Vital Therapies Announces First Quarter 2015 Financial Results and Provides a Corporate Update

SAN DIEGO, May 12, 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 first quarter ended March 31, 2015 and provided a corporate update.

"We are working diligently to advance our clinical programs while continuing important research into ELAD's mechanisms of action," said Terry Winters, Ph.D., Chief Executive Officer and Co-Chairman of Vital Therapies. "We look forward to reporting topline results from our phase 3 VTI-208 trial in the third quarter of this year."

Key Developments

- On track for database lock and release of topline results for the VTI-208 clinical trial in the third quarter of 2015. VTI-208 is a phase 3 randomized, controlled, open-label trial, evaluating the ELAD System in subjects with alcohol-induced liver decompensation (AILD). Enrollment was completed in January with 203 subjects.

- Enrolled the ninth subject as of May 11, 2015 in the Company's second phase 3 trial, VTI-210, a randomized, controlled, open-label study evaluating the ELAD System in severe acute alcoholic hepatitis subjects who have failed standard therapy. Twenty-four sites have been opened to date and the Company expects to open over 40 sites for enrollment in this trial by year-end. Enrollment and site openings are currently behind plan due to prioritization of VTI-208 data completion at the sites also anticipated to participate in the VTI-210 trial. This event-driven trial targets enrollment of a minimum of 150 subjects with a primary endpoint of overall survival up to at least study day 91. The Company continues to expect to release topline results from VTI-210 in early 2017.

- Enrolled the sixth subject as of May 11, 2015 in VTI-212, a single-arm phase 2 trial, evaluating the ELAD System in 40 subjects with either fulminant hepatic failure or surgery-induced liver failure. The Company continues to expect topline results from VTI-212 in 2016.

- Presented two posters at the annual meeting of the European Association for the Study of the Liver (EASL) in Vienna last month. The first poster describes the demographics and baseline laboratory values of subjects enrolled in the VTI-208 trial showing that the key parameters of average age and MELD (Model of End-stage Liver Disease) score at baseline were both within the trial's target ranges established from VTI-206, the Company's phase 2b AILD trial. The second poster describes research into ELAD's possible mechanisms of action. The poster characterizes the expression levels of liver-specific cytochrome P450 isoenzymes and oxygenases in ELAD C3A cells during cartridge production and after use in clinical treatment. Both posters are available on the Company's web site.

First Quarter 2015 Financial Results

Cash Position

Cash and cash equivalents at March 31, 2015, totaled $88.3 million compared to $102.2 million at December 31, 2014. Based on the current business plan, the Company believes it has enough cash to fund the Company into the third quarter of 2016, although the Company’s projected cash runway will be highly dependent on the topline results of the VTI-208 clinical trial. The Company is filing a universal shelf registration statement on Form S-3 with the United States Securities and Exchange Commission (SEC) today. However, the Company will not access the public markets prior to the release of VTI-208 topline results in the third quarter of 2015.

Results of Operations

Three Months Ended March 31, 2015

The Company reported both a net loss and net loss attributable to common stockholders of $14.8 million for the quarter ended March 31, 2015, which compared with a net loss of $10.7 million, and a net loss attributable to common stockholders of $13.8 million for the same prior year period. This resulted in a net loss attributable to common stockholders of $0.62 per share for the three months ended March 31, 2015, as compared to a net loss of $24.49 per share for the corresponding period in 2014, on both a basic and fully diluted basis. These per share figures are based on weighted-average common shares outstanding of
23,972,599 shares and 564,186 shares, respectively, with the large increase in common shares outstanding in 2014 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 offering in the fourth quarter of 2014.

Total operating expenses for the three months ended March 31, 2015 were $14.8 million as compared to $11.9 million for the comparable period of 2014. Research and development expenses increased to $11.8 million during the three months ended March 31, 2015 as compared to $9.2 million in the three months ended March 31, 2014. This was primarily associated with an increase in clinical trial-related activities. General and administrative expenses were $3.1 million for the three months ended March 31, 2015, up from $2.7 million for the comparable period of 2014.

Conference Call Details

Vital Therapies will host a conference call to discuss these results and provide a corporate update today, May 12, 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 28877104. 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/](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 May 12, 2015 to 11:59 p.m. ET on May 19, 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 28877104. Additionally, an archive of the webcast will be available on the Company's website for 90 days.

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 conduct of our clinical trials and the timing of patient enrollment, site openings, data release, accomplishment and timing of certain development goals including regulatory filings, and our projected cash runway and future plans for fundraising. 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 Food and Drug Administration (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 we begin building any significant commercial infrastructure prior to the fourth quarter of 2016; 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 Quarterly Report on Form 10-Q for the quarter ended March 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 Statements of Operations
(unaudited and in thousands, except per share data)

Three Months Ended March 31, 2015 2014

Operating expenses:
Research and development $ 11,753 $ 9,219
General and administrative 3,064 2,657
Total operating expenses 14,817 11,876
Loss from operations (14,817) (11,876)
Revaluation of future purchase rights liabilities and other income (expense), net 59 1,128
Net loss (14,758) (10,748)
Accretion to redemption value and deemed dividend on preferred stock -- (3,070)
Net loss attributable to common stockholders $ (14,758) $ (13,818)

Net loss per share attributable to common stockholders, basic and diluted $ (0.62) $ (24.49)
Weighted-average common shares outstanding, basic and diluted 23,972,599 564,186

CONTACT: Vital Therapies, Inc.

Al Kildani
Vice President, Investor Relations and Business Development

858-673-6840

akildani@vitaltherapies.com