VITAL THERAPIES®

TARGETING LIVER DISEASE

Vital Therapies, Inc. (VTL:NASDAQ)

Corporate Introduction

June 2018

Forward Looking Statements

This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation are forward-looking statements, including, among others, statements relating to plans and objectives of management for future operations and future results; pre-specified and post-hoc analyses of VTI-208 data; the timeline for future operations, including VTL-308; the design of VTL-308, including inclusion and exclusion criteria, and the timing for the release of data; hypotheses relating to the ELAD® system's mechanisms of action; market opportunity and size; reimbursement matters and pricing of the ELAD System; and timing for regulatory filings. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Risks and uncertainties include, but are not limited to the uncertainties inherent in our clinical and development programs, including, without limitation, our ability to adequately demonstrate the safety and efficacy of the ELAD System, clinical results, which may not support further development of the ELAD System, and challenges related to conducting pivotal clinical trials, including, but not limited to, the impact of VTI-208, failure to achieve favorable results in clinical trials, the participation of clinical sites and their ongoing adherence to protocols, assumptions regarding enrollment rates, changes to protocols or regulatory requirements, the ability to comply with and meet applicable laws and regulations, and unexpected adverse events or safety issues; the ability to obtain regulatory approval for the ELAD System; and the sufficiency of funding. There can be no assurance that data from any of our clinical trials will be sufficient to support an application for marketing in any country or that any such application will ever be approved.

You should review the risks and uncertainties contained in our filings with the United States Securities and Exchange Commission, including risks and uncertainties described in detail under the caption "Risk Factors" in such filings. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. All statements made in this presentation speak only as of May 8, 2018 (except financial information, which is as of March 31, 2018). Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

VTL: Focused on Saving Lives

80,000 people suffer from acute forms of liver failure each year in the US and Europe with up to 50% mortality

Our goal is to save their lives

Our technology seeks to use the power of human liver-derived cells to promote liver recovery

Phase 3 trial underway driven by large clinical data set from prior trial with topline results in third quarter of 2018

A multi-billion orphan market opportunity where transplant is generally not available

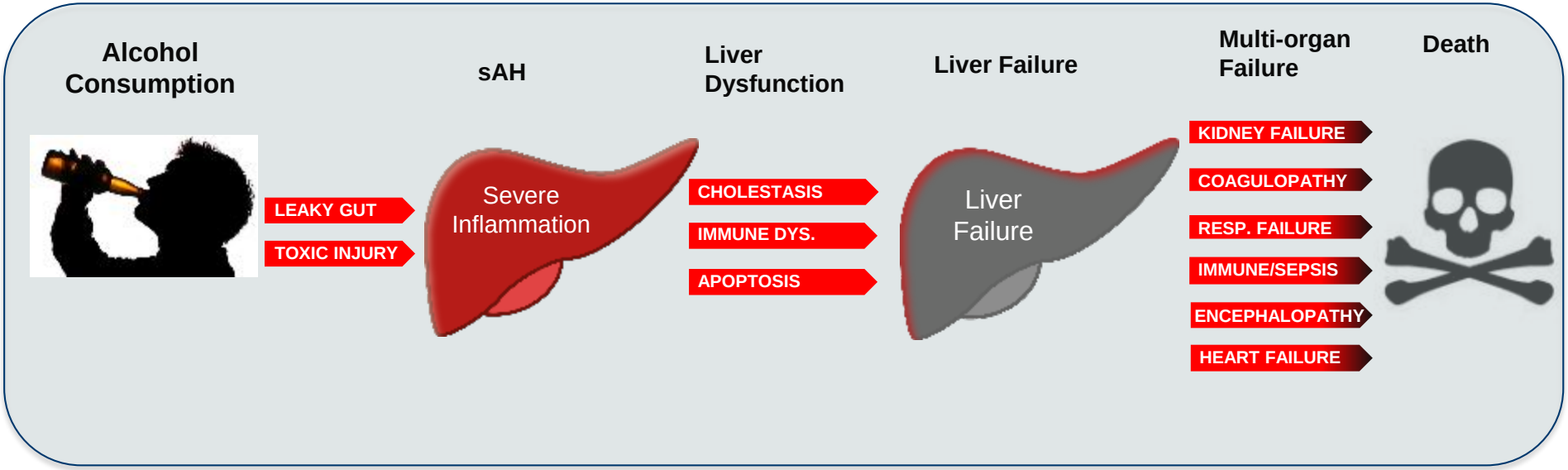
Management & Board: Proven Record of Success

Russell J. Cox **CEO**	Jazz Pharmaceuticals, IPSEN Innovation for patient care, Genentech
Duane Nash, MD, JD, MBA President	WEDBUSH, Davis Polk, UCSF
Rob Ashley, MA EVP / CTO	CollaGenex pharmaceuticals, Amersham, Bristol-Myers Squibb
Michael Swanson, MBA EVP / CFO	amira pharmaceuticals, PROMETHEUS Therapeutics & Diagnostics
Jan Stange, MD, PhD CMO	MARS, GAMBRO
Andrew Henry VP, Clinical Operations	MedImmune, NOVARTIS, Schering-Plough
Rich Murawski VP, Manufacturing	Dendreon, CYTOGEN, Baxter
John Dunn, JD General Counsel	Biogen, IDEC Pharmaceuticals Corporation

Faheem Hasnain Chairman	Former CEO and President of Receptos, Inc. receptos
Jean-Jacques Bienaimé	CEO of BioMarin Pharmaceutical BIOMARIN
Cheryl Cohen	Former Chief Commercial Officer of Medivation, Inc. MEDIVATION
Russell J. Cox	CEO of Vital Therapies VITAL THERAPIES
Doug Godshall	President and CEO of Shockwave Medical SHOCKWAVE
Errol Halperin, JD, LLM	Strategic Advisor at DLA Piper DLA PIPER
Michael Millis, MD	Chief of Transplant, University of Chicago
Muneer A. Satter	Chairman - Satter Investment Mgmt.; Chairman – Akebia Therapeutics Goldman Sachs, Akebia
Lowell Sears	Former CFO of Amgen AMGEN

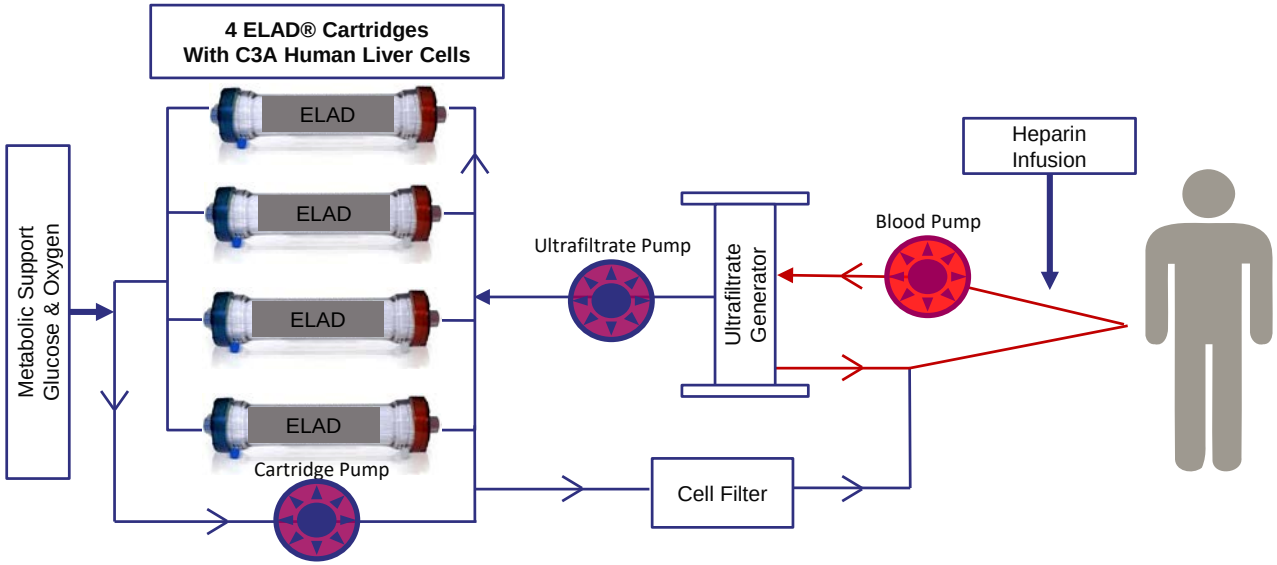
Severe Alcoholic Hepatitis (sAH)

