Vital Therapies Inc. (VTL)

ELAD Phase III Data on Track for ~June '15

Buy

Price Target: $50.00
Prior: $50.00

Price (Jan. 13, 2015)	$21.89
52-Wk Range	$33.31-$11.21
Market Cap ($M)	$475
ADTV	81,174
Shares Out (M)	21.7
Short Interest Ratio/% Of Float	3.1%
TR to Target	128.4%

Cash Per Share	$4.34
Total Debt	$0.0
Cash And Equivalents ($M)	$112.5

	2013A	2014E		2015E	
		Curr.	Prior	Curr.	Prior
Revenue ($M)					
FY	$0	$0	$0	$0	$0
EPS Adjusted					
FY	($74.86)	($3.61)	($3.61)	($2.39)	($2.39)
P/E	NM	NM		NM	
Consensus Rev					
FY	$0	$0	$0	$0	$0
Consensus EPS Adjusted					
FY	($74.86)	($3.56)	($3.56)	($2.54)	($2.54)
FYE Dec					

What's Incremental

We met with Vital management who highlighted their positive outlook on their interaction with the FDA on chemistry, manufacturing, and controls (CMC) for lead product ELAD (in pivotal testing for acute alcoholic liver decompensation). With 193/200 targeted patients enrolled in the Phase III VTI-208 trial, topline data is on track for Q2/15 (~June 2015). We note the binary nature of this key upcoming catalyst. However, we are optimistic on ELAD's prospects in acute alcoholic liver disease, given VTL's ability to evaluate ELAD in solely AAH patients, as well as the broader AILD population.

The VTI-208 trial should complete enrollment by end-Jan 2015, with 193 our of the targeted 200 patients enrolled to date. With a 90-day follow up required for last patients enrolled in the VTI-208 trial, we expect topline data could read out by end-June 2015. We are reassured about the consistent enrollment trends for this trial (~10-12 patients/month).

A number of regulatory updates bode well for VTL's progress. The company announced on Monday that a Clinical Trial Application (CTA) was approved in Germany to enable the company to open additional sites in the E.U. for VTI-210 (second Phase III; AAH). These will add to sites open in the U.S., U.K., and Spain. Next VTL is planning on obtaining regulatory approval to bring sites online in Austria and Ireland. VTL's management noted their optimism with respect to interactions with the FDA and written guidance related to CMC which is in line with their plans. Recall that VTL's lead product ELAD is an extracorporeal (outside of the body) liver support system that includes a biological component as well as a standardized bedside support unit.

The Phase III VTI-210 study provides an additional shot on goal for VTL. The Phase III VTI-208 study is designed to stratify alcohol-induced liver decompensation (AILD) patients as 1) "pure" acute alcoholic hepatitis (AAH), who have no underlying liver disease, 2) non-AAH AILD. While noting the binary risk of the VTI-208 study, we believe VTL has two shots on goal. In the event of a mixed result for VTI-208 (positive AAH cohort data), the VTI-210 Phase III study, targeted to enroll only AAH patients, could still provide a narrower market opportunity. Management commented that the VTI-210 study protocol entails an adaptive aspect, allowing for more than the initially targeted 150 patients. As the VTI-210 targeted population is encompassed by the VTI-208 trial, VTL anticipates significant enrollment will occur starting in 2015.

Reimbursement work underway. Management noted that, should ELAD be approved, their pricing would be in line with other orphan drugs. Unlike

Salveen Richter, CFA
212-319-3728
salveen.richter@suntrust.com

Raluca Pancratov, Ph.D.
212-303-4178
raluca.pancratov@suntrust.com

SEE PAGE 4 FOR REQUIRED DISCLOSURE INFORMATION

other orphan therapies, however, ELAD would be reimbursed in an inpatient setting, likely in the DRG system (for Medicare).

