

## Vital Therapies, Inc.

### Second-Quarter Financials Non-event; VTI-208 on Track for Second Quarter 2015 Readout

On Wednesday, August 6, after markets closed, Vital Therapies reported second-quarter financial results (exhibit 1). The company ended the quarter with \$90.6 million in cash, which included proceeds of \$51.9 million from its IPO. We estimate that current cash should sustain operations through the data release of the Phase III VTI-208 study expected during the first half of 2015 and through year-end 2015. Net loss for the quarter was \$16.3 million with a per-share loss of \$0.91, versus our estimates of \$12.0 million and \$0.58, respectively; the greater-than-expected losses were due to the accretion on the redeemable preferred stock in the quarter. We updated our model as illustrated in exhibit 1.

**ELAD clinical development program update: As of August 5, 138 of the 200 expected patients have been enrolled into the VTI-208 study, which is on track for top-line data release during second quarter 2015. Further, enrollment of the first patient in the Phase III VTI-210 study is expected in late 2014, following protocol amendment. Lastly, the first patient in the Phase II/III VTI-212 was enrolled during the second quarter, slightly ahead of plan.** The extracorporeal liver-assist device (ELAD) system clinical development program covers several major subgroups of acute liver failure (ALF) and acute-on-chronic liver failure (ACLF) with survival as the primary endpoint. We illustrate the ELAD system development timeline in exhibit 3.

- **As of August 5, 138 of the 200 expected patients have been enrolled into the VTI-208 study in AILD, up from 111 at the end of first quarter. The study is on track to report top-line data in second quarter 2015. VTI-208 is primarily conducted in the United States and, if successful, may satisfy the regulatory requirement in the United States.** VTI-208 is a Phase III, randomized, open-label, multicenter, controlled study investigating the effects of ELAD in combination with standard therapy of the study site versus standard therapy alone in patients with alcohol-induced liver decompensation (AILD). The primary endpoint is overall survival at 90 days; secondary endpoints of the study include overall survival at 28 days and model for end-stage liver disease (MELD)-based time to progression. Long-term effects of ELAD will also be reported, as subjects will be followed for an additional five years in an extension study. We note that the VTI-208 study is designed with 95% power to achieve statistical significance for the primary endpoint of overall survival. Management continues to expect top-line data from the study by first half 2015.

*Vital Therapies, Inc. is a hybrid biopharmaceutical-medical technology company based in San Diego, California, focused on the development of its ELAD technology system as a treatment for patients with acute liver failure.*

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August 07, 2014

Stock Rating: **Outperform**  
Company Profile: **Aggressive Growth**  
Price Target: \$36.00

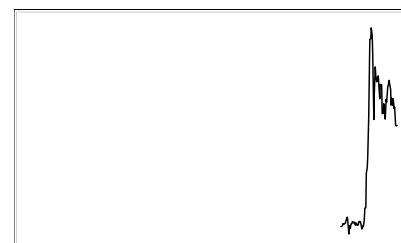
Symbol: VTL (NASDAQ)  
Price: \$22.21 (52-Wk.: \$11-\$35)  
Market Value (mil.): \$477  
Fiscal Year End: December  
Long-Term EPS Growth Rate:  
Dividend/Yield: None

	2013A	2014E	2015E
<b>Estimates</b>			
EPS Q1	NA	A\$-24.49	NA
Q2	NA	A\$-0.91	NA
Q3	NA	\$-0.54	NA
Q4	NA	\$-0.55	NA
FY	\$-74.86	\$-3.60	\$-4.54
CY		\$-3.60	\$-4.54
<b>Valuation</b>			
FY P/E	NM	NM	NM
CY P/E		NM	NM

<b>Trading Data (FactSet)</b>	
Shares Outstanding (mil.)	1
Float (mil.)	15
Average Daily Volume	82,152

<b>Financial Data (FactSet)</b>	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	-95.7
Return on Equity (TTM)	-45.0

#### Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

- ***For the second Phase III study, VTI-210, which is primarily conducted in Europe in acute alcoholic hepatitis (AAH) patients who failed steroids, the recent EMA guidance stipulates that patients be stratified based on AAH diagnosis by biopsy or clinical grounds without biopsy. Vital Therapies will amend study protocols to comply with the EMA guidance, and increase the total targeted patient enrollment from 120 to 150. Top-line data from the study is now expected during 2016 instead of early 2016. We note that the VTI-210 study alone, if successful, should satisfy the regulatory requirements in Europe.*** VTI-210 is a randomized, open-label, multicenter, controlled study investigating the effects of ELAD in combination with standard therapy of the study site versus standard therapy alone in AAH patients, a subset of AILD. The VTI-210 study will be primarily conducted in Europe, where steroid use in AAH patients is considered frontline therapy. Initiated in April 2014, the study expects to enroll AAH patients who have failed at least seven days but no more than nine days of steroid therapy, according to predefined criteria. The primary endpoint of the study is overall survival at 90 days; the secondary endpoint of the study is survival at 28 days. Similar to the VTI-208 study, the VTI-210 study is designed with 95% power to achieve statistical significance for the primary endpoint of overall survival.

As part of the process for preparing a possible marketing authorization application (MAA) based primarily on the VTI-210 study, the company submitted a request for advice through the Scientific Advice Working Party (SAWP) process at the EMA on topics related to the production and testing section of a future MAA, as well as on aspects of the VTI-210 protocol design. On June 30, the company received a detailed response from SAWP, which confirmed that the production and testing guidance was consistent with the company's prior interaction with the regulatory agency. In addition, the SAWP guidance also allowed for the stratification of study patients into groups based on AAH diagnosis either by biopsy or by clinical grounds without biopsy. As a result, the company will amend the study protocol to be consistent with the SAWP guidance, and will increase the size of the VTI-210 study from 125 patients to a minimum of 150 patients. The company now expects preliminary data from the study to be available during 2016, as compared to the previous guidance of late 2015 or early 2016. The company noted that five sites are currently open, but have not enrolled any patients.

- ***Vital Therapies has initiated its Phase II/III VTI-212 study in patients with FHF or SILF and enrolled its first patient during second quarter. The goal of VTI-212 is to support the registration of ELAD and expand indications.*** The Phase II single-arm portion of the study with target enrollment of 40 patients with fulminant hepatic failure (FHF) or surgery-induced liver failure (SILF) has enrolled its first patient. The planned primary endpoint of the Phase II component of the study is 28-day survival, which will be compared with historical or matched controls. We anticipate top-line data from the Phase II portion of the study by late 2015 or early 2016. We note that results from the Phase II portion of the study might be sufficient for an expedited regulatory approval pathway; however, in the event a Phase III study is necessary for the indication, the study design would be finalized based on analysis of the Phase II component.
- ***Background on ELAD.*** The ELAD System is the first human-cell-based bioartificial liver (BAL) therapy to be evaluated in Phase III clinical development for the treatment of ALF. ELAD is an allogeneic cellular therapy system in which human-liver-derived cells, known as C3A cells, contained in a single-use disposable set of four hollow fiber cartridges, are incorporated into a reusable, customized heart-lung machine—a device typically used in open-heart surgery to support the body during the surgical procedure. The heart-lung machine provides extracorporeal circulation of the patient's blood plasma to the cartridges containing the C3A cells for a two-way exchange of toxins, metabolites, and nutrients, and then returns the plasma to the patient. The ELAD system is specifically designed to simulate liver function while the patient's liver is given an opportunity to recover its regenerative properties.

**We believe a number of catalysts will drive value in Vital Therapies stock over the next 12-24 months, including:** 1) top-line data from the Phase III VTI-208 study in AILD patients expected in second quarter 2015; 2) potential submission of the ELAD biological license application to the FDA by year-end 2015; 3) top-line data from the Phase III VTI-210 study in AAH in 2016; 4) top-line data from the Phase II component of the VTI-212 study in FHF and SILF in late 2015 or early 2016; and 5) potential FDA approval and U.S. commercial launch of the ELAD system in second half 2016.

