# **US Equity Research**

30 January 2015

#### **BUY**

unchanged

#### PRICE TARGET US\$35.00

unchanged

Price (30-Jan) US\$20.36 Ticker VTL-NASDAQ

52-Week Range (US\$): 10.66 - 35.20
Avg Daily Vol (M): 72.2
Shares Out. (M): 21.8
Market Cap (US\$M): 443

FYE Dec	2013A	2014E	2015E
Revenue (US\$M)	0.0	0.0	0.0
EPS Adj&Dil (US\$)	(1.85)	(3.61)	(2.62)

Quarterly Revenue	Q1	Q2	Q3	Q4
2013A	0.0	0.0	0.0	0.0
2014E	0.0A	0.0A	0.0A	0.0
2015E	0.0	0.0	0.0	0.0

Quarterly EPS Adj&Dil	Q1	Q2	ŲЗ	Q4
2013A	(0.49)	(0.34)	(0.43)	(0.59)
2014E	(24.49)A	(0.91)A	(0.59)A	(0.60)
2015E	(0.75)	(0.79)	(0.83)	(0.87)



Vital Therapies is a biotherapeutic company focused on its ELAD system for treatment of acute liver disease and failure.

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# **Company Update**

# VTI-208 enrollment complete, top-line Phase 3 data expected Q2/15

#### VTI-208 enrollment complete, data by end of Q2/15

The VTI-208 Phase 3 trial in patients with alcohol-induced liver decompensation (AILD) reached enrollment completion (n = 200), which is a positive move forward towards expected data readout by the end of Q2/15. We continue to expect positive data for the ELAD technology in demonstrating 90-day survival benefit due to a refined inclusion criteria that only targets patients who have regenerable liver and are not expected to die imminently. Additionally, Vital has also powered the Phase 3 study at 90% with p  $\leq$  0.01, and 95% for p  $\leq$  0.05 to detect a difference in median survival of  $\sim$ 50 days (122 vs. 68 days), which should be suitable considering the fact that the prior Phase 2B trial had a median survival of >100 days vs. 65 days in the control arm.

# Estimate ~\$564M potential peak sales in AILD patients

We model ~\$564M peak sales for Vital in 2021 based on a market build of patients receiving treatment for acute alcoholic hepatitis, estimating a patient population of ~15,000 in 2013. We assume a peak market share of ~28% and an estimated treatment cost of \$100,000 in 2017 when the product launches to reach our peak sales. However, if results are positive, we believe our market share could significantly increase, particularly due to the recent data from the English group (STOPAH trial) demonstrating no survival benefit with current standard of care with steroids or pentoxifylline.

#### VTL moves forward in acute alcoholic hepatitis, expect data by 2016

We expect top-line data for both VTI-210, a Phase 3 study evaluating the ELAD technology in severe acute alcoholic hepatitis (AAH) patients, by 2016. The trial plans on enrolling 150 patients, with overall survival at day 91 to be the primary endpoint. In combination with fulminant liver failure (VTI-212), we value the total market opportunity to be substantial at ~\$2.5 - \$3B. We are confident in the success of this technology, considering the fact that Vital's robust ELAD system from human liver cells provides a full complement of enzymes and proteins vs. prior mechanical approaches that were unsuccessful in demonstrating survival outcomes.

#### Maintain \$35 price target, BUY recommendation

We maintain our \$35 PT with a BUY recommendation given the current on-track enrollment of VTI-208, with expected positive data by end of 2Q15. Our price target is based on a probability-adjusted NPV valuation.

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Figure 1: VTL income statement

