compared to \$39.5 million for the year ended December 31, 2014. General and administrative expenses were \$12.3 million for the year ended December 31, 2015, up from \$10.9 million for 2014.

Conference Call Details

Vital Therapies will host a conference call to discuss these results and provide a corporate update today, March 8, 2016, 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 44479307. 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 listen in at the designated time, a conference call replay will be available for one week following the conference call beginning approximately 7:30 p.m. ET on March 8, 2016. 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 44479307.

About Vital Therapies, Inc.

Vital Therapies, Inc. is a biotherapeutic company developing a cell-based therapy targeting the treatment of acute forms 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

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 timing of patient enrollment, site openings, 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, 2015. 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)

	December 31,	
	2015	2014
Cash and cash equivalents	\$83,416	\$102,238
Restricted cash, prepaid expenses and other current assets	1,672	2,578
Property and equipment, net	3,809	3,068
Other assets	184	198
Total assets	<u>\$89,081</u>	<u>\$108,082</u>
Accounts payable, accrued expenses and other current liabilities	\$ 6,655	\$ 10,278
Long-term liabilities	101	241
Stockholders' equity	<u>82,325</u>	<u>97,563</u>
Total liabilities and stockholders' equity	<u>\$89,081</u>	<u>\$108,082</u>

Vital Therapies, Inc.
Condensed Consolidated Statements of Operations
(unaudited and in thousands, except per share data)

	Three Months		Year	
	Ended December 31,		Ended December 31,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 6,829	\$ 10,891	\$ 39,773	\$ 39,479
General and administrative	3,061	3,127	12,347	10,863
Total operating expenses	<u>9,890</u>	<u>14,018</u>	<u>52,120</u>	<u>50,342</u>

Loss from operations	(9,890)	(14,018)	(52,120)	(50,342)
Revaluation of future purchase rights liabilities and other income (expense), net	31	64	97	2,675
Net loss	(9,859)	(13,954)	(52,023)	(47,667)
Accretion to redemption value and deemed dividend on preferred stock	—	—	—	(9,154)
Net loss attributable to common stockholders	<u>\$ (9,859)</u>	<u>\$ (13,954)</u>	<u>\$ (52,023)</u>	<u>\$ (56,821)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.59)</u>	<u>\$ (2.07)</u>	<u>\$ (3.54)</u>
Weighted-average common shares outstanding, basic and diluted	<u>28,578,955</u>	<u>23,689,613</u>	<u>25,152,948</u>	<u>16,054,452</u>

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