US Equity Research

27 April 2015

BUY

Ticker

unchanged

PRICE TARGET US\$35.00

unchanged Price (27-Apr)

US\$28.24 VTL-NASDAQ

52-Week Range (US\$): Avg Daily Vol (M): Shares Out. (M): Market Cap (US\$M): 10.66 - 35.20 68.3 21.8 614

FYE Dec	2013A	2014A	2015E
Revenue (US\$M)	0.0	0.0	0.0
EPS Adj&Dil (US\$)	(1.85)	(3.56)	(2.56)

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

Quarterly EPS Adj&Dil	Q1	Q2	QЗ	Q4
2013A	(0.49)	(0.34)	(0.43)	(0.59)
2014A	(24.49)	(0.91)	(0.59)	(0.59)
2015E	(0.73)	(0.77)	(0.81)	(0.85)



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

Phase 3 VTI-208 baseline characteristics representative of AILD population, tight standard deviation, positive

Baseline characteristics reflective of AILD patients with high 90-day mortality

VTL presented a poster today on the baseline characteristics of patients in the VTI-208 trial with tight standard deviations, which we believe is reflective of their target AILD patient population. First, the mean Model of End-stage Liver Disease (MELD) score was 27.2 +/- 3.8 (representing a 90-day survival rate of 49% [64% - 34%]) and the Maddrey Discrimination Function was 72.9 +/- 25 (scores of >32 indicate severe alcoholic hepatitis), which we believe captures AILD patients with high mortality rate. Second, mean INR was 2.0 +/- 0.5 and platelets of 152 +/- 82.4, which demonstrates that these patients are not actively bleeding and will not die imminently, a positive in preventing very sick patients that can muddle the survival endpoints. Finally, the average liver size was 19.1 cm +/- 4.4 (well above 10 cm) and Tbili was 25.0 +/- 9.2, which demonstrates that these patients are not spontaneously getting better, decreasing another confounding variable around the ELAD technology.

Expression of CYP450 liver enzymes high in ELAD system, affirms mechanism of action

Specific CYP450 enzymes, including CYP1A2, 2C9, 2D6, 2C19, and 3A4, were highly expressed in the ELAD cartridges vs. monolayer cultures, a positive in clarifying the mechanism of action for AlLD livers since these enzymes are responsible for liver detoxification. Additionally, up-regulation of these enzymes (CYP11B2, CYP2A6, CYP2A7, CYP2C19, and CYP1A2) was observed after the ELAD cells were given to subject treatments, illustrating that the activity is not seen only in vitro, but in patients as well.

Expect top-line data for VTI-208 3Q15, significant catalyst

Top-line data results for VTI-208 expected to be released in 3Q15, a significant catalyst for the stock if results remain positive. Given the baseline characteristics that were presented today at EASL conference, we have higher conviction for positive data in the ELAD technology in demonstrating 91-day survival benefit vs. placebo. We maintain our BUY position and \$35 price target.

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The recommendations and opinions expressed in this research report accurately reflect the research analyst's personal, independent and objective views about any and all the companies and securities that are the subject of this report discussed herein.

Figure 1: Baseline characteristics of VTI-208



A RANDOMIZED, OPEN-LABEL, MULTICENTER, CONTROLLED STUDY TO ASSESS SAFETY AND EFFICACY OF ELAD®, A HUMAN CELL-BASED BIO-ARTIFICIAL LIVER SUPPORT SYSTEM, IN SUBJECTS WITH ALCOHOL-INDUCED LIVER DECOMPENSATION (AILD)

Rob A. Ashley*¹, Jan Stange², Andrew J. Henry³, Zheng Li¹

¹Research & Development, ²Medical Affairs, ³Clinical Operations, Vital Therapies, Inc., San Diego, United State:



BACKGROUND

Treatment options for patients with AILD are limited, leading to significant morbidity and mortality. ELAD is designed to provide liver support continuously for up to 10 days to a subject with compromised liver function and allow time for the native liver to regenerate by circulating patient plasma through a hollow fiber cartridge containing metabolically active, immortalized VTL C3A human liver cells.