- Associated with binge drinking
- Severe liver inflammation
  - Swelling leading to obstruction of bile flow and jaundice
  - Increased oxidative stress
  - Decreased hepatocyte function
- Can progress through increasing morbidity to death



The ELAD® System: Human-cell Bio-Artificial Liver

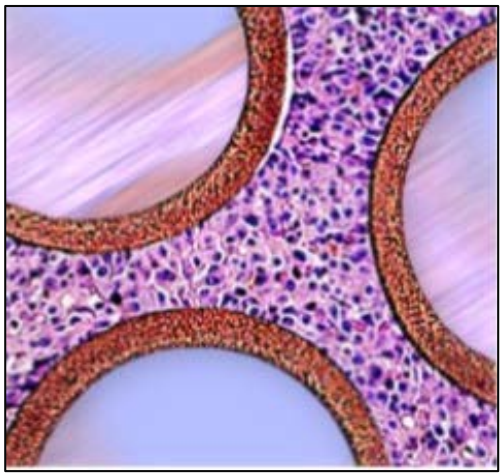
- **Bio-artificial liver system designed to improve survival in acute forms of liver failure**
  - Several hundred billion liver-derived cells (about one pound of cells)
  - Continuous treatment for 5 days



- **Allogeneic <u>cellular therapy</u> based on VTL C3A cells**
  - Human — No animal safety issues with the cells
  - Scalable — Can be grown in large quantities
  - Proprietary — VTL owns cell banks

ELAD Uses Human Liver-derived Cells to Support Liver Function

VTL C3A cells produce over 300 identified proteins, many of which are critical to life, and carry out multiple metabolic functions



Reduction in inflammation*

- Interleukin-1 Receptor Antagonist
- Alpha-1-Antitrypsin
- Complement C3
- Gelsolin
- Interleukin-8

Promotion of Cell Survival*

- Amphiregulin
- Vascular Endothelial Growth Factor
- Placental Growth Factor
- Platelet-Derived Growth Factor-BB
- Growth/differentiation factor 15 (GDF-15)

Physiological Support*

- Albumin
- Transferrin
- Alpha Fetoprotein
- Fatty Acid-Binding Protein (FABP), liver
- Erythropoietin

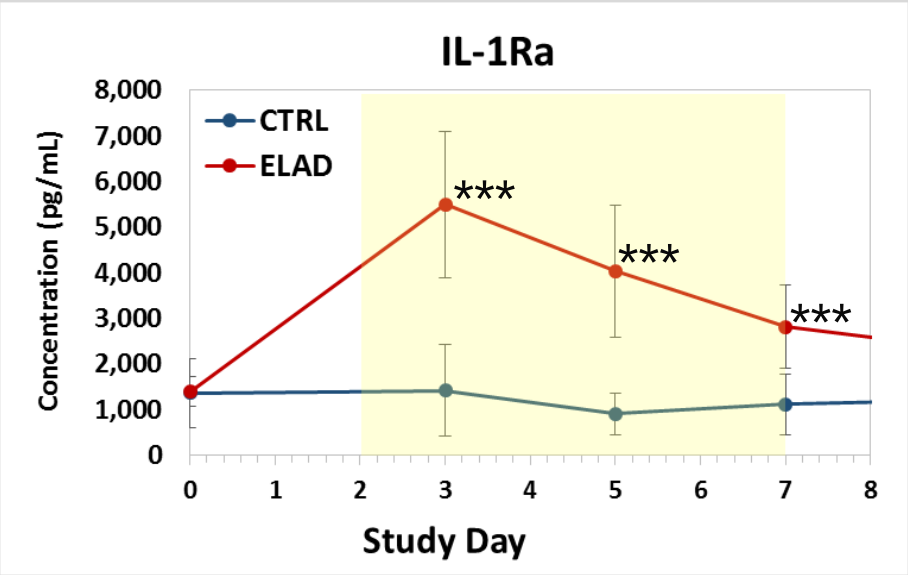
Metabolic Support*

- Reduction of circulating bilirubin
- Increase of secondary conjugated bile acids
- Provision of energy (e.g. creatine phosphate)
- Improvement in amino acid metabolism
- Detoxification through Cytochrome P-450 activity

*Proteins may have multiple roles depending on concentration and targeted cell type. MOA theories are based on laboratory studies and need correlation with in vivo studies and patient outcomes.

Anti-Inflammatory IL-1Ra Increases During ELAD Treatment

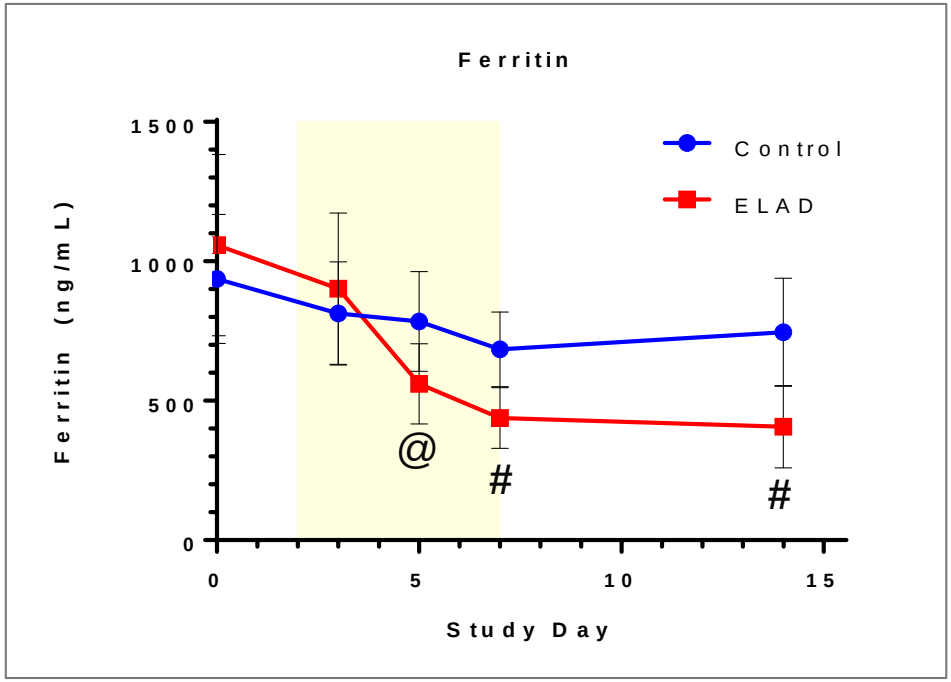
- Systemic inflammation contributes to mortality in sAH patients
- Interleukin-1 receptor antagonist (IL-1Ra) is a **potent anti-inflammatory protein** (Kineret® anakinra) used in the treatment of severe inflammatory diseases
  - VTL C3A cells secrete IL-1Ra *in vitro*
  - sAH subjects treated with ELAD experience an increase in plasma IL-1Ra concentrations over control subjects
  - IL-1Ra may contribute to resolution of inflammation and reduced cell death