Vital Therapies, Inc

(NASDAQ: VTL)

Salveen Richter, CFA
(212) 319-3728
salveen.richter@suntrust.com

Consolidated Income Statement
($thousands, except per share data)

	FY 2013A	Mar Q1 2014A	Jun Q2 2014A	Sep Q3 2014A	Dec Q4 2014E	FY 2014E	Mar Q1 2015E	Jun Q2 2015E	Sep Q3 2015E	Dec Q4 2015E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E
Revenue																			
AILD (AAH + non-AAH) revenue													$ 58,019	$ 157,857	$ 330,636	$ 586,900	$ 808,299	$ 1,161,329	$ 1,535,491
AILD - U.S.													58,019	100,239	148,614	202,033	273,994	438,838	575,308
AILD - E.U.													-	57,618	177,954	310,909	438,858	567,410	748,519
AILD - ROW													-	-	4,068	73,958	95,447	155,080	211,664
FHF revenue													$ -	$ -	$ -	$ 1,657	$ 13,094	$ 39,436	$ 62,567
FHF - U.S.													-	-	-	1,657	11,378	24,615	31,396
FHF - E.U.													-	-	-	-	1,717	13,870	22,764
FHF - ROW													-	-	-	-	-	951	8,407
Total other revenue													$ -	$ -	$ -	$ -	$ -	$ -	$ -
Total Revenue													$ 58,019	$ 157,857	$ 326,568	$ 514,598	$ 725,947	$ 1,044,733	$ 1,377,988
COGS													-	47,357	82,659	135,368	180,707	240,153	319,612
Gross profit													58,019	110,500	243,909	379,230	545,240	804,580	1,058,376
Operating expense																			
R&D (GAAP)	21,787	9,219	9,125	10,244	11,013	39,601	11,101	11,250	10,752	10,002	43,105	40,222	45,221	50,023	55,223	60,231	65,162	70,023	75,212
SG&A (GAAP)	9,615	2,657	2,513	2,566	2,590	10,326	2,511	2,653	2,750	3,000	10,914	22,305	34,802	39,555	45,003	50,232	55,232	60,223	65,123
Total operating expense	31,402	11,876	11,638	12,810	13,603	49,927	13,612	13,903	13,502	13,002	54,019	62,527	80,023	89,578	100,226	110,463	120,394	130,246	140,335
Operating income (loss)	**(31,402)**	**(11,876)**	**(11,638)**	**(12,810)**	**(13,603)**	**(49,927)**	**(13,612)**	**(13,903)**	**(13,502)**	**(13,002)**	**(54,019)**	**(62,527)**	**(22,004)**	**20,922**	**143,683**	**268,767**	**424,846**	**674,334**	**918,041**
Interest income	5	2	4	5	6	17	6	5	5	9	25	8	7	23	46	103	229	501	960
Interest expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other income (expense), net	(15)	(2)	(5)	7	(5)	(5)	(2)	(5)	(5)	(5)	(17)	-	-	-	-	-	-	-	-
Revaluation of preferred stock warrant liabilities	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Revaluation of future purchase rights liabilities	(1,306)	1,128	1,472	-	-	2,600			-	-	-	-	-	-	-	-	-	-	-
Total other (expense) income, net	**(1,316)**	**1,128**	**1,471**	**12**	**1**	**2,612**	**4**	**0**	**0**	**4**	**8**	**8**	**7**	**23**	**46**	**103**	**229**	**501**	**960**
Net gain (loss)	**(32,718)**	**(10,748)**	**(10,167)**	**(12,798)**	**(13,602)**	**(47,315)**	**(13,608)**	**(13,903)**	**(13,502)**	**(12,998)**	**(54,011)**	**(62,519)**	**(21,997)**	**20,945**	**143,729**	**268,871**	**425,075**	**674,835**	**919,001**
Income Tax Provision	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	13,444	21,254	101,225	294,080
Net income (loss) attributable to common stockholders	**$ (39,085)**	**$ (13,818)**	**$ (16,251)**	**$ (12,798)**	**$ (13,602)**	**$ (56,469)**	**$ (13,608)**	**$ (13,903)**	**$ (13,502)**	**$ (12,998)**	**$ (54,011)**	**$ (62,519)**	**$ (21,997)**	**$ 20,945**	**$ 143,729**	**$ 255,427**	**$ 403,821**	**$ 573,610**	**$ 624,921**
GAAP EPS (basic and diluted)	**$ (74.86)**	**$ (1.49)**	**$ (0.91)**	**$ (0.59)**	**$ (0.62)**	**$ (3.61)**	**$ (0.62)**	**$ (0.63)**	**$ (0.61)**	**$ (0.53)**	**$ (2.39)**	**$ (2.73)**	**$ (0.95)**	**$ 0.83**	**$ 5.54**	**$ 8.49**	**$ 13.28**	**$ 18.68**	**$ 20.15**
Weighted shares outstanding basic and diluted	522	9,274	17,888	21,759	21,868	17,697	21,977	22,087	22,198	24,309	22,643	22,869	23,098	25,086	25,922	30,101	30,402	30,706	31,013
Margin Analysis:																			
Cost of product sales	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	30%	25%	23%	22%	20%	20%
Product gross margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	70%	75%	77%	78%	80%	80%
R&D (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	78%	32%	17%	12%	9%	7%	5%
SG&A (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	60%	25%	14%	10%	8%	6%	5%
Total operating expense	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	138%	57%	31%	21%	17%	12%	10%
Operating margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	52%	59%	65%	67%
Income tax provision	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	5%	5%	15%	32%
Net margin (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	44%	50%	56%	55%	45%
Y/Y change:																			
Total revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	172%	107%	58%	41%	44%	32%
ELAD revenue (AILD)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	172%	109%	78%	38%	44%	32%
ELAD revenue (FHF)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	690%	201%	59%
R&D (GAAP)	327%	N/A	N/A	N/A	N/A	82%	N/A	N/A	N/A	N/A	9%	-7%	12%	11%	10%	9%	8%	7%	7%
SG&A (GAAP)	114%	N/A	N/A	N/A	N/A	7%	N/A	N/A	N/A	N/A	6%	104%	56%	14%	14%	12%	10%	9%	8%
Total operating expense	228%	N/A	N/A	N/A	N/A	59%	N/A	N/A	N/A	N/A	8%	16%	28%	12%	12%	10%	9%	8%	8%
Operating income	228%	N/A	N/A	N/A	N/A	59%	N/A	N/A	N/A	N/A	8%	16%	-65%	-195%	587%	87%	58%	59%	36%
Net income (loss)	301%	N/A	N/A	N/A	N/A	44%	N/A	N/A	N/A	N/A	-4%	16%	-65%	-195%	586%	78%	58%	42%	9%
GAAP EPS (diluted)	228%	N/A	N/A	N/A	N/A	-95%	N/A	N/A	N/A	N/A	-34%	14%	-65%	-188%	564%	53%	57%	41%	8%
Shares outstanding - GAAP	122%	N/A	N/A	N/A	N/A	3290%	N/A	N/A	N/A	N/A	3876%	4280%	149%	40%	19%	38%	72%	36%	36%