STUDY OBJECTIVE

Based on preliminary findings from a subset of subjects with AILD enrolled in a prior Phase 2 study (VTI-206), the aim is to provide data on the safety and clinical utility of ELAD in a larger, prospectively defined population with AILD. The primary endpoint will evaluate overall survival of subjects with a clinical diagnosis of AILD up to at least Study Day 91 The secondary objectives are to determine the proportion of survivors at Study Days 28 and 91. Exploratory objectives are to evaluate the ability of ELAD to stabilize liver function, measured using the Model of End-stage Liver Disease (MELD)-based time to progression (TTP) up to Study Day 91, and the proportion of progression-free survivors (PFS) up to Study Days 28 and 91. The objective of this poster is to provide an overview of study enrollment and study population characteristics for this randomized trial.

MATERIALS & METHODS

Eligibility requirements (Table 1) were established in order to replicate the AILD population in VTI-206. Target age based on the VTI-206 population is 45-55 and baseline target MELD is 27-29 for the current study. A total of 200 evaluable subjects meeting these requirements will be randomly assigned in a 1:1 ratio to receive either standard of care treatmer for All D plus treatment with the FLAD System (FLAD group) or standard of care of treatment for AILD alone (Control group). ELAD treatment will take place for a maximum of five 24-hour periods unless any of the discontinuation criteria are met. It was anticipated that enrollment would take approximately 2 years.

Source: EASL poster presentation

Table 1. Key inclusion/exclusion criteria

Inclusion criteria

Exclusion criteria

RESULTS

Graph 1. # of subjects enrolled by site

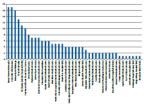


Table 3. Baseline demographics

Parameters		
Age – Mean±SD	45.6±10.0	
(range, unit)	(25, 68, years)	202
Gender		
Male - n (%)	118 (59%)	200
Female - n (%)	82 (41%)	200
Race		
White - n (%)	173 (86.5%)	200
Other - n (%)	27 (13.5%)	200
HE stage 0 - n (%)	103 (53.4%)	193
HE stage 1&2 - n (%)	77 (39.9%)	193
HE stage 3&4 - n (%)	13 (6.7%)	193
	19.1±4.4	
Liver Size – Mean±SD (range, unit)	(10, 29, cm)	171
Mean/Median time since enrollment		
(as of May 1, 2015)	374/360 days	203

Table 2. The top 10 sites by enrollment:

Site Name	Subjects Enrolled
University of Minnesota	17
Emory University	17
University of Pittsburgh	16
Drexel University	13
Sir Charles Gairdner Hospital-Perth	11
Southern California GI and Liver Center	10
NYU Medical Center	8
Beth Israel Deaconess Medical Center	7
University of Arkansas	7
Piedmont Atlanta Hospital	7

Table 4. Baseline labs

Parameters	Mean	SD	n
MELD	27.2	3.8	196
MADDREY	72.9	25.0	197
PT (secs)	22.4	5.2	198
INR	2.0	0.5	196
Total Bilirubin (mg/dl)	25.0	9.2	196
Direct Bilirubin(mg/dl)	16.0	7.3	165
Creatinine (mg/dl)	1.0	0.7	196
ALB (g/dl))	2.7	0.7	196
ALT (IU/L)	61.8	42.3	198
AST (IU/L)	134.7	73.8	196
Sodium (mmol/l)	133.9	5.5	198
WBC (X10 ³ /mm ³)	14.5	7.4	198
HCT (%VOL)	29.5	5.9	197
PLT (X10 ³ /mm ³)	152.5	82.4	196

The first subject was enrolled in March 2013 and enrollment was completed in January 2015. A total of 203 subjects were enrolled in 40 clinical sites in the United States, Europe and Australia (Graph 1) and the top ten enrollers are listed in Table 2. Based on data captured as of February 10, 2015 in the electronic data capture system for the study, the investigated population mainly comprised white (86.5%) males (59.0%). The age ranged from 25 to 68 years (mean= 45.6 years, SD=10.0 years, n=202). Hepatic encephalopathy was observed in 46.6% subjects at enrollment (Table 3). Major baseline laboratory variables include: MELD (27.2±3.8, n=196), Maddrey (72.9±25.0, n=197), bilirubin (25.0±9.2 mg/dl, n=196), INR (2.0±0.5, n=196), creatinine (1.0±0.7 mg/dl, n=196), PT (22.4±5.2 seconds, n=198), ALT (61.8± 42.3 IU/L, n=198), AST (134± 73.8 IU/L, n=196), sodium (133.9± 5.5 mmol/l, n=198), WBC (14.5±7.4 X10³/mm³, n=198), etc. (Table 4).