**We maintain our Outperform rating and \$36 price target (exhibit 2). Our Outperform rating is centered on our belief that the ELAD system will become the standard of care for the treatment of ALF in both the United States and Europe, and could generate peak worldwide sales of \$1.6 billion by 2032.** Our probability adjusted NPV model assumes a 70% probability of success for the ELAD system development program, and suggests a fair value for the ELAD system of \$36 at mid-2015, with \$22 attributed to the United States and \$13 to Europe. Adding \$1 of cash at mid-2015, we derive our price target at \$36.

Potential sources of upside to our revenue estimates include: 1) pricing for ELAD therapy. Pricing consultants to Vital Therapies suggest that ELAD could be priced in the range of \$150,000 to \$275,000 per treatment, suggesting a potential market for ELAD of over \$4.5 billion in the United States alone. We currently model pricing conservatively at \$150,000. We note that the cost associated with a liver transplant is estimated to be more than \$500,000. If ELAD can not only save but also prolong the lives of patients by decades who are either ineligible for transplant or waitlisted for transplant, the value proposition for ELAD therapy would be strong, in our opinion; 2) expansion from AAH to full AILD patient population in Europe could lead to an additional \$300 million in peak sales on the continent; and 3) sales outside the United States and Europe are further upside.

**While evidence to date supports ELAD being a promising treatment for various forms of ALF, we currently assign the ELAD Phase III program a 70% probability of success based on the following arguments and rationale:**

1. ***Survival trends were demonstrated from three Phase II studies.*** It is encouraging that three randomized, controlled Phase II studies conducted in the United States, Europe, and China have demonstrated survival trends in favor of ELAD, and that one of the three studies reached statistical significance. The studies informed powering and design for the current Phase III studies, and also informed patient selection criteria for the Phase III program.
2. ***However, each of the three Phase II studies has its caveats.*** First, VTI-206, a randomized, controlled Phase IIb study in AILD and non-AILD subjects, was stopped early due to a lack of benefit in the non-AILD cohort. Upon termination of the study, per protocol, an analysis of the AILD cohort was performed and demonstrated a survival trend. This study informed that ELAD is not effective in non-AILD patients whose livers are not readily regenerable. Second, in the FHF studies, only a post hoc meta-analysis in a subset of patients who were listed for transplant suggested a survival benefit. Lastly, VTIC-301, the Chinese study in subjects with acute flare hepatitis, was halted early due to observed efficacy in subjects. But a protocol amendment led to further enrollment of patients with less severe disease. Analyses on the two different populations led to different sets of data, and consistent statistical significance was only observed among the first 49 enrolled patients. Overall, each of the aforementioned studies and their data analyses had various degrees of limitations. Nonetheless, the signals observed warrant well-designed and well-executed Phase III studies.
3. ***Biomarker data from Phase II studies, including improvement in bilirubin, serum sodium, and creatinine, are all pointing in the right direction.*** Bilirubin is a byproduct of hemoglobin degradation, which can accumulate and result in jaundice if it is not properly cleared and excreted by the liver. In previous Phase II studies, ELAD-treated subjects demonstrated a significant reduction in serum bilirubin levels over the five days of therapy as compared with the standard of care, indicating that the ELAD system was able to carry out the functions of a liver. Further, serum creatinine, a biomarker of kidney function, was reduced in the first six days, while the control did not reduce serum creatinine. Lastly, sodium, an electrolyte that typically decreases with acute liver failure, increased in ELAD-treated subjects over the first six days as compared with the control. Taken as a whole, these biomarkers suggest an improvement in liver function in ELAD-treated subjects.
4. ***Proper patient selection is critical for success of the Phase III program: expected mortality rate of 50% and liver is regenerable.*** The key to the success of the Phase III program is to enroll patients with an expected mortality rate of around 50% and also with regenerable livers so that ELAD can make the strongest difference in improving survival. Specifically, we point to a few of the screening criteria. Patients enrolled are required to have a MELD score of 18-35, which would include patients who are neither too healthy nor too sick; we note that a MELD score in the mid-20s predicts 40% mortality rate. They must also have a Maddrey discrimination function test score greater than 32; this test is a predictor of disease severity and mortality and a score greater than 32 predicts probability of death of 40-50% by 90 days. In addition, patients with cirrhotic livers are excluded, as such livers are not regenerable and ELAD would not make a difference. Further, patients who are rapidly improving or deteriorating too quickly on admission are also excluded.
5. ***Statistical powering of Phase III program is high.*** We note that the Phase III statistical plans for VTI-208 and VTI-210 are conservative based on the results from the Phase II VTI-206. Both ongoing Phase III studies are designed with 95% power to achieve statistical significance for the primary endpoint of overall survival. In other words, the studies are 95% powered to reach a p-value of 0.05 assuming 90-day survival for the control arm to be around 50% and for the ELAD arm to be 75%, with a median survival of 45 days for the control arm and 90 days for the ELAD arm.

