Vital Therapies Inc. (VTL)

Q4 EPS: Pivotal Data Now Expected In Q3, Filing Still On Track for H1/16

Buy

Price Target: $50.00
Prior: $50.00

Price (Mar. 19, 2015)	$27.37
52-Wk Range	$33.31-$11.21
Market Cap ($M)	$594
ADTV	64,713
Shares Out (M)	21.7
Short Interest Ratio/% Of Float	4.7%
TR to Target	82.7%

Cash Per Share	$4.13
Total Debt	$0.0
Cash And Equivalents ($M)	$102.0

	2014E	2015E		2016E	
		Curr.	Prior	Curr.	Prior
Revenue ($M)					
FY	$0A	$0	$0	$0	--
EPS Adjusted					
FY	($3.58)A	($2.34)	($2.39)	($2.85)	--
P/E	NM	NM		NM	
Consensus Rev					
FY	$0	$0	$0	--	
Consensus EPS Adjusted					
FY	($3.58)A	($2.54)	($2.54)	($2.21)	--
FYE Dec					

What's Incremental
VTL reported Q4/14 EPS of $(0.59), in line with consensus and higher than STRH of $(0.62). Topline data from the VTI-208 Phase III study of lead asset ELAD for acute alcoholic liver decompensation (AILD) are now expected in Q3/15 vs. Jun' 15 previously, with filing guidance unchanged (H1/16). VTI-208 patient baseline characteristics will be featured in a presentation at EASL (Apr 22-26, Vienna). We remain optimistic on ELAD's prospects for alcohol-induced liver diseases, while acknowledging the binary nature of this play, and note VTL's two shots on goal with the VTI-208 and 210 studies.

Timelines for the pivotal study readout slightly pushed back, VTL taking the more conservative route. The VTI-208 Phase III study is evaluating overall survival (OS) at day 91, in AILD patients treated with ELAD or standard of care (steroids, pentoxyfilline). Per previous guidance and our discussions with management, topline results were expected in Q2/15 (potentially ~June 2015). The 91-day follow-up period for the last of the 203 enrolled patients (study accrual completed on Jan 31) falls in "early May". VTL had previously planned for data analysis to yield topline results "soon after" 91 days of follow-up for the last patient, in "mid-May", before the database lock-up. The company discussed this plan with the FDA and based on the agency's feedback elected to perform the analysis after the full database lock-up. Thus, data analysis and the announcement of topline results are expected in Q3/15. The announcement will detail: 1) if the VTI-208 met its primary endpoint, and 2) preliminary safety observations. Filing of a BLA remains on track for H1/16 and a full presentation of these data will likely be featured at a conference in the fall (we believe potentially AASLD). While we reiterate the binary risk of the VTI-208 study, we view the company's approach as conservative and continue to model for a potential approval in late 2016 and slow patient ramp-up in 2017.

We are looking towards color on patient baseline characteristics at the EASL conference. Baseline details for VTI-208 study participants will be featured in a poster presentation at the European Association for the Study of the Liver (EASL) to take place on April 23 (abstract body published online Apr 8, ~4.00am ET). The trial is designed to stratify AILD patients as 1) "pure" acute alcoholic hepatitis (AAH), who have no underlying liver disease, 2) non-AAH AILD. A large enough AAH subset could allow for analyses and evaluation of trends towards potential clinical benefit for ELAD. We believe VTL may have a second shot on goal if the VTI-208 study has mixed results, but the AAH patient subset is suggestive of ELAD activity, to be confirmed by the ongoing Phase III VTI-210 study (slated to enroll only AAH patients).

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SEE PAGE 6 FOR REQUIRED DISCLOSURE INFORMATION

Pipeline updates entailed updated timelines for the VTI-210 trial and color on patient enrollment. The design of the Phase III VTI-210 was amended to allow for enrollment of AAH patients that failed the standard of care, rather than steroids, as previously stated. This change was spurred by the failure of the consortium-sponsored STOPAH ("Steroids or Pentoxyfilline for Alcoholic Hepatitis") trial to demonstrate a survival benefit associated with steroid treatment in AAH patients. With enrollment of the VTI-208 study completed, patient accrual is expected to pick up pace for the VTI-210 study (targeted 150 patients at >40 sites). The decision to delay analyses until database lockup results in a timeline change for the readout of VTI-210 to early 2017 (vs. 2016 previously). 6 patients had been enrolled as of 03/18/15 and 18 sites are open for enrollment in the U.S. and the U.K. All targeted study sites (including in Germany) are expected to come online by YE15. The Phase II VTI-212 study is targeting accrual of 40 patients with fulminant hepatic failure. As of 03/18/15, 4 patients had been enrolled and topline results are expected in 2016.