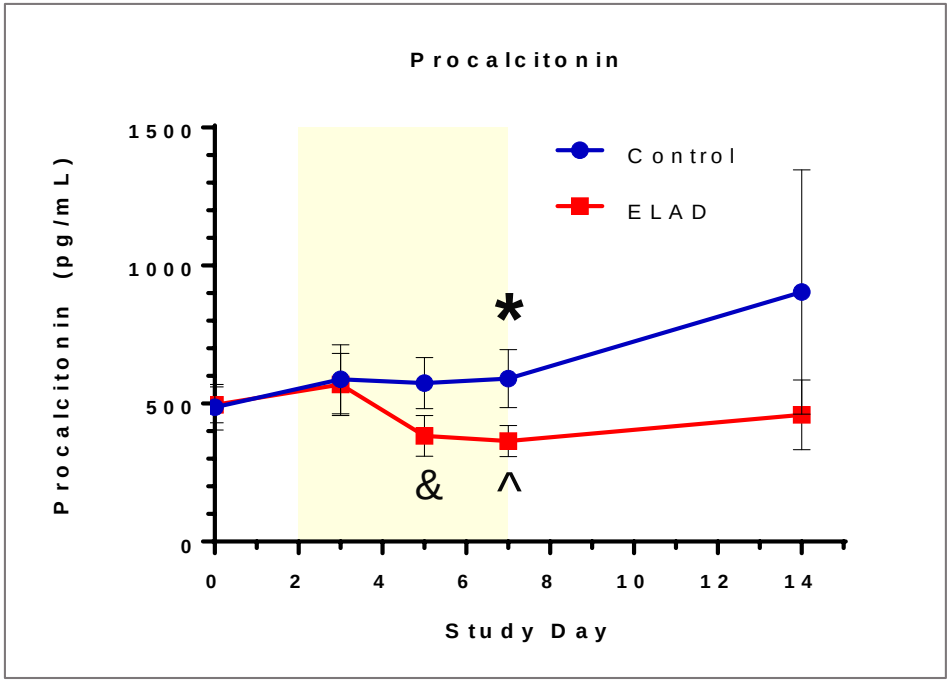


- 25 subjects (n=14 ELAD, n=11 Ctrl) from VTI-208 Phase III study meeting VTL-308 inclusion criteria
- Data presented as Mean ± SEM (Std. Error of the Mean)
  - ***ELAD vs. CTRL D3 ($p<0.0001$), D5 ($p<0.0001$), and D7 ($p=0.003$)
  - ***D0 vs. D3 ($p<0.0001$), D5 ($p<0.0001$), and D7 ($p=0.0012$)

ELAD Associated with Reduction in Inflammation

- Ferritin and Procalcitonin are markers of inflammation
- Both are elevated in patients with sAH[1]
- ELAD treatment significantly reduces these markers





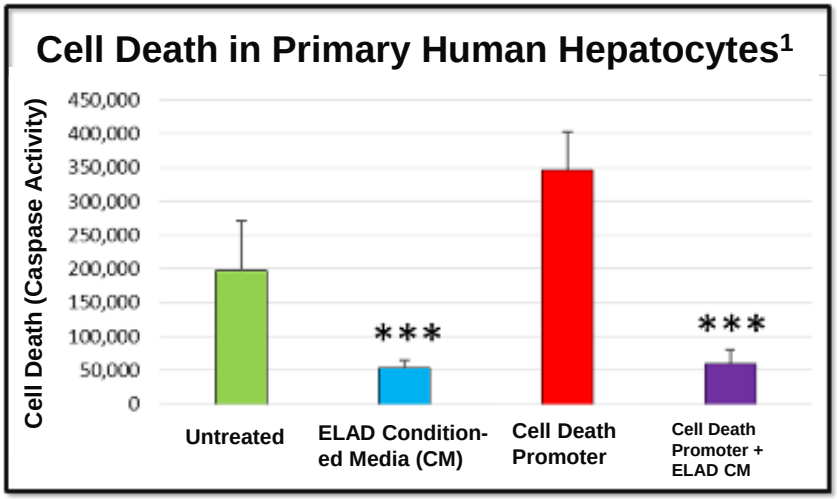
Comparison	Ferritin	Procalcitonin
ELAD vs. Ctrl	No Difference (D14, p=0.14)	* p=0.049 (D7)
ELAD D0 vs DX	@ p=0.0025 (D5)	& p=0.034 (D5) ^ p=0.025 (D7),
	# p<0.0001(D7, D14)	

25 subjects (n=14 ELAD, n=11 Ctrl) from VTI-208 Phase III study meeting VTL-308 inclusion criteria

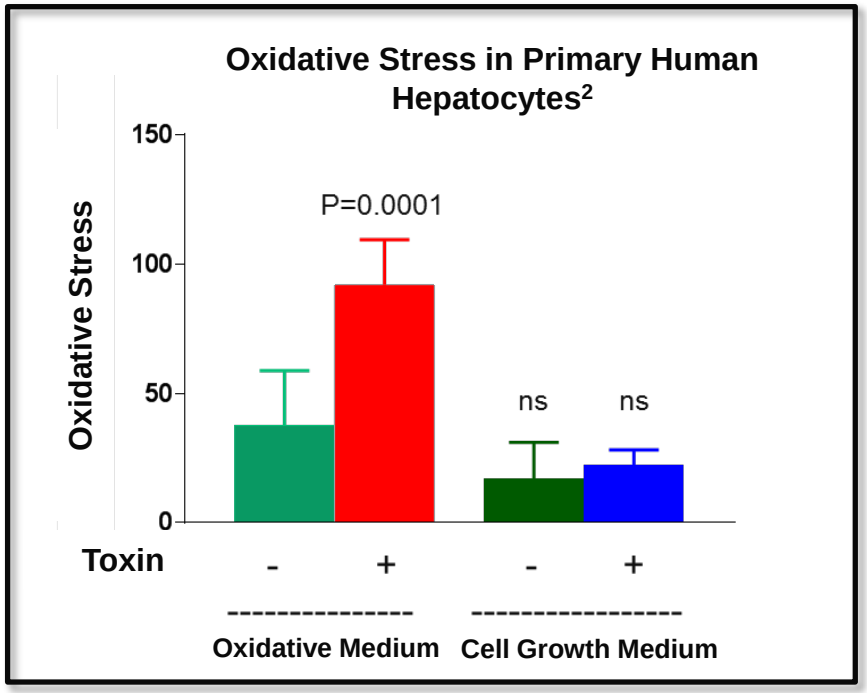
[1] Michelena, J et al Systemic inflammatory response and serum lipopolysaccharide levels predict multiple organ failure and death in alcoholic hepatitis. *Hepatology*, 62, 762-72; and Harrison-Findik, D. D. (2010) Gender-related variations in iron metabolism and liver diseases. World J Hepatol, 2, 302-10.