6. ***There are a number of confounding factors due to the open-label design; a standard patient follow-up protocol has been devised to minimize potential imbalances.*** We note that there is concern regarding the ELAD Phase III programs that ELAD-treated patients would be biased to have better care and attention compared with the control group. To minimize such potential bias, a detailed patient follow-up protocol is incorporated into the Phase III studies.
7. ***The encouraging survival trend observed with Circe Biomedical's HepatAssist bodes well for ELAD, in our opinion.*** We note that the design of the porcine-cell-based BAL HepatAssist system, previously developed by Circe Biomedical, looks to be inferior to the ELAD system in terms of: 1) the number of cells supplied (ELAD system uses 11 times more cells than HepatAssist); 2) the duration of treatment: ELAD can be connected to ALF patients 24/7 and the four cartridges can continue to function for up to 17 days without the need for replacement, whereas one HepatAssist cartridge can only be used for six to eight hours per day and a fresh cartridge is needed every day, likely not enough treatment time for the liver to regenerate; and 3) high immunological risks (porcine [pig] versus human cells). Despite all these shortcomings, HepatAssist demonstrated a survival trend in a Phase II/III study in ALF patients. In fact, a subset analysis of the study demonstrated borderline statistical significance in 30-day survival. We are encouraged by such data and believe such data might bode well for ELAD, which appears to exceed the HepatAssist system in supplementing liver function in almost every aspect.

Key risks to our Outperform rating and price target include: 1) clinical risk of the Phase III program, which was based on trends observed in previous Phase II studies; 2) regulatory risk given the FDA's concern that the Phase III VTI-208 and VTI-210 studies are open label and not blinded; 3) regulatory risk associated with a drug/device combination requiring approval from FDA's Center for Biologics Evaluation and Research and Center for Devices and Radiological Health; 4) reimbursement risk provided that the process might be long and arduous; 5) commercialization risk if the ALF market is smaller than expected and/or difficult to penetrate; 6) manufacturing risks associated with Vital Therapies' proprietary C3A cells and cartridges; and 7) technical risk, considering that the ELAD system comprises a hybrid biologic and medical device and that a number of components of the medical device are outsourced by third parties.