Changes to model post Q4 EPS. VTL reported $10.8M Q4 R&D expense, in line with our $11M estimate. Q4 SG&A came in at $3.1M, versus our $2.5M estimate. The company ended the year with $102M in cash, expected to provide sufficient runway now into Q3/16 (versus Q4/16 previously). However, should the 208 results not support BLA filing, VTL may focus on preserving cash. Given the current OpEx trajectory and the company's expected cash runway guidance, we are increasing our FY15+ OpEx estimates. Our FY15 R&D estimate is increased to $43.7M from $43.1M previously, while our FY15 SG&A estimate is increased to $13.3M from $10.9M previously. Our FY15 EPS estimate is now $(2.34) versus $(2.39) previously on adjusted share count.

Figure 1: Q4/14 Variance Table

($thousands, except per share data)

	Dec Q4 2014A	Dec Q4 2014E	Variance A-E	Variance %	Y/Y %	Q/Q %
Revenue						
Total other revenue	-	-				
Total Revenue	$ -	$ -	$ -	N/A	N/A	N/A
Operating expense			-			
R&D (GAAP)	10,891	11,013	(122)	-1%	42%	19%
SG&A (GAAP)	3,127	2,590	537	17%	21%	24%
Total operating expense	14,018	13,603	415	3%	37%	20%
Operating income (loss)			-			
Interest income	-	6	(6)			
Interest expense	-	-	-			
Other income (expense), net	-	(5)	5			
Revaluation of preferred stock warrant liabilities	64	-	64	100%		
Revaluation of future purchase rights liabilities	-	-				
Total other (expense) income, net	**64**	**1**	63	98%	611%	-96%
Net gain (loss)	(13,954)	(13,602)	(352)	3%	36%	37%
Income Tax Provision	-	-				
Amortziation of deemed dividend	-	-				
Accretion to redemption value of senior redeemable conv	-	-				
Net income (loss) attributable to common stockhold	**$ (13,954)**	**$ (13,602)**	(352)	3%	12%	-14%
			-			
GAAP EPS (basic and diluted)	**$ (0.59)**	**$ (0.62)**	0	-6%	-97%	-35%
			-			
Weighted shares outstanding			-			
basic and diluted	23,690	21,868	1,822	8%	4060%	32%

Source: STRH analysis and Company reports

Figure 2: Upcoming Expected Milestones

Product	Indication	Timing	Milestone
ELAD	Alcohol-induced liver decompensation (AILD)	April 8, 2015	Online publication of EASL Abstracts
ELAD	Alcohol-induced liver decompensation (AILD)	April 23, 2015	Poster presentation of baseline VTI-208 patient data
ELAD	**Alcohol-induced liver decompensation (AILD)**	**Q3 2015**	**Phase III VTI-208 data**
ELAD	Alcohol-induced liver decompensation (AILD)	July 8-11	Presentation of molecular data on C3A cells
ELAD	Acute alcoholic hepatitis (AAH)	YE 2015	All 40 targeted sites are online
ELAD	Alcohol-induced liver decompensation (AILD)	H1 2016	ELAD filing for AILD
ELAD	**Alcohol-induced liver decompensation (AILD)**	**YE 2016**	**U.S. Approval for AILD**
ELAD	Fulminant hepatic failure (FHF) or surgery-induced liver failure (SILF)	2016	Phase II VTI-212 data
ELAD	**Acute alcoholic hepatitis (AAH)**	**Early 2017**	**Phase III VTI-210 data**

