



## Vital Therapies Announces Third Quarter 2017 Financial Results

October 25, 2017

**- 118 of Targeted 150 Subjects Enrolled in VTL-308 as of October 24th**

SAN DIEGO, Oct. 25, 2017 (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 third quarter ended September 30, 2017.

### Key Recent Developments

- As of October 24<sup>th</sup>, the VTL-308 trial was 79% enrolled based on its target of at least 150 subjects and the Company is expecting to report topline data in the third quarter of next year. VTL-308 is the Company's phase 3 randomized, controlled, open-label trial, designed to evaluate the ELAD System in subjects with severe alcoholic hepatitis (sAH). 118 subjects were enrolled in the trial with 45 sites open for enrollment. Since the Company's last quarterly update reported on August 3, 2017, enrollment has continued at a rate of more than 8 subjects per month at sites in the United States and Europe. If it is decided more than 150 subjects are needed to reach 55 deaths under the event-driven design of the trial, the topline data could be delayed.
- Today, the Company has updated the baseline characteristics of subjects enrolled in VTL-308 to include the first 115 subjects. The data continue to show that the means for these baseline characteristics continue to track the reference population from VTI-208, the Company's prior phase 3 clinical trial with ELAD in subjects with sAH on which the design of VTL-308 is based. The updated baseline data are presented in the table below:

Data	Age (years)	MELD	Bilirubin (mg/dL)	INR	Creatinine (mg/dL)
VTL-308 enrollment limits	<50 yrs	<30	≥16 mg/dL	≤2.5	<1.3mg/dL
VTI-208 reference population (n=60)	<b>Mean (range)</b> 40.10 (28 - 49)	<b>25.60</b> (20 - 29)	<b>26.62</b> (16.6 - 52.6)	<b>1.86</b> (1.0 - 2.5)	<b>0.71</b> (0.10 - 1.30)
VTL-308 (n=115)	<b>Mean (range)</b> 38.88 (23 - 49)	<b>25.20</b> (19 - 29)	<b>24.94</b> (16.0 - 44.7)	<b>1.83</b> (0.95 - 2.50)	<b>0.71</b> (0.30 - 1.27)

- During the quarter the Company made a number of poster presentations at scientific meetings, including a presentation titled "Elaborating ELAD Mechanism of Action and Linking Cell-Based Models to the Clinic" made on September 9, 2017 at a conference in Rostock, Germany. The key finding was that levels of interleukin-1 receptor antagonist, or IL-1Ra, were significantly elevated during ELAD treatment compared with controls in a selected group of 25 subjects from the Company's prior VTI-208 study who met the enrollment criteria for VTL-308. IL-1Ra is an anti-inflammatory protein that blocks the interaction of the pro-inflammatory cytokine, IL-1, with its receptor, thereby potentially reducing inflammation. Posters and associated presentations are made available at <http://ir.vitaltherapies.com> in the "Clinical Publications and Presentations" section promptly after they have been made publicly.
- On September 6<sup>th</sup> the Company announced the appointment of Faheem Hasnain as Chairman of the Board of Directors, succeeding Co-Chairmen Terry Winters, Ph.D., and Muneer Satter, both of whom remain on the Board with Dr. Winters remaining as Chief Executive Officer. Previously Mr. Hasnain served as President, Chief Executive Officer and a Director of Receptos, Inc. from November 2010 to August 2015. Prior to Receptos, Mr. Hasnain was President, Chief Executive Officer and a director of Facet Biotech Corporation. He held those positions from December 2008 until Facet's acquisition by Abbott Laboratories in April 2010. Previously, Mr. Hasnain was President, Chief Executive Officer and a director of PDL BioPharma, Inc. from October 2008 until Facet Biotech was spun off from PDL BioPharma in December 2008. Mr. Hasnain also held senior executive positions with Biogen Idec Inc., Bristol-Myers Squibb, and GlaxoSmithKline.