DISCUSSION

Study power assumptions included defining a 90-day control survival rate of approximately 50% and a study treatment arm survival improvement of approximately 20%, consistent with findings from prior studies. According to the AAH-MELD calculator a MELD of 27.2 translates to a 90-day survival rate of 49%. A recent study of sAAH subjects in the UK (the STOPAH trial²) enrolled a less sick subject population (mean baseline MELD ~22) which was reflected in a 90-day survival of approximately 72%, als consistent with the MELD calculator (69%), irrespective of treatment arm (prednisolone, pentoxifylline, the combination or placebo).

CONCLUSIONS

Trial enrollment has proceeded in accordance with the anticipated timelines. Average age and MELD score at baseline are within the trial target ranges established during VTI-206. Baseline data characterize a group of subjects with alcohol-induced liver decompensation.

REFERENCES

1.MELD score and 90-day mortality rate for alcoholic hepatitis. MAYO clinic http://www.mayoclinic.org/, Accessed on 10Feb2015. 2.M.R. Thursz, et al. Steroids or Pentoxifylline for Alcoholic Hepatitis: Results of the STOPAH Trial. AASLD. 2014.

Figure 2: CYP450 liver expression high prior to and after ELAD treatment



EXPRESSION OF LIVER-SPECIFIC CYTOCHROME P450 ISOENZYMES AND OXYGENASES IN C3A CELLS PRIOR TO AND AFTER TREATMENT WITH THE ELAD LIVER SUPPORT SYSTEM

VITAL THERAPIES*

Lee K. Landeen, Ph.D., Jason Lapetoda, Jessica Van Allen, Nancy Heredia, John Brotherton, Ph.D., and Robert Ashley Research & Development, Vital Therapies, Inc., 15010 Avenue of Science #200, San Diego, CA 92128. www.vitaltherapies.com

BACKGROUND

Acute-on-chronic liver failure (ACLF) and acute liver failure (ALF) are characterized by impaired liver function, multi-organ failure, and high short-term mortality. Cell-based support of liver function could therefore be of therapeutic benefit if the cell therapy was demonstrated to provide metabolic functions required of normal hepatocytes, such as detoxification. The ELAD System (Fig. 1c) provides extracorporeal exposure to human hepatoblastoma-derived C3A cells and is under evaluation in several clinical trials for various liver disease indications.

OBJECTIVES

The aims of this study were to characterize the expression levels of liver-specific cytochrome P450 isoenzymes (CYP) and oxygenases in ELAD C3A cells during clinical product production and after use in clinical treatment.

MATERIALS & METHODS

C3A cells were harvested as monolayer cultures (Fig 1a), from ELAD C3A hollow-fiber cartridges at production maturity (Fig 1b), or after 5 days of clinical use in alcohol-induced liver disease (AILD) subjects (Fig 1c).

Monolayer C3A cells (n=4) cultured in proprietary MM Media (Hyclone) were harvested for mRNA isolation (Qiagen RNeasy) and analyzed on TaqMan Human CYP450 and Oxygenases Array Plates (ABI); however, not all array gene targets are liver-specific. ELAD C3A hollow-fiber cartridges were recovered at production maturity (n=5), and after 5 days of clinical use (n=9) and processed as above. Gene expression levels vs. controls were calculated by the ΔΔCT method using the GUSB gene as an endogenous control. The relative expression of each gene was determined as fold increase or decrease relative to the average expression in monolayer cells using the formula: Relative Expression = 2 - ΔΔCT.

RESULTS

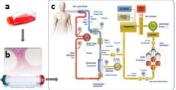


Figure 1. C3A cells were harvested as monolayer cultures (a), from ELAD C3A hollow-fiber cartridges at production maturity (b), or after 5 days of clinical use in alcohol-induced liver decompensation (AILD) subjects (c).