VTL C3A Secretome Inhibits Hepatocyte Cell Death

- Workhorse cell of the liver is the hepatocyte
  - sAH patients experience increased hepatocyte death from oxidative stress, steatosis, inflammation, cholestasis, etc.
- VTL C3A cells secrete factors that block hepatocyte cell death
  - sFAS Receptor
  - Amphiregulin
  - Antioxidants



(*** p<0.001 One-way ANOVA with Tukey post-hoc test)



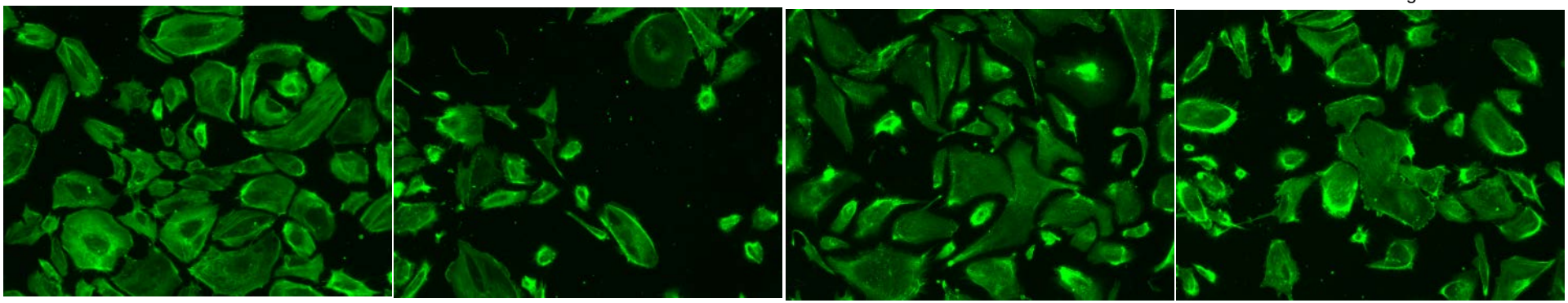
1 Anti-Apoptotic Effects of Cellular Therapy: VTL C3A Cell-Secreted Factors Reduce in vitro Hepatocellular Injury via Multiple Mechanisms (Lapetoda et al, ISAD 2016)
2 Elaborating ELAD Mechanism of Action and Linking Cell-based Models to the Clinic (Bedard, et al, ISAD 2017)

VTL C3A Secretome Inhibits Endothelial Cell Death

- Endothelial cells are key contributors to liver regeneration
  - sAH patients experience increased endothelial cell death from oxidative stress, steatosis, inflammation, cholestasis, etc.
- VTL C3A cells secrete factors in vitro that combine to protect endothelial cells
  - Vascular endothelial growth factor (VEGF); placental growth factor (PlGF); antioxidants

Cytoskeleton Staining of Human Endothelial Cells[1]

*Magnification: 10x

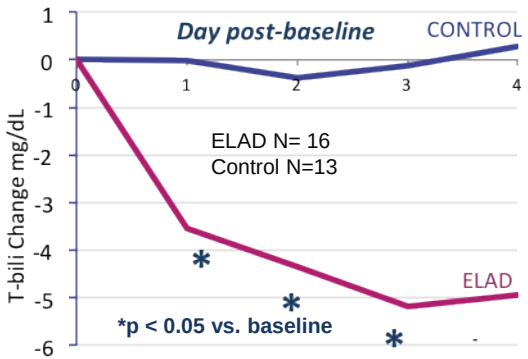


Untreated	Endotoxin only	Endotoxin + ELAD Conditioned Media	Endotoxin + VEGF
Reveals large number of healthy, intact cells.	Significant cell death and fragmentation.	Large number of healthy and intact cells.	Moderate number of healthy and intact cells.

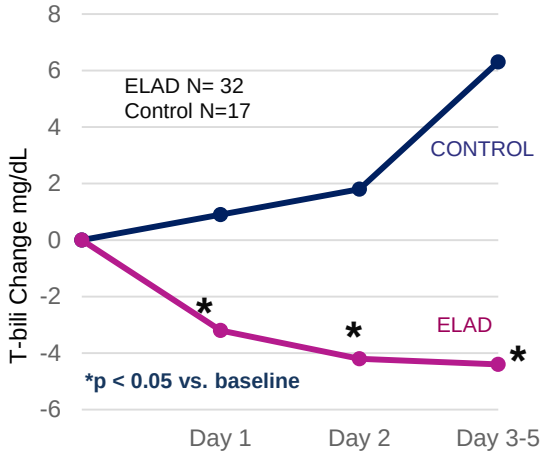
1 Elaborating ELAD Mechanism of Action and Linking Cell-based Models to the Clinic (Bedard, et al, ISAD 2017)

ELAD Associated with Improvement in Bilirubin*

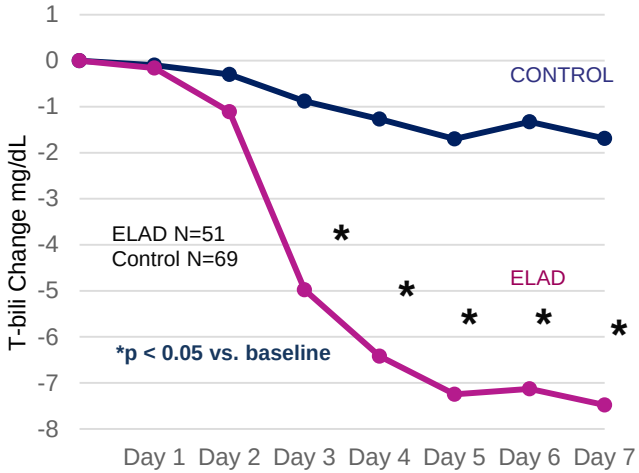
VTI-206



VTIC-301 (China)



VTI-208 MELD<28



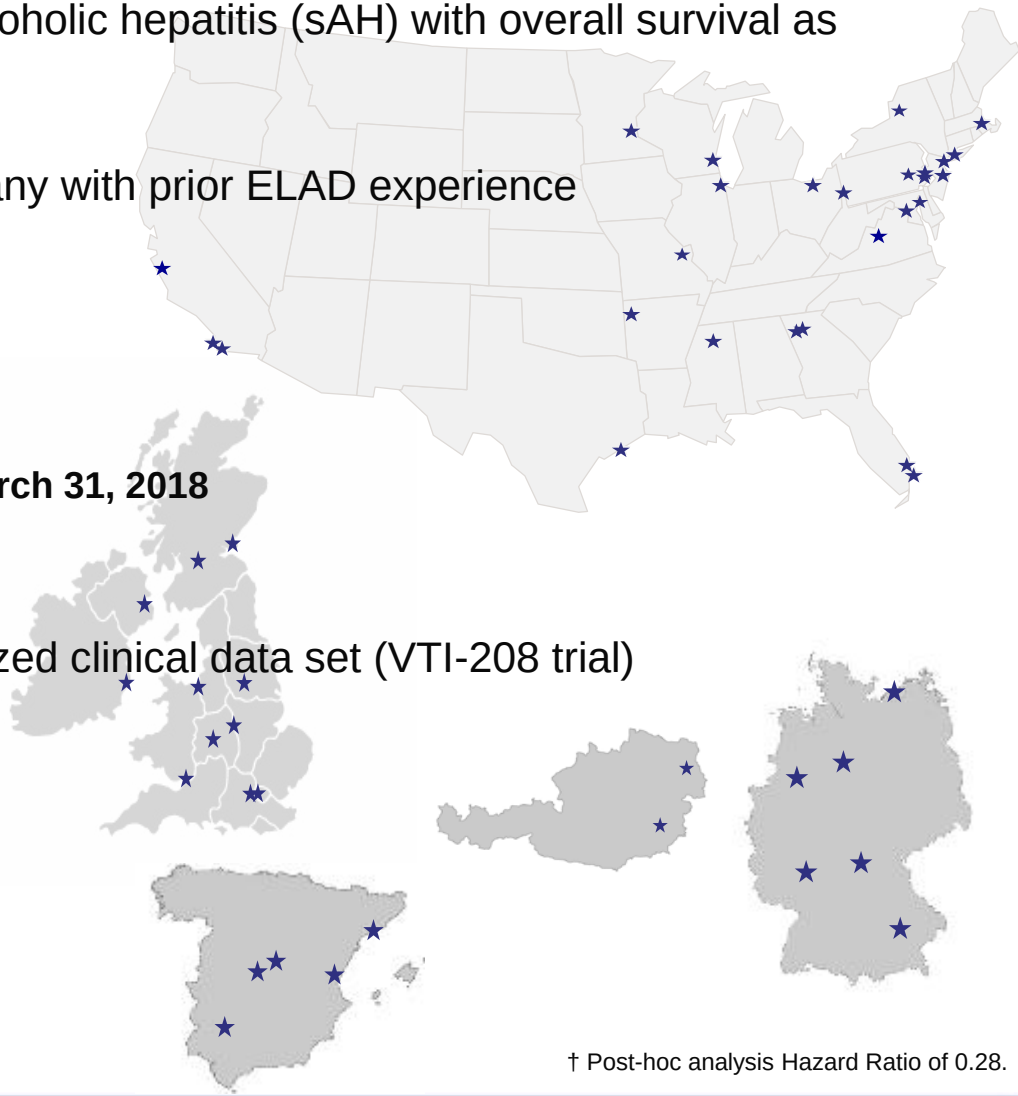
Note: Not all subjects had data at all time points.