**Exhibit 1**  
**Vital Therapies, Inc.**  
**Income Statement**  
(dollars in thousands)

	2012A	2013A	2014					2015E	2016E
			Q1A	Q2A	Q3E	Q4E	FY:14E		
<b>Revenues</b>									
ELAD US revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$5,795
ELAD OUS revenues	-	-	-	-	-	-	-	-	-
Collaboration and licensing revenue	-	-	-	-	-	-	-	-	-
<b>Total Revenues</b>	-	-	-	-	-	-	-	-	<b>5,795</b>
<b>Expenses</b>									
COGS	-	-	-	-	-	-	-	-	1,159
R&D expense	5,097	21,787	9,219	9,125	9,216	9,308	36,869	70,000	70,000
SG&A expense	4,483	9,615	2,657	2,513	2,538	2,564	10,272	16,319	34,974
<b>Total Operating Expenses</b>	9,580	31,402	11,876	11,638	11,754	11,872	47,140	86,319	106,133
<b>Operating income</b>	(9,580)	(31,402)	(11,876)	(11,638)	(11,754)	(11,872)	(47,140)	(86,319)	(100,338)
Interest income	4	5	-	-	9	8	17	16	(22)
Interest expense, net	(413)	-	-	-	-	-	-	-	-
Other (expense) income, net	7	(15)	-	1,471	1,486	1,501	4,457	-	-
Revaluation of preferred stock warrant liabilities	180	-	-	-	-	-	-	-	-
Revaluation of future purchase rights liabilities	3,101	(1,306)	1,128	-	-	-	1,128	-	-
<b>Total other income (expense)</b>	(6,701)	(32,718)	(10,748)	(10,167)	(10,260)	(10,363)	(41,538)	(86,303)	(100,360)
Pretax income/(loss)	(6,701)	(32,718)	(10,748)	(10,167)	(10,260)	(10,363)	(41,538)	(86,303)	(100,360)
Other comprehensive gain/(loss)	-	(64)	-	-	-	-	-	-	-
Accretion to redemption value of redeemable convertible preferred stock	(942)	(6,303)	(3,070)	(6,084)	-	-	(9,154)	-	-
Provision for income taxes/(income)	-	-	-	-	-	-	-	-	-
Tax rate	0%	0%	0%	0%	0%	0%	0%	0%	0%
<b>Net Income/(Loss)</b>	<b>(7,643)</b>	<b>(39,085)</b>	<b>(13,818)</b>	<b>(16,251)</b>	<b>(10,260)</b>	<b>(10,363)</b>	<b>(50,692)</b>	<b>(86,303)</b>	<b>(100,360)</b>
<b>GAAP EPS</b>	<b>(\$17.89)</b>	<b>(\$74.86)</b>	<b>(\$24.49)</b>	<b>(\$0.91)</b>	<b>(\$0.54)</b>	<b>(\$0.55)</b>	<b>(\$3.60)</b>	<b>(\$4.54)</b>	<b>(\$5.24)</b>
Weighted average shares outstanding, diluted	427	522	564	17,888	18,913	18,938	14,076	19,013	19,158

Sources: Vital Therapies, Inc., and William Blair & Company, L.L.C. estimates

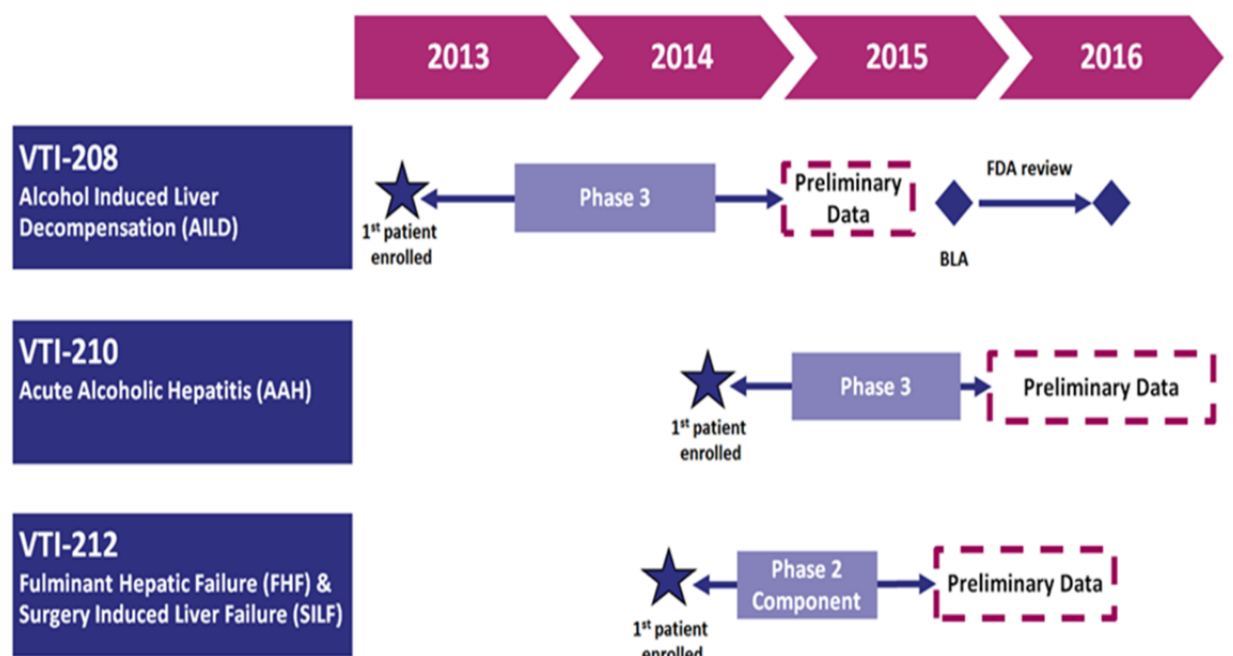
**Exhibit 2**  
**Vital Therapies, Inc.**  
**Sum-of-the-Parts Fair Value**  
(dollars in thousands, except shares)