Over 60 gene targets evaluated were detected in C3A cells. Among these included CYP1A2, CYP2C9, CYP2C19, CYP2D6, CYP3A4 and CYP3A5 (Fig. 2), which are collectively responsible for metabolizing nearly 90% of all drugs [1] as well as other CYPs involved in detoxification.

Up-regulation in ELAD cartridge C3A cells vs. monolayer was observed for CYP11B2, CYP17A1, CYP21A2, CYP2A6, CYP2A7, CYP2E1, CYP3A7, CYP4A11/CYP4A22, CYP51A1 and CYP7A1 (Fig. 3), whereas CYP19A1, CYP24A1, CYP2S1, NENF and SC4MOL were down-regulated (Fig. 4).

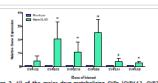


Figure 2. All of the major drug-metabolizing CYPs (CYP1A2, CYP2C9, CYP2C19, CYP2C96, CYP3A4 and CYP3A5) are expressed in monolayer and ELAD C3A cells (* p<0.05 ELAD vs. monolayer, Student's t test).

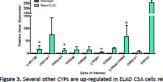
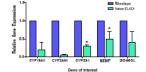


Figure 3. Several other CYPs are up-regulated in ELAD C3A cells relative to monolayer C3A cells (* p<0.05 vs. monolayer, Student's t test).



Gene of Interest
Figure 4. Some CYP isoenzymes were down-regulated in ELAD C3A cells relative to monolayer C3A ce3lls (*p<0.05 vs. monolayer, Student's t test).

Up-regulation in ELAD C3A cells prior to vs. after AILD subject treatment was observed for CYP1182, CYP2A6, CYP2A7, CYP2C19 and CYP1A2, whereas down-regulation was noted for and CYP17A1 (Fig. 5). Apparent downregulation of TYR and CYP51A1 disappeared with additional clinical sample replicates.

C3A cells from AILD subject-recovered ELAD cartridges exhibited differences in up- or down-regulation between individual subjects among 16-22 different gene targets (Fig. 6).

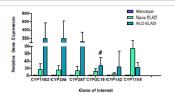


Figure 5. Several CYPs were up-regulated in ELAD C3A cells after AlLD subject treatment (# p=0.06, Student's t test), whereas CYP17A1 was down-regulated subsequent to subject exposure.

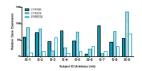


Figure 6. Relative gene expression of selected major drug-metabolizing CYPs in ELAD C3A cells subsequent to use in treatment of nine different AILD subjects shows variable expression from subject to subject.

SUMMARY

ELAD C3A cells express a variety of cytochrome P450 isozymes including those most involved in drug metabolism such as CYPLA2, CYP2C9, CYP2C19, CYP2D6, CYP3A4 and CYP3A5. The mRNA expression of these CYPs and several others increases when the C3A cells are cultured three-dimensionally within the ELAD cartridges relative to monolayer culture.

The C3A cells in the ELAD System show different and varied expression patterns after exposure to subject treatment. It remains to be shown whether or not these changes correlate with functional changes in subjects' metabolic intermediates.

CONCLUSIONS

This study provides supporting evidence that the C3A cells comprising the ELAD System exhibit a diverse expression of various critical liver metabolic enzymes, and is supportive of previous studies using drug metabolites as evidence of the presence of selected CYP isoenzymes.

Culturing the C3A cells three-dimensionally within the ELAD cartridges enhanced the overall pattern of CYP expression and illustrates how organizational structure may positively benefit metabolic function.

It also illustrates that unique responses can be observed in cell-based therapies as a result of dynamic interactions with an individual subject's unique physiology.

These data may help clarify the mechanism of action of the ELAD System in supporting detoxification and potentially improving survival in subjects with ACLF and ALF.

ACKNOWLEDGMENTS

Gilman, G., The Pharmacological Basis of Therapeutics
 Eleventh ed. 2006: McGraw-Hill.