Source: STRH analysis and Company reports

Revision Table

($thousands, except per share data)	FY15E		FY16E		FY17E		FY18E		FY19E		FY20E		FY21E		FY22E		FY23E	
	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior
Revenue																		
AILD (AAH + non-AAH) revenue	-	-	-	-	58,019	58,019	157,857	157,857	330,636	330,636	586,900	586,900	808,299	808,299	1,161,329	1,161,329	1,535,491	1,535,491
AILD - U.S.	-	-	-	-	58,019	58,019	100,239	100,239	148,614	148,614	202,033	202,033	273,994	273,994	438,838	438,838	575,308	575,308
AILD - E.U.	$ -	$ -	$ -	$ -	$ -	$ -	$ 57,618	$ 57,618	$ 177,954	$ 177,954	$ 310,909	$ 310,909	$ 438,858	$ 438,858	$ 567,410	$ 567,410	$ 748,519	$ 748,519
AILD - ROW	-	-	-	-	-	-	-	-	4,068	4,068	73,958	73,958	95,447	95,447	155,080	155,080	211,664	211,664
FHF revenue	-	-	-	-	-	-	-	-	-	-	1,657	1,657	13,094	13,094	39,436	39,436	62,567	62,567
FHF - U.S.	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 1,657	$ 1,657	$ 11,378	$ 11,378	$ 24,615	$ 24,615	$ 31,396	$ 31,396
FHF - E.U.	-	-	-	-	-	-	-	-	-	-	-	-	1,717	1,717	13,870	13,870	22,764	22,764
FHF - ROW	-	-	-	-	-	-	-	-	-	-	-	-	-	-	951	951	8,407	8,407
Total other revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	$ -	$ -	$ -	$ -	$ 58,019	$ 58,019	$ 157,857	$ 157,857	$ 326,568	$ 326,568	$ 514,598	$ 514,598	$ 725,947	$ 725,947	$ 1,044,733	$ 1,044,733	$ 1,377,988	$ 1,377,988
COGS	-	-	-	-	-	-	47,357	47,357	82,659	82,659	135,368	135,368	180,707	180,707	240,153	240,153	319,612	319,612
Gross profit	-	-	-	-	58,019	58,019	110,500	110,500	243,909	243,909	379,230	379,230	545,240	545,240	804,580	804,580	1,058,376	1,058,376
Operating expense																		
R&D (GAAP)	43,785	**43,105**	**48,222**	**40,222**	**52,221**	**45,221**	**57,023**	**50,023**	**61,223**	**55,223**	**67,231**	**60,231**	**71,162**	**65,162**	**75,023**	**70,023**	**79,212**	**75,212**
SG&A (GAAP)	13,350	10,914	22,305	22,305	34,802	34,802	39,555	39,555	45,003	45,003	50,232	50,232	55,232	55,232	60,223	60,223	65,123	65,123
Total operating expense	57,135	**54,019**	**70,527**	**62,527**	**87,023**	**80,023**	**96,578**	**89,578**	**106,226**	**100,226**	**117,463**	**110,463**	**126,394**	**120,394**	**135,246**	**130,246**	**144,335**	**140,335**
Operating income (loss)	**(57,135)**	(54,019)	(70,527)	(62,527)	(29,004)	(22,004)	13,922	20,922	137,683	143,683	261,767	268,767	418,846	424,846	669,334	674,334	914,041	918,041
Total other (expense) income, net	9	**8**	**7**	**8**	**5**	**7**	**19**	**23**	**39**	**46**	**93**	**103**	**215**	**229**	**481**	**501**	**935**	**960**
Net gain (loss)	**(57,126)**	(54,011)	(70,520)	(62,519)	(28,998)	(21,997)	13,941	20,945	137,722	143,729	261,861	268,871	419,061	425,075	669,816	674,835	914,976	919,001
Income Tax Provision	-	-	-	-	-	-	-	-	-	-	**13,093**	**13,444**	**20,953**	**21,254**	**100,472**	**101,225**	**292,792**	**294,080**
Amortization of deemed dividend	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Accretion to redemption value of senior redeem	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) attributable to common stoc	$ (57,126)	$ (54,011)	$ (70,520)	$ (62,519)	$ (28,998)	$ (21,997)	$ 13,941	$ 20,945	$ 137,722	$ 143,729	$ 248,768	$ 255,427	$ 398,108	$ 403,821	$ 569,343	$ 573,610	$ 622,184	$ 624,921
GAAP EPS (basic and diluted)	$ (2.34)	$ (2.39)	$ (2.85)	$ (2.73)	$ (1.16)	$ (0.95)	$ 0.52	$ 0.83	$ 4.95	$ 5.54	$ 7.76	$ 8.49	$ 12.30	$ 13.28	$ 17.42	$ 18.68	$ 18.85	$ 20.15
Weighted shares outstanding basic and diluted	24,487	22,643	24,732	22,869	24,979	23,098	26,986	25,086	27,842	25,922	32,039	30,101	32,360	30,402	32,683	30,706	33,010	31,013