### Third Quarter 2017 Financial Results

#### Cash Position

Cash and cash equivalents at September 30, 2017, totaled \$66.4 million compared to \$60.0 million at December 31, 2016. The Company believes its current cash position could provide funding through the first quarter of 2019, well past the expected announcement of VTL-308 top-line trial results.

#### Results of Operations

Three Months Ended September 30, 2017

The Company reported a net loss of \$12.5 million for the three months ended September 30, 2017, which compared with a net loss of \$10.2 million for the same prior year period. This resulted in a net loss of \$0.30 per share for the three months ended September 30, 2017, as compared to a net loss of \$0.32 per share for the corresponding period in 2016, on both a basic and diluted basis. These per share figures are based on weighted-average common shares outstanding of

42,207,376 shares and 31,645,838 shares, respectively, with the increase in common shares outstanding at September 30, 2017 primarily attributable to shares issued as part of the Company's follow-on offering in the first quarter of 2017.

Research and development expenses increased to \$9.7 million for the three months ended September 30, 2017 as compared to \$7.5 million for the three months ended September 30, 2016. This was primarily due to an increase in clinical trial and related costs in comparison to the prior year period. General and administrative expenses were \$3.0 million for the three months ended September 30, 2017, as compared to \$2.8 million for the three months ended September 30, 2016.

#### Conference Call Details

Vital Therapies will host a conference call to discuss these results and provide a corporate update today at 4:30 PM 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 9042599. Participants can 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. 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 9042599.

#### 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 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 statements concerning or implying the timing and conduct of our clinical trials and the timing of the release of the results from these trials, and statements regarding 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, difficulty obtaining or maintaining regulatory approval in the United States or Europe, in particular for a combination product and open-label clinical trials; the timing of incurring costs for activities to support our clinical trials and any applications for marketing approval; 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 continued participation of clinical sites and their ongoing adherence to protocols; assumptions regarding the number of subjects to be enrolled, enrollment rates, and the timing and availability of subjects meeting inclusion and exclusion criteria; changes to protocols or regulatory requirements; the need to comply with and meet applicable laws and regulations; and unexpected adverse events or safety issues. 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-Q for the quarter ended September 30, 2017. 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.*

Contact:

Vital Therapies, Inc.  
Al Kildani  
Vice President, Investor Relations and Business Development  
858-673-6840  
[akildani@vitaltherapies.com](mailto:akildani@vitaltherapies.com)

Vital Therapies, Inc.

Condensed Consolidated Balance Sheets

(unaudited, in thousands)

	September 30, 2017	December 31, 2016
Cash and cash equivalents	\$ 66,391	\$ 59,991
Prepaid expenses and other current assets	1,569	1,472
Property and equipment, net	2,272	2,505
Other assets	126	58
Total assets	\$ 70,358	\$ 64,026
Accounts payable, accrued expenses and other current liabilities	\$ 8,234	\$ 5,480
Long-term liabilities	46	100
Stockholders' equity	62,078	58,446
Total liabilities and stockholders' equity	\$ 70,358	\$ 64,026

Vital Therapies, Inc.

Condensed Consolidated Statements of Operations

(unaudited and in thousands, except share and per share data)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Operating expenses:				
Research and development	\$ 9,689	\$ 7,469	\$ 29,151	\$ 21,184
General and administrative	2,950	2,770	8,724	8,257
Total operating expenses	12,639	10,239	37,875	29,441
Loss from operations	(12,639 )	(10,239 )	(37,875 )	(29,441 )
Other income	158	61	385	206
Net loss	\$ (12,481 )	\$ (10,178 )	\$ (37,490 )	\$ (29,235 )
Net loss per share, basic and diluted	\$ (0.30 )	\$ (0.32 )	\$ (0.96 )	\$ (0.94 )
Weighted-average common shares outstanding, basic and diluted	42,207,376	31,645,838	39,054,978	31,153,801

 [Primary Logo](#)

Source: Vital Therapies, Inc.