CONTACT INFORMATION

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Source: EASL poster presentation



Figure 3: VTL income statement

(\$000's) [FY-DEC]																
Revenues	2013A		2014A	1Q15E		2Q15E	3Q15E	4Q15E		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		2014A	1Q15E		2Q15E	3Q15E	4Q15E		2015E	2016E	2017E		2018E	2019E	2020E
Revenue																
Total Revenue	-		-					-				116,218		419,047	612,335	685,841
Cost of Revenue	_		_	-		-	-	-		-	-	17,433	•	62,857	91,850	102,876
Gross Profit			-	•		-	-	•		-		98,785		356,190	520,485	582,965
Operating Expenses																
Stock-based Compensation in SGA	537	•	722	286		301	316	332	•	1,235	1,482	3,225		3,566	4,078	4,821
Stock-based Compensation in R&D	411		675	286		301	316	332	•	1,235	1,482	1,743		1,928	2,204	2,606
Research & Development	21,376		39,479	9,751	1	0,078	10,582	11,111	•	41,521	37,045	43,582		40,480	38,577	37,790
General & Administrative	9,078		10,863	4,011		4,362	4,580	4,809	•	17,762	34,082	38,352		50,118	65,030	84,701
Total Operating Expense	31,402		50,342	14,335	1	5,041	15,793	16,583		59,283	71,127	81,934		90,598	103,607	122,491
EBITDA																
Operating Income		_	(50,342)	(14,335	(1	5,041)	(15,793)	(16,583)		(59,283)	(71,127)	16,852		265,592	416,878	460,474
Interest Income	5		_	<u>-</u>		_	-			-	_	_		_	_	_
Interest Expenses	0		_			_	_	-			_	_		-	_	_
Other (ex pense) income, net	(15)		_	-		_	-	-		-	-	_		_	_	-
Revaluation of preferred stock warrant liabilities	Ò		_	-		-	-	-		-	-	_		-	-	-
Revaluation of future purchase rights liabilities	(1,306)		_	-		-	-	-		-	-	_		-	-	-
Pretax income	(32,718)		(50,342)	(14,335	(1	5,041)	(15,793)	(16,583)		(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%	37%		37%	37%	37%		37%	37%	37%)	37%	37%	37%
Net Income	(32,718)		(50,342)	(14,335	(1	5,041)	(15,793)	(16,583)		(59,283)	(71,127)	10,617		167,323	262,633	290,099
Amortization of deemed dividend																
Accretion to redemption value of convert preferred																
Net Income (Non-GAAP)	(39,085)	,	(56,821)	(14,335	(1	5,041)	(15,793)	(16,583)		(59,283)	(71,127)	10,617		167,323	262,633	290,099
GAAP EPS (Diluted)	\$ (1.55)		(3.56)	\$ (0.73	\$	(0.77)	\$ (0.81) \$	(0.85)	\$	(2.56) \$	(2.56) \$	0.38	\$	6.03	\$ 9.46	\$ 10.45
Non-GAAP EPS (Diluted)	\$ (1.85)	\$	(3.56)	\$ (0.73	\$	(0.77)	\$ (0.81)	(0.85)	\$	(2.56) \$	(2.56)	0.38	\$	6.03	\$ 9.46	\$ 10.45
Diluted Weighted Average Shares			15,975	19,547		19,547	19,547	19,547		23,118	27,761	27,761		27,761	27,761	27,761

Source: Company reports, Canaccord Genuity estimates



Figure 4: VTL valuation

	Peak Sales	Year	Current Value	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	•				
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: Company reports, 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 04/27/15)

Rating	Coverage	e Universe	IB Clients		
_	#	%	%		
Buy	578	58.21%	32.70%		
Hold	331	33.33%	17.22%		
Sell	40	4.03%	2.50%		
Speculative Buy	44	4.43%	61.36%		
	993*	100.0%			

^{*}Total includes stocks that are Under Review

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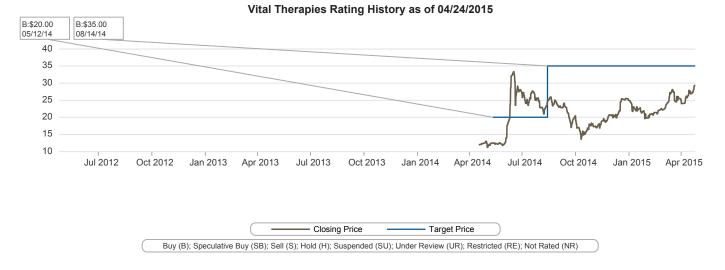
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