Source: STRH Research, Company Reports

Vital Therapies, Inc

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

	FY 2013A	FY 2014A	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
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	39,479	11,233	11,350	10,952	10,250	43,785	48,222	52,221	57,023	61,223	67,231	71,162	75,023	79,212
SG&A (GAAP)	9,615	10,863	3,289	3,312	3,345	3,404	13,350	22,305	34,802	39,555	45,003	50,232	55,232	60,223	65,123
Total operating expense	31,402	50,342	14,522	14,662	14,297	13,654	57,135	70,527	87,023	96,578	106,226	117,463	126,394	135,246	144,335
Operating income (loss)	**(31,402)**	**(50,342)**	**(14,522)**	**(14,662)**	**(14,297)**	**(13,654)**	**(57,135)**	**(70,527)**	**(29,004)**	**13,922**	**137,683**	**261,767**	**418,846**	**669,334**	**914,041**
Total other (expense) income, net	**(1,316)**	**2,675**	**4**	**1**	**0**	**4**	**9**	**7**	**5**	**19**	**39**	**93**	**215**	**481**	**935**
	-														
Net gain (loss)	**(32,718)**	**(47,667)**	**(14,518)**	**(14,661)**	**(14,297)**	**(13,650)**	**(57,126)**	**(70,520)**	**(28,998)**	**13,941**	**137,722**	**261,861**	**419,061**	**669,816**	**914,976**
Income Tax Provision	-	-	-	-	-	-	-	-	-	-	-	13,093	20,953	100,472	292,792
Net income (loss) attributable to common stockholders	**$ (39,085)**	**$ (56,821)**	**$ (14,518)**	**$ (14,661)**	**$ (14,297)**	**$ (13,650)**	**$ (57,126)**	**$ (70,520)**	**$ (28,998)**	**$ 13,941**	**$ 137,722**	**$ 248,768**	**$ 398,108**	**$ 569,343**	**$ 622,184**
GAAP EPS (basic and diluted)	**$ (74.86)**	**$ (3.58)**	**$ (0.61)**	**$ (0.61)**	**$ (0.59)**	**$ (0.52)**	**$ (2.34)**	**$ (2.85)**	**$ (1.16)**	**$ 0.52**	**$ 4.95**	**$ 7.76**	**$ 12.30**	**$ 17.42**	**$ 18.85**
Weighted shares outstanding basic and diluted	522	16,054	23,808	23,927	24,047	26,167	24,487	24,732	24,979	26,986	27,842	32,039	32,360	32,683	33,010

Margin Analysis:

Cost of product sales	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	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	90%	36%	19%	13%	10%	7%	6%
SG&A (GAAP)	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	150%	61%	33%	23%	17%	13%	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	51%	58%	64%	66%
Income tax provision	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	42%	48%	55%	54%	45%

Y/Y change:

Total revenue	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	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	690%	201%	59%
R&D (GAAP)	327%	81%	N/A	N/A	N/A	N/A	11%	10%	8%	9%	7%	10%	6%	5%	6%
SG&A (GAAP)	114%	13%	N/A	N/A	N/A	N/A	23%	67%	56%	14%	14%	12%	10%	9%	8%
Total operating expense	228%	60%	N/A	N/A	N/A	N/A	13%	23%	23%	11%	10%	11%	8%	7%	7%
Operating income	228%	60%	N/A	N/A	N/A	N/A	13%	23%	-59%	-148%	889%	90%	60%	60%	37%
Net income (loss)	301%	45%	N/A	N/A	N/A	N/A	1%	23%	-59%	-148%	888%	81%	60%	43%	9%
GAAP EPS (diluted)	228%	-95%	N/A	N/A	N/A	N/A	-35%	22%	-59%	-144%	858%	57%	58%	42%	8%
Shares outstanding - GAAP	122%	2975%	N/A	N/A	N/A	N/A	4200%	4637%	169%	51%	28%	35%	102%	33%	33%

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 $23.71/share from ELAD revenue from AILD (AAH population alone), $21.11/share from AILD (non-AAH population), $1.33/share for ELAD from FHF and $4.13/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, $27.37, Buy)

Analyst Certification

I, Salveen Richter , hereby certify that the views expressed in this research report accurately reflect my personal views about the subject company(ies) and its (their) securities. I also certify that I have not been, am not, and will not be receiving direct or indirect compensation in exchange for expressing the specific recommendation(s) in this report.