Source: STRH Research, Company Reports

Company Description

Vital Therapies, Inc. is a biotherapeutic company, focused on developing a bio-artificial cell-based therapy for the treatment of acute liver failure. ELAD is Vital's product, is a human cell-based bio-artificial liver support system that operates outside the body or extracorporeal. The ELAD is designed to enable a patient's liver to regenerate to a functional state or to stabilize the patient until liver transplant.

Investment Thesis

VTL intends to be the first company to commercialize a "liver dialysis" product. Its bio-artificial cellular therapy ELAD is in two Phase III studies in alcohol-induced liver failure, with pivotal data from the lead program (VTI-208) expected in Q2/15. We note the binary nature of this key upcoming catalyst; however are optimistic based on signs of activity in prior studies and physician feedback.

Valuation and Risks

We arrive at our 12-month price target of $50 by means of a sum-of-the-parts discounted cash flow analysis, which ascribes $23.49/share from ELAD revenue from AILD (AAH population alone), $20.67/share from AILD (non-AAH population), $1.49x/share for ELAD from FHF and $4.30/share in cash, with the following assumptions: we do not assign a terminal value for ELAD in AILD, and assume cash flows through expiration of a key patent in 2027. We assign a 35% probability of success in AAH AILD, and a 30% probability of success in non-AAH AILD. We assign ELAD in FHF a 25% chance of success. We assign a WACC of 12% and a 1% terminal growth rate to ELAD in FHF.