Revenues	2013A	Mar-14	A	Jun-14A	Sep	-14A	Dec-14E		2014E	2015E		2016E	2017E		2018E	2019E		2020E
AILD												-	79,591		286,980	447,563		493,626
SILF												-	10,612		38,264	47,740		55,691
FHF												-	26,015		93,803	117,033		136,524
Total												-	116,218		419,047	612,335		685,841
Income Statement	2013A	Mar-14	A	Jun-14A	Sep	-14A	Dec-14E		2014E	2015E		2016E	2017E		2018E	2019E		2020E
Revenue																		
Total Revenue	-			-		•	-		-	-		-	116,218		419,047	612,335		685,841
Cost of Revenue	-	-		-		-	-		-	-		-	17,433	ı	62,857	91,850		102,876
Gross Profit	•			•		•	-		•	•		-	98,785		356,190	520,485		582,965
Operating Expenses																		
Stock-based Compensation in SGA	537	20	2	247			273	7	722	1,235		1,482	3,225		3,566	4,078		4,821
Stock-based Compensation in R&D	411	15	4	247			273	7	675	1,235		1,482	1,743		1,928	2,204		2,606
Research & Development	21,376	9,21	9	9,125	10	,244	9,287	7	37,875	41,521		37,045	43,582		40,480	38,577		37,790
General & Administrative	9,078	2,65	7	2,513	2	,566	3,820	7	11,556	17,762		34,082	38,352		50,118	65,030		84,701
Total Operating Expense	31,402	11,87	6	11,638	12	,810	13,107		49,431	59,283		71,127	81,934		90,598	103,607		122,491
EBITDA																		
Operating Income		(11,87	6)	(11,638)	(12	,810)	(13,107)		(49,431)	(59,283)		(71,127)	16,852		265,592	416,878		460,474
Interest Income	5		2															
Interest income	0		2	-		-	-		-	-		-	-		-	-		-
Other (expense) income, net	(15)	- (1	2)	-		-	-		-	-		-	-		-	-		-
Revaluation of preferred stock warrant liabilities	(13)	- (-	۷)	_		-	-		-	-		-	-		-	-		-
Revaluation of future purchase rights liabilities	(1,306)	1,12	0	1,471		12	-		-	-		-	-		-	-		-
Pretax income	(32,718)	(10,74		(10,167)	(12	,798)	(13,107)		(49,431)	(59,283)		(71,127)	16,852		265,592	416,878		460,474
Provision for Income Taxes									_				6.235		98,269	154,245		170.375
Tax Rate	37%	37'	٥/	37%		37%	37%		37%	37%		37%	37%		37%	37%		37%
Tax Rate	31%	31	70	31%		31%	3170		3176	31%		31 %	31%		3170	3170		31%
Net Income	(32,718)	(10,74	B)	(10,167)	(12	,798)	(13, 107)		(49,431)	(59,283)		(71,127)	10,617		167,323	262,633		290,099
Amortization of deemed dividend		(2)	2)															
Accretion to redemption value of convert preferred		(3,04		(6,084)														
Net Income (Non-GAAP)	(39,085)	(13,81	B)	(16,251)	(12	,798)	(13,107)	,	(55,974)	(59,283)		(71,127)	10,617		167,323	262,633		290,099
GAAP EPS (Diluted)	\$ (1.55)		*	(0.91)	•		\$ (0.60)		(3.61) \$	,		(2.61)	\$ 0.39	\$	6.13	\$ 9.63	\$	10.63
Non-GAAP EPS (Diluted)	\$ (1.85)	\$ (24.4		(0.91)			\$ (0.60)		(3.61)			(2.61)	0.39	\$	6.13	\$ 9.63	_	10.63
Basic Weighted Average Shares	 21,116	56		17,889		1,759	21,759		15,493	22,636	· ·	27,278	 27,278		27,278	 27,278		27,278
Diluted Weighted Average Shares		56	64	17,889	2	1,759	21,759	•	15,493	22,636		27,278	27,278		27,278	27,278		27,278

Source: Canaccord Genuity Estimates



Figure 2: VTL Valuation

	Peak Sales	Year	<b>Current Value</b>	Probability	Value Per Share
US					
AILD	\$564	2021	\$867	60%	\$25
SILF	\$158	2021	\$266	25%	\$3
FHF	\$64	2021	\$109	25%	\$1
EU - Royalty	l				
AILD	\$90	2021	\$215	45%	\$5
SILF	\$23	2021	\$55	25%	\$1
FHF	\$9	2021	\$21	25%	\$0
Total			\$1,532		\$35
Risk Free Rate	2%				
Beta	1.45			Shares (M)	21
Risk Premium	6%				
Discount Rate	11%				

Source: Canaccord Genuity Estimates



# **Appendix: Important Disclosures**

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# Target Price / Valuation Methodology:

Vital Therapies - VTL

Our price target is based on a probability-adjusted NPV valuation.

#### Risks to achieving Target Price / Valuation:

Vital Therapies - VTL

Risks to our outlook and price target include the following: Vital Therapies' clinical studies may fail, requiring additional clinical trials and further capital; clinical trials may be terminated altogether, decreasing the overall value of the company's pipeline; competitors may attain the technology surrounding the ELAD system, increasing the likelihood of a competitive/generic product. Even if the ELAD system is approved, resulting revenues may be below investor expectations due to lack of efficacy, competition, complexity, or all three. Safety issues may also emerge after FDA approval that could limit the usage of the ELAD system, also reducing sales. Competitors could gain access to the ELAD systems technology and potentially create a competitor product. Vital Therapies' keeps much of its IP as trade secrets, creating the opportunity for competitors to poach employees for intelligence. In addition, competitors may be able to gather ELAD's technology through reverse engineering the ELAD system after appropriating it from a hospital. Congress has recently questioned high pricing for biotech drugs, which could become a trend, creating broad downward pressure across the biotech sector. Although we believe oncology drugs will receive less pricing pressure due to the seriousness of the disease, lawmakers may eventually make public calls for lower pricing.

#### **Distribution of Ratings:**

# Global Stock Ratings (as of 01/30/15)

Rating	Coverage	e Universe	IB Clients
	#	%	%
Buy	597	58.30%	32.83%
Hold	331	32.32%	14.50%
Sell	45	4.39%	2.22%
Speculative Buy	51	4.98%	58.82%
	1024*	100.0%	

<sup>\*</sup>Total includes stocks that are Under Review

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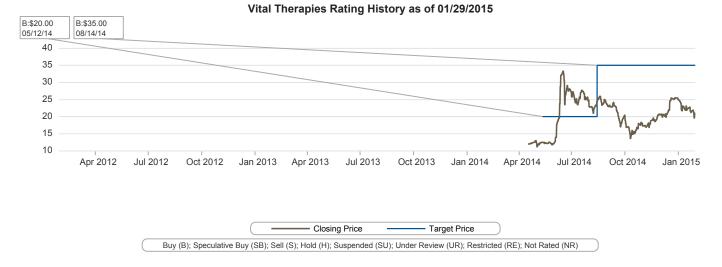
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