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SunTrust Robinson Humphrey, Inc. makes a market in the following companies at the time of this report: VTL, VTL-US

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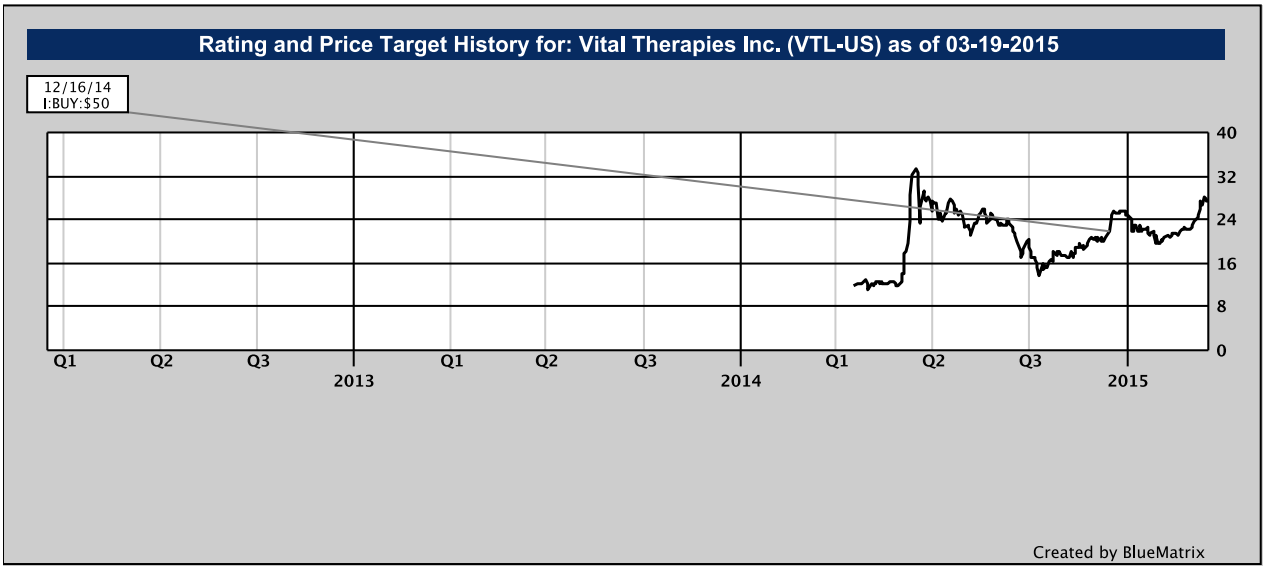

STRH Ratings System for Equity Securities

3 designations based on total returns* within a 12-month period**

- **Buy** – total return ≥ 15% (10% for low-Beta securities)***
- **Reduce** – total return ≤ negative 10% (5% for low Beta securities)
- **Neutral** – total return is within the bounds above
- **NR** – NOT RATED, STRH does not provide equity research coverage
- **CS** – Coverage Suspended

*Total return (price appreciation + dividends)
**Price targets are within a 12-month period, unless otherwise noted
***Low Beta defined as securities with an average Beta of 0.8 or less, using Bloomberg's 5-year average Beta

Legend for Rating and Price Target History Charts:
D = drop coverage
I = initiate coverage
T = transfer coverage

SunTrust Robinson Humphrey ratings distribution (as of 03/20/2015):

Coverage Universe			Investment Banking Clients Past 12 Months		
Rating	**Count**	**Percent**	**Rating**	**Count**	**Percent**
Buy	280	52.73%	Buy	100	35.71%
Neutral	244	45.95%	Neutral	43	17.62%
Sell/Reduce	7	1.32%	Sell/Reduce	2	28.57%

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