The primary investment risks for Vital include the following:

· **Highly binary clinical risk:** More than ~145 patients have been treated with ELAD to date; while there have been hints of survival benefit with data available from ~100 of these patients, there remains a risk that ongoing pivotal studies do not achieve the primary endpoint of improvement in survival (potentially due to powering, patient baseline characteristics, better than anticipated clinical outcomes for control arm patients, and others).
· **Safety signal:** Data from studies conducted to date suggest that ELAD is generally safe and well tolerated. However, should any safety signal occur, or should any issues related to ELAD manufacturing, in particular cell packaging arise, Vital shares would be negatively impacted.
· **Manufacturing and regulatory risk:** ELAD would be, to the best of our knowledge, the first bio-artificial liver support cellular therapy to be potentially evaluated by the FDA. Without an established precedent, the company may require extensive CMC protocols and analyses for a likely FDA review. Any delays in establishing additional manufacturing facilities in the U.S., or lack of ability to deliver cellular cartridges in a timely fashion would negatively impact sales.
· **Commercial Risk:** While the company anticipates that a significant portion of the 30K U.S. (similar incidence in the E.U.) patients with AILD can be addressed with ELAD therapy, physicians may be reluctant to rapidly refer their patients to this treatment. Should the clinical benefit be marginal (albeit statistically significant and appropriate for approval), physicians may take a “wait and see” approach, treating first a small number of patients and looking for favorable outcomes. There remains a risk that the addressable market is smaller than modeled, penetration ramp is slower, and reimbursement is more burdensome than anticipated.
· **Financial risk:** Given the expenses associated with conducting clinical trials and launch of the product, we anticipate that Vital may have to issue additional equity through follow-on offerings.

Companies Mentioned in This Note

Vital Therapies Inc. (VTL, $21.89, Buy)

Analyst Certification

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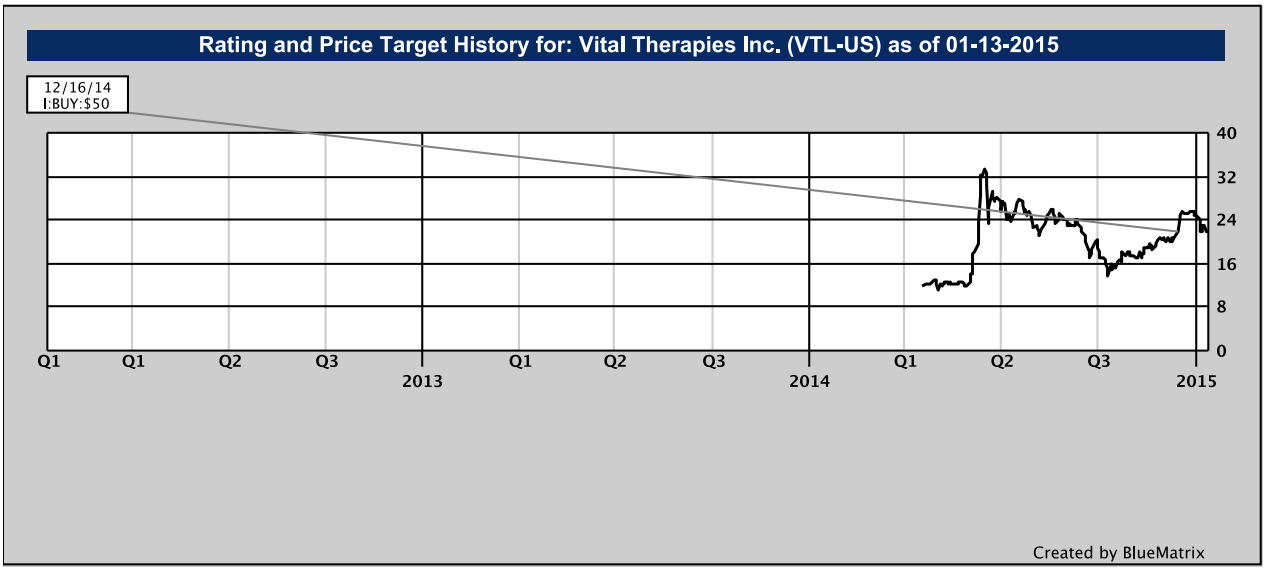

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*Total return (price appreciation + dividends)
**Price targets are within a 12-month period, unless otherwise noted
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Legend for Rating and Price Target History Charts:
D = drop coverage
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T = transfer coverage

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Sell/Reduce	7	1.29%	Sell/Reduce	0	0.00%

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