* While yet to be proven, VTL-308 is designed to prospectively confirm these findings.

VITAL THERAPIES®

Pivotal VTL-308 Trial Fully Enrolled

- Randomized, controlled trial in severe alcoholic hepatitis (sAH) with overall survival as primary endpoint
- Target of ~50 sites in US and Europe, many with prior ELAD experience
- Timeline:
  - FDA written guidance received Q4:2015
  - First subject enrolled in Q2:2016;
  - **Fully enrolled with 151 subjects as of March 31, 2018**
  - Topline data expected in Q3:2018
- VTL-308 criteria guided by large randomized clinical data set (VTI-208 trial)
- Powering at various hazard ratios:
  - ~ 99% for 0.30 †
  - > 95% for 0.40
  - > 85% for 0.50



† Post-hoc analysis Hazard Ratio of 0.28.

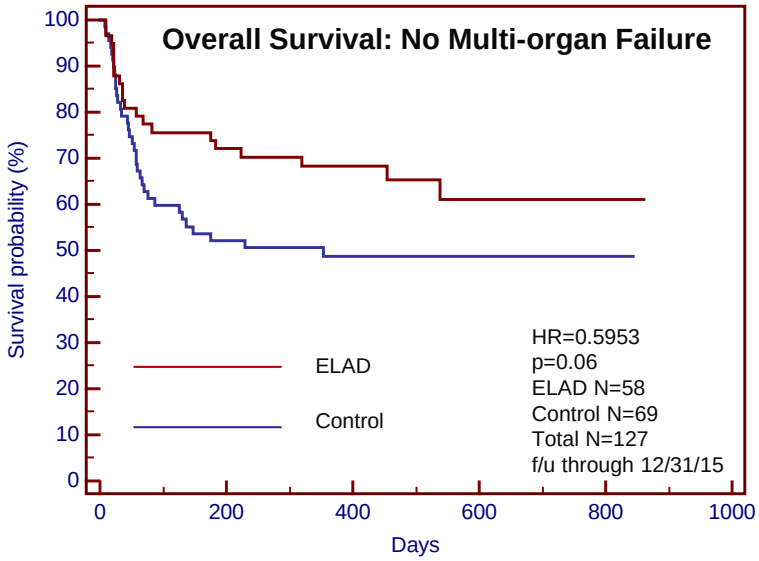
Large Data Set from Prior Trial Drives VTL-308

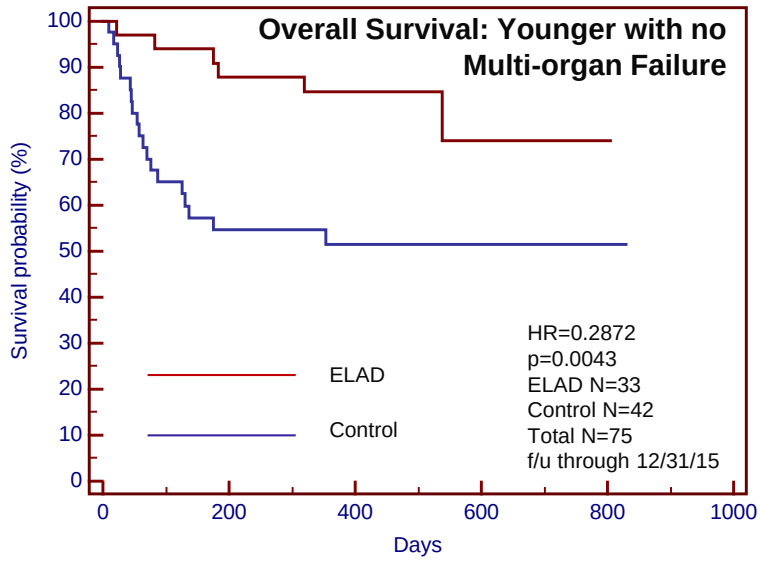
VTI-208 – 1:1 randomized, controlled data set with 203 subjects followed up to 800 days

- Did not reach primary endpoint in ITT population
- Trend in improved survival in younger subjects with no multi-organ failure

91 day survival – Combination of Pre-specified parameters	ELAD Survival	Control Survival	Relative Improvement	Absolute Improvement	P value*	N
No multi-organ failure (Creatinine<1.3 mg/dL, INR≤2.5)	75.9%	60.9%	24.6%	15.0%	0.072	127
Younger with no multi-organ failure (Age<50, creatinine<1.3 mg/dL, INR≤2.5)	93.9%	66.7%	40.8%	27.2%	0.004	75

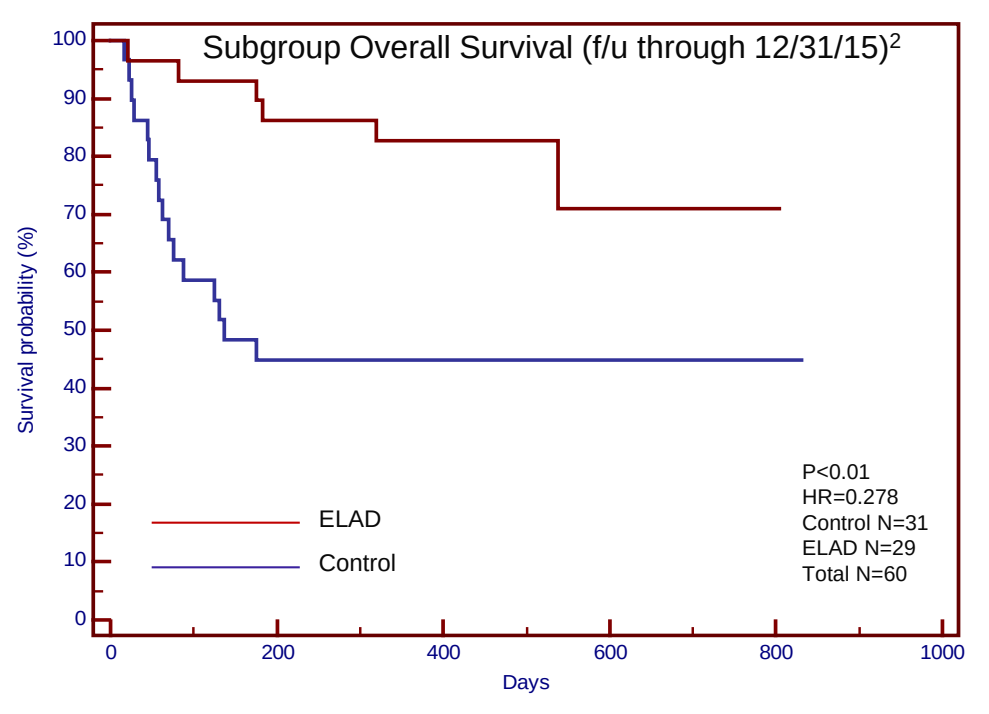
* Pearson's chi-squared test, ELAD vs. Control