Drug Candidate	Peak Sales	Stage of Development	Estimated Launch Date	Probability of Commercialization	Percentage of Sales to Company	Probability-Adjusted NPV	Value per Share	Percentage of Fair Value
ELAD system—United States	\$964,177	Phase III	H2:2016	70%	100%	\$421,671	\$22.20	61.2%
ELAD system—European Union	\$627,036	Phase III	H1:2017	70%	100%	\$253,670	\$13.35	36.8%
<b>Subtotal</b>						<b>\$675,341</b>	<b>\$35.55</b>	<b>98.1%</b>
<b>Net Cash at mid-Year 2015</b>						\$31,126	\$1.64	4.5%
<b>Net Present Value of additional Gain (Loss)*</b>						(\$17,857)	(\$0.94)	(2.6%)
<b>Sum-of-Parts Fair Value</b>						<b>\$688,610</b>	<b>\$36.25</b>	<b>100.0%</b>

\* Includes costs not directly related to programs above

Sources: Vital Therapies, Inc., and William Blair & Company, L.L.C. estimates

**Exhibit 3**  
**Vital Therapies, Inc.**  
**Clinical and Regulatory Timelines for ELAD System**



Source: Vital Therapies, Inc.

William Blair & Company, L.L.C.

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William Blair intends to seek investment banking compensation in the next three months from Vital Therapies, Inc.

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Additional information is available upon request.

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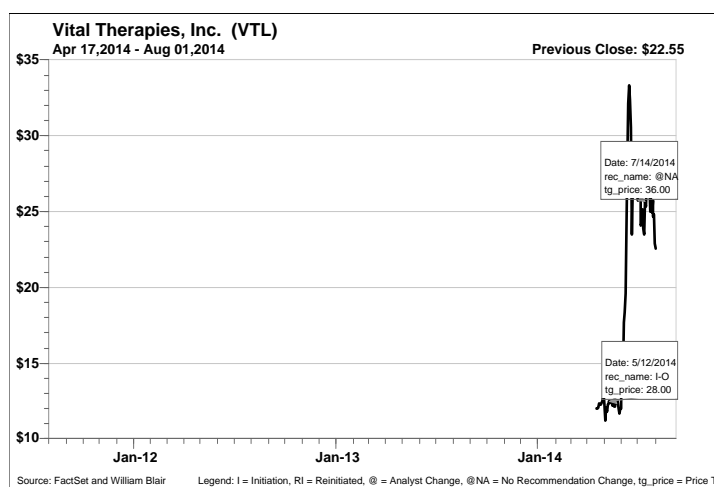
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DOW JONES: 16,443.34

S&P 500: 1,920.24

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Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	66	Outperform (Buy)	16
Market Perform (Hold)	31	Market Perform (Hold)	3
Underperform (Sell)	1	Underperform (Sell)	0

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