Vital Therapies Inc. (VTL)

ELAD Designed to Help (De)Liver; Initiating with Buy & $50 PT

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.

- **ELAD is a bedside unit containing ~1lb functional, human liver cells designed to temporarily supplant liver function.** The liver has the unique ability to regenerate following significant chemical or physical injury. Hepatic failure pts. have a ~50% mortality rate, and liver function cannot be replaced artificially (unlike the heart, lungs, or kidney). ELAD is designed to serve as: 1) temporary replacement as the liver regenerates or 2) bridge to liver transplant.
- **VTL's initial focus is on alcohol induced liver decompensation (AILD), an orphan indication of high unmet need**. The VTI-208 Phase III study is testing ELAD in AILD, where no therapies have demonstrated survival improvement to date. Enrollment completion is expected by YE14, and readout in Q2/15. A 2nd ongoing Phase III study, VTI-210, is evaluating ELAD in a subset of AILD called AAH (no underlying liver damage). Should 208 fail but demonstrate efficacy trends in AAH pts., VTL may have a 2nd shot on goal. 210 is enrolling, with data expected in 2016. These pivotal studies draw on encouraging signs of efficacy from: 1) a Phase II study (U.S. & U.K.), 2) a Phase II study conducted in China with promising 3- and 5-year benefit for ELAD-treated patients, and 3) a meta-analysis of 2 studies in severe liver failure pts. A Phase II study of ELAD in the ultra-orphan diseases FHF and SILF (severe liver shock rapidly progressing to coma and death) is underway, readout exp. in 2016.
- **Physicians highlight the unmet need in alcoholic hepatitis and the unique potential for ELAD.** Key opinion leaders (KOLs) note the dire prognosis for liver failure patients, with survival benefit only via transplant. However, organ availability is limiting (~6.5K transplants for 16.5K waiting pts. in the U.S.). KOLs believe 208 enrollment criteria and statistical powering are positioned to highlight ELAD's potential benefit. A KOL discussed the striking anecdote of a patient waking up from coma after 6 hrs of therapy.
- **ELAD could reach $3.1B peak WW sales in 2027.** We model separately for AAH (~14K U.S., ~23K E.U. pts,) and non-AAH AILD (~16K U.S., ~25K E.U. pts) with WW peak sales of $1.5B and $1.5B respectively in 2027; rest reflects FHF (2K pts.). Upside could come from a China filing (~1.6M liver failures/yr) and support for 1) liver transplant (16.5K), and 2) cancer-related resections (20K+ in the U.S.).

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Initiate Buy

Price Target: $50.00

Price (Dec. 15, 2014)	$22.00
52-Wk Range	$33.31-$11.21
Market Cap ($M)	$477
ADTV	82,732
Shares Out (M)	21.7
Short Interest Ratio/% Of Float	3.3%
TR to Target	127.3%

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	--
EPS Adjusted					
FY	($74.86)	($3.61)	--	($2.39)	--
P/E	NM	NM		NM	
Consensus Rev					
FY	$0	$0	--	$0	--
Consensus EPS Adjusted					
FY	($74.86)	($3.56)	--	($2.54)	--
FYE Dec					

SEE PAGE 34 FOR REQUIRED DISCLOSURE INFORMATION

Vital Bull / Bear Case

Figure 1: Vital Bull vs Bear Analysis

	Bear Case	STRH Case	Bull Case
ELAD - AILD (AAH)	$0.00	$23.49	$50.34
ELAD - AILD (non-AAH)	$0.00	$20.67	$44.28
ELAD - FHF	$0.00	$1.49	$2.99
Cash/share	$4.30	$4.30	$4.30
Implied Price Target	**$4.30**	**$49.95**	**$101.91**
STRH est. scenario probability	25%	50%	25%
Price as of 12/15/2014		$22.00	
Upside/downside	*-80%*	*127%*	*363%*

Source: STRH estimates

Our base case valuation scenario reflects a 35% probability of success for Vital's bio-artificial therapy ELAD in the acute alcoholic hepatitis (AAH) subpopulation of alcohol-induced liver decompensation (AILD), a 30% probability of success for ELAD in the non-AAH, and a 25% probability of success for ELAD in fulminant hepatic failure (FHF), translating into a price target of $50, 127% higher than the most recent share price of $22.00, as of 12/15/14. Given the binary nature of the key catalyst for Vital, the readout of the VTI-208 Phase III study in AILD, we assign this base case a 50% probability.

Our bear case assumes failure of the VTI-208 Phase III study of ELAD in AILD. This entails a 0% probability of success for ELAD in all indications, and translates in $4.30 cash/share., 80% below the last close price of 12/15/2014 for VTL shares. We note, however, that efficacy trends in the AAH subset in the VTI-208 study could inform an amended design of the ongoing VTI-210 study, and the company could have a second shot on goal with this patient population. We forecast that WW peak sales in stringently defined AAH patients could reach $1.5B in 2027. Using a 30% probability of success adjustment for this revenue stream, we value the AAH opportunity at $20.67/share. We assign this scenario a 25% probability.

A bull case for Vital would entail a 75% probability of success for ELAD in both AILD patients subsets, AAH and non-AAH. This scenario