Phase 3 Trial Targets sAH with No Other Organ Failures

VTI-208 Subgroup: Age <50; INR ≤2.5; creatinine <1.3 mg/dL; and bilirubin ≥16 mg/dL[1]



Baseline	ELAD Treatment (N=29)	Control (N=31)
Age	39.6±5.07	40.5±6.38
MELD	25.3±2.18	25.8±2.08
Creatinine	0.66±0.23	0.75±0.27
Bilirubin	26.6±7.2	26.7±5.6
INR	1.84±0.36	1.88±0.30
Sodium	133.1±5.6	133.7±4.2

60 subjects with hazard ratio of 0.28; p < 0.01

- 91-day survival: **ELAD 93% versus Control 61%**
- 180-day survival: **ELAD 89% versus Control 48%**
- 365-day survival: **ELAD 82% versus Control 41%**[3]

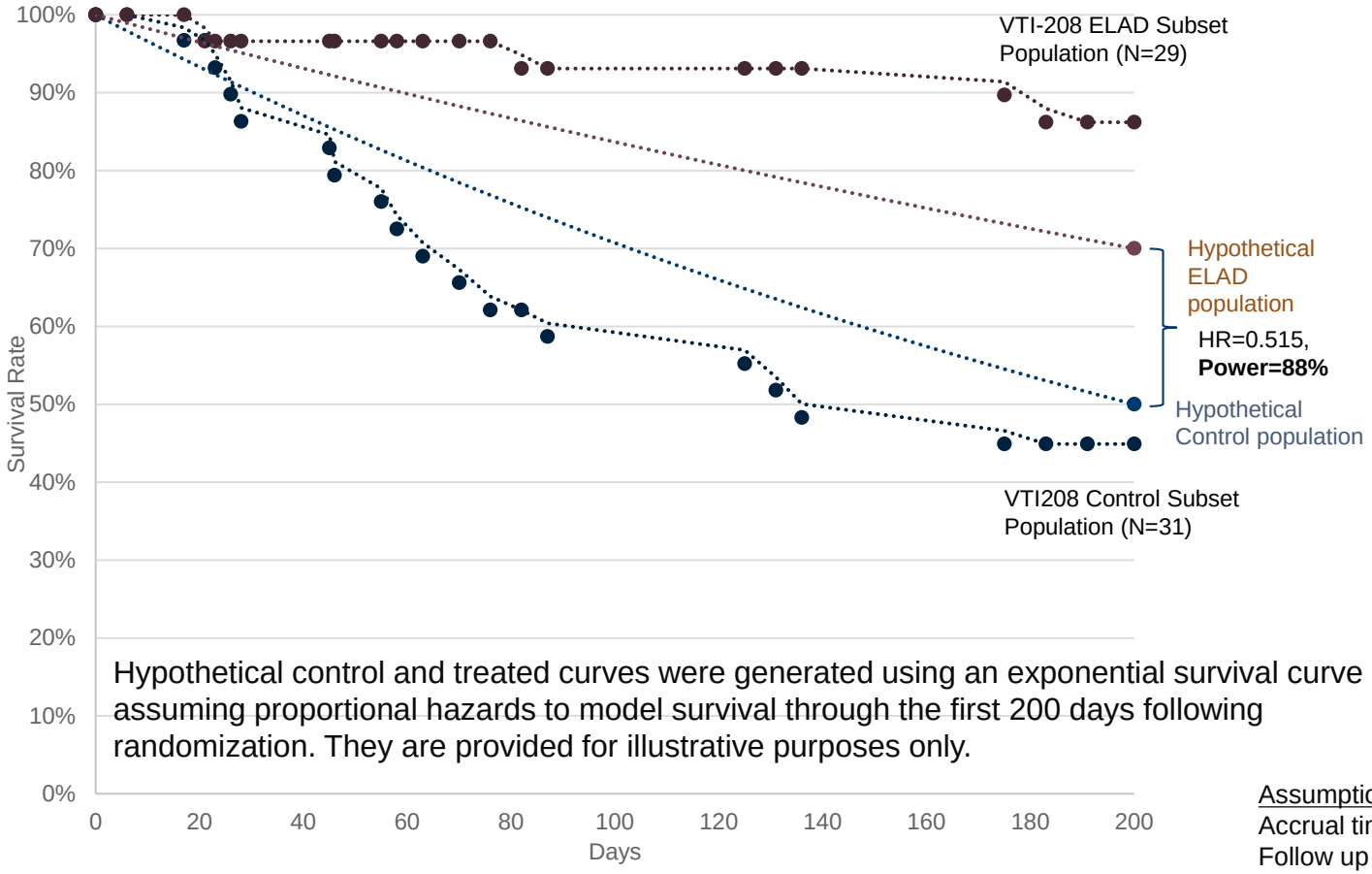
[1] Bilirubin minimum added to increase mortality in both ELAD and control arms.

[2] There were no transplants in this subgroup.

[3] Excludes from calculation 1 ELAD-treated subject and 4 control subjects who had not reached 365 days as of 12/31/15.

VTL-308 is Highly Powered

Comparison of VTI-208 Subset Population versus Hypothetical VTL-308 Performance Assumed for Statistical Powering Calculation



Hypothetical control and treated curves were generated using an exponential survival curve assuming proportional hazards to model survival through the first 200 days following randomization. They are provided for illustrative purposes only.

Assumptions
Accrual time: 720 days
Follow up time: 150 days
Sample size: 150 subjects
(10% lost data)

Baseline Characteristics of Subjects Enrolled in VTL-308

- Current baseline characteristics of 151 subjects enrolled in VTL-308 indicate[1]:
  - No subjects outside the enrollment criteria have been enrolled
  - Subject characteristics are closely tracking the reference VTI-208 subset population on which the design of VTL-308 is based

	Data	Age (years)	MELD	Bilirubin (mg/dL)	INR	Creatinine (mg/dL)
VTL-308 enrollment limits		<50 yrs	<30	≥16 mg/dL	≤2.5	<1.3mg/dL
VTI-208 reference population *(n=60)*	**Mean** *(range)*	**40.10** *(28 - 49)*	**25.60** *(20 - 29)*	**26.62** *(16.6 - 52.6)*	**1.86** *(1.0 - 2.5)*	**0.71** *(0.10 - 1.30)*
VTL-308 early subjects *(n=151)*	***Mean*** *(range)*	**39.30** *(23 - 49)*	**25.14** *(19 - 29)*	**24.93** *(16.0 – 44.7)*	**1.82** *(0.95 - 2.50)*	**0.73** *(0.30 - 1.27)*

[1] *Updated 5/8/2018*

Next Generation Therapies are at an Inflection Point

Over 950 ongoing trials in RMATs*

93 ongoing phase 3 trials in RMATs*

16 Cellular and Gene Therapy products approved by FDA†

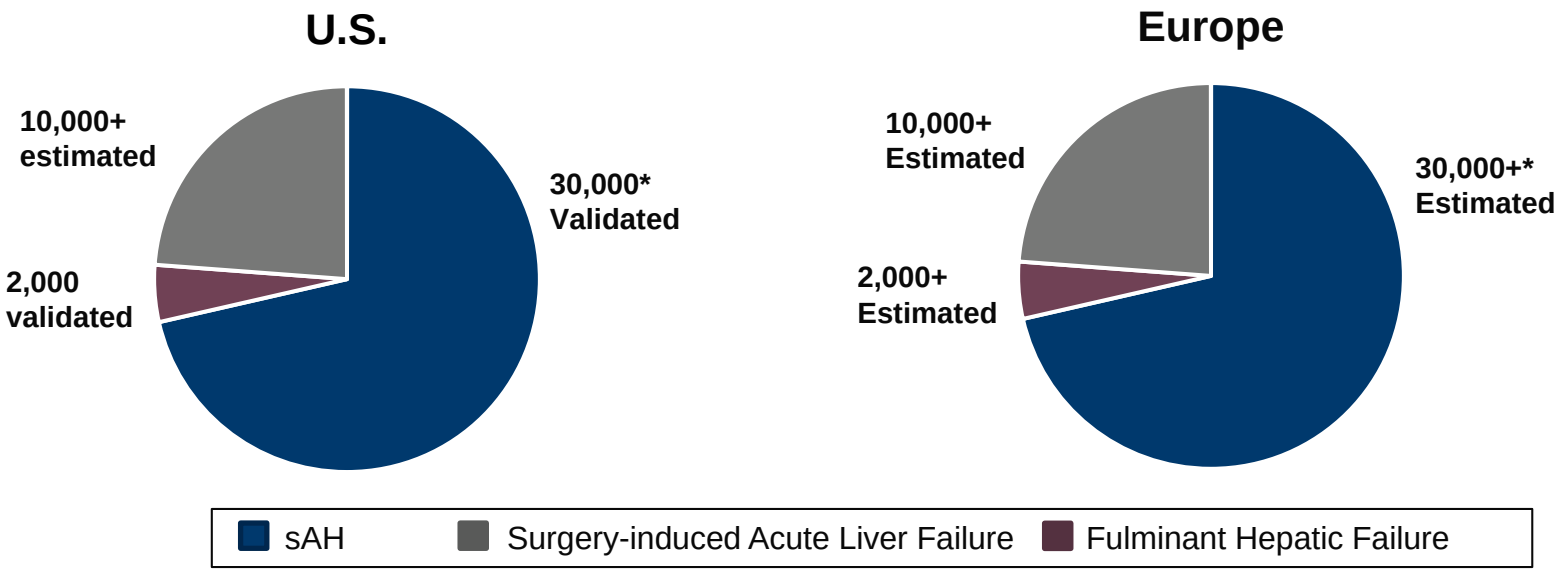
- Regenerative medicine advanced therapies (RMAT), including cellular and gene therapies, are now at the forefront of medical innovation
- FDA and other regulatory bodies are recognizing this and adopting new policy frameworks to spur innovation in RMAT
  - FDA announced new guidance for regenerative medicine in November 2017, which builds on the 21st Century Cures Act
  - Other regulatory bodies are adopting similar approaches to encourage and accelerate development of RMATs (e.g. Japan)
- The maturing regulatory environment is enabling approval of RMAT products, such as recent FDA approvals for:
  - First CAR-T, Novartis' Kymriah in acute lymphoblastic leukemia
  - Second CAR-T, Gilead's Yescarta in non-Hodgkins lymphoma
  - First gene therapy for a gene mutation, Luxturna for rare inherited retinal disease from Spark Therapeutics
- ELAD® is positioned as a significant advancement among cellular therapies in the event of positive VTL-308 results

* Source: Alliance for Regenerative Medicine 7th Annual Partnering Forum (May 2018) via Informa

† List of licensed products per FDA's Office of Tissues and Advanced Therapies (OTAT)

Sizeable Orphan Market

- Approximately 80,000 patients per year across US and EU



- sAH is lead indication, but potential addressable market includes all acute and sub-acute forms of liver failure

* 18,000 patients in each of US and EU estimated to be under age 50, which represents initial targeted indication for ELAD.

† Estimated based on US data and relative population sizes.

Blockbuster Opportunity

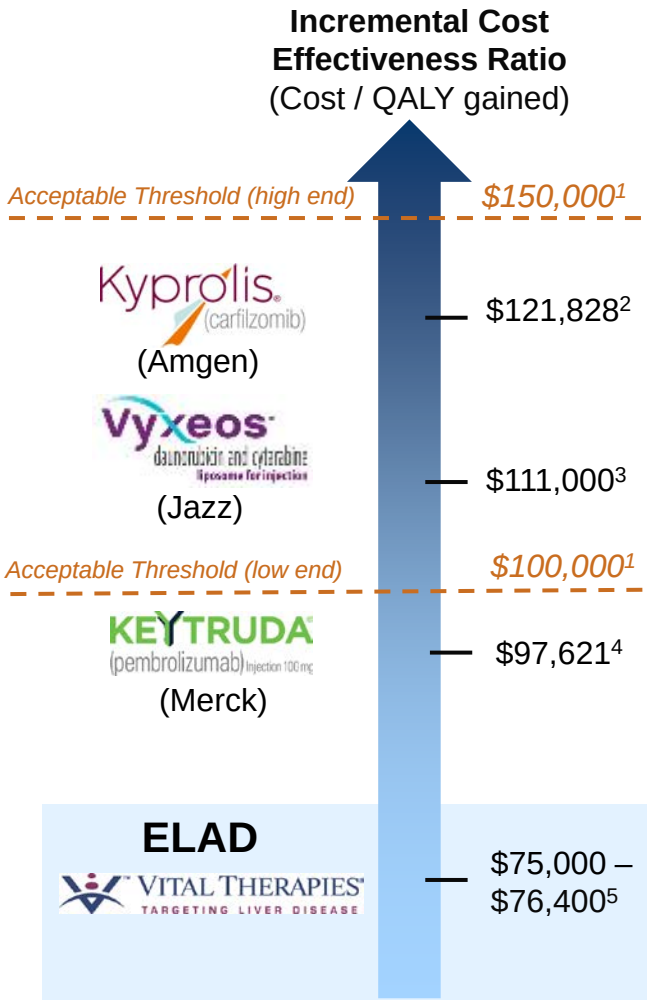
- Expert consultant (MME) recommended price range from $150 to $275K for ELAD:
  - Substantial pricing precedence with orphan therapies

Product	Company	Approval		Indication	US Disease Prev	US Annual WAC	EU Annual ex-Factory Price Range
		FDA	EMA				
Soliris	Alexion	2007	2007	PNH	4,000	$444K[2]	$345K to 482K[2]
Cinryze	ViroPharma	2008	2011	HAE	6K to 10K	$392K[2]	$171K to 334K[2]
Carbaglu	Orphan Europe	2010	2003	NAGS deficiency	300	$635K[1]	$373K to 497K[1]
Kalydeco	Vertex	2012	2012	CF	30,000	$297K[2]	$238K to $349K
Juxtapid	Aegerion	2012	N/A	HoFH	300	$235-$295K[2]	N/A
Gattex	NPS	2012	N/A	Short Bowel Syndrome	10K – 20K	$284K[2]	N/A

1. 25kg patient; 2. Fixed dose

- Compelling value proposition:
  - Penetration of 20-30% suggests multi-billion dollar market opportunity
    - If VTL-308 is successful, ELAD will have shown durable improvement in overall survival
    - In a market that is concentrated and lacks competition
  - Anticipate attractive gross margins at commercial volume and a modest sales force targeting up to 200 centers in each of the US and EU
  - Could it become a frontline therapy and standard of care?

ELAD May Offer Compelling Value Proposition



	Price[6]	Sales[7,8]	Indication	Clinical Benefit[9]
Kyprolis (carfilzomib) (Amgen)	$14,632 per cycle[7]	$562M (US 2017)	Relapsed or refractory multiple myeloma	20% longer OS in combination w/ dexamethasone compared to bortezomib + dexamethasone (48 vs. 40 months)
Vyxeos daunorubicin and cytarabine liposome for injection (Jazz)	$85,250[3]	$34M (US 2017, launch year)	Acute myeloid leukemia (AML)	60% or +3.6 months median overall survival (OS) (9.6 months for Vyxeos vs. 6.0 months for standard of care)
KEYTRUDA (pembrolizumab) Injection 100 mg (Merck)	$150,000 per year[7]	$2,309M (US 2017)	Non-small cell lung cancer	31% less death compared to chemotherapy (29% vs. 42%)
ELAD VITAL THERAPIES TARGETING LIVER DISEASE	$150,000 – $275,000 per treatment[10]	*N/A*	Severe alcoholic hepatitis	If 20-30% absolute improvement in overall survival; assumes average survival 10-12 years[11]

Source: 1) Neumann 2014; 2) Jakubowiak 2017; 3) Jazz investor presentation (Aug 2017); 4) Huang 2017; 5) VTL Analysis; 6) Assumes cost of drug only, not hospitalization; 7) company press release; 8) Globaldata; 9) Product Prescribing Information; 10) Third party recommended price range (MME, 2016); 11) VTL assumptions

ROW Also Presents Large Opportunity

- ELAD market in ROW anticipated to focus on future indications:
  - Acute flares of hepatitis B (see VTIC-301 for clinical data)
  - Supporting resections of liver cancer (anecdotal evidence from compassionate use; formal trial would likely be required)
- Large patient populations highlight the significant need and even a small % of ROW represents a multi-billion dollar opportunity
  - ELAD may be an effective therapy in subgroups of these populations:

	Hepatitis B	Liver Cancer
China	130M (estimated to result in 2M acute hepatocellular dysfunction/liver failure cases per year)	395,000
India	40M+	27,000
Russia	2-7% of pop. (~3-10M)	7,000
Brazil	2% of pop. (~4M)	10,000
Middle East	2-5% of pop. (~8-19M)	25,000
Japan	2% of pop. (~2.5M)	36,000
Worldwide	2B have been infected in lifetime. 10 - 50 million new cases per year 350-400 million chronic carriers; 75% in Asia	750,000 new cases/yr 6th most common cancer 3rd leading cause of cancer death

Intellectual Property and Exclusivity

Patent Protection

- Key U.S. Patent Issued in 2012, term to April 2027
  - Covers use of the C3A cell-line in ELAD System to treat liver failure
- December 2013 patent covers bedside unit; term to May 2025
- Other patents granted and pending in US and around the world

Orphan Designation

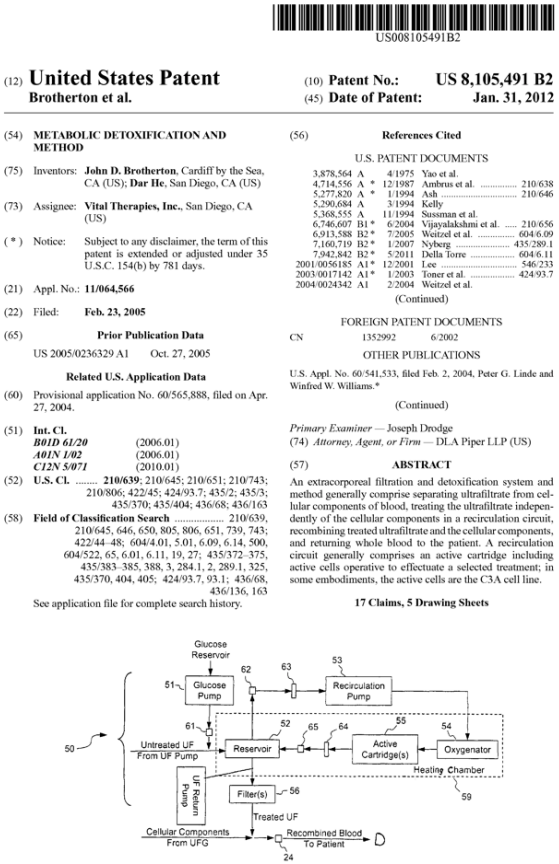
- Granted by FDA and EMA for treatment of acute liver failure
- Provides 7 years of market exclusivity upon FDA approval; 10 years in EU

Biologics Price Competition and Innovation Act

- 12 years of data exclusivity upon FDA approval
- Keeps bio-similars off the market during exclusivity period

Trade Secrets

- Maintaining and growing C3A cells is very difficult
- Know-how is held as trade secrets



US008105491B2

(12) **United States Patent**
Brotherton et al.

(10) **Patent No.: US 8,105,491 B2**
(45) **Date of Patent: Jan. 31, 2012**

(54) **METABOLIC DETOXIFICATION AND METHOD**

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(73) Assignee: **Vital Therapies, Inc.**, San Diego, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 781 days.

(21) Appl. No.: **11/064,566**

(22) Filed: **Feb. 23, 2005**

(65) **Prior Publication Data**

US 2005/0236329 A1 Oct. 27, 2005

Related U.S. Application Data

(60) Provisional application No. 60/565,888, filed on Apr. 27, 2004.

(51) **Int. Cl.**
B01D 61/20 (2006.01)
A01N 1/02 (2006.01)
C12N 5/071 (2010.01)

(52) **U.S. Cl.** **210/639**; 210/645; 210/651; 210/743; 210/806; 422/45; 424/93.7; 435/2; 435/3; 435/370; 435/404; 436/68; 436/163

(58) **Field of Classification Search** 210/639, 210/645, 646, 650, 805, 806, 651, 739, 743; 422/44–48; 604/4.01, 5.01, 6.09, 6.14, 500, 604/522, 65, 6.01, 6.11, 19, 27; 435/372–375, 435/383–385, 388, 3, 284.1, 2, 289.1, 325, 435/370, 404, 405; 424/93.7, 93.1; 436/68, 436/136, 163

See application file for complete search history.

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Primary Examiner — Joseph Drodge
(74) *Attorney, Agent, or Firm* — DLA Piper LLP (US)

(57) **ABSTRACT**

An extracorporeal filtration and detoxification system and method generally comprise separating ultrafiltrate from cellular components of blood, treating the ultrafiltrate independently of the cellular components in a recirculation circuit, recombining treated ultrafiltrate and the cellular components, and returning whole blood to the patient. A recirculation circuit generally comprises an active cartridge including active cells operative to effectuate a selected treatment; in some embodiments, the active cells are the C3A cell line.

17 Claims, 5 Drawing Sheets

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Lew Teperman, MD, Vice Chair of Surgery, North Shore University Hospital, Manhasset, NY

Russ Wiesner, MD, Professor of Medicine, Mayo Clinic

Win Williams, MD, Nephrologist, Massachusetts General Hospital (Harvard)

Cash Position and Capitalization

Cash and Equivalents: **$43.6 million as of March 31, 2018**

Cash Runway: Anticipate current cash position should provide funding through Q1 2019.

- In the event of positive topline results from VTL-308, the Company plans to raise additional capital.

Capitalization:

	As of March 31, 2018
Common shares outstanding	42.4M
Options outstanding	7.7M
Total	**50.1M**

Other:

Options available for grant (as of 3/31/18)	0.3M
Warrants (exercise price of $92.99 expiring September 2019)	0.2M

Current Focus

Complete the work required to achieve **database lock** for VTL-308

- Conduct follow up until 90 days after the last subject was enrolled
- Monitor and verify all data collected to date

Preparations for submitting a **Biologics License Application (BLA)** in the event of positive VTL-308 results

- Anticipate submitting approximately 12 months after topline results

Preparations for commercialization in the event of positive VTL-308 results

- Build on relationships with liver transplant centers in the US and Europe established during trial and that represent potential commercial treatment sites
- Evaluate liver transplant centers to determine optimal targets for commercial launch
- Establish the ELAD value proposition

Investment Summary

- **Orphan cellular therapy designed to improve survival in acute forms of liver failure**
- **New phase 3 trial fully enrolled directed by data from prior VTI-208 trial**
  - **Topline results expected third quarter of 2018**
- **Unique market position and strong IP:**
  - **No other known bio-artificial liver in clinical trials in US or EU**
- **Multi-billion dollar market opportunity in each of US, EU and ROW**
  - **Orphan pricing and biologic margins lead to high value**
- **Plan to capture benefit in US and EU without partnership:**
  - **VTL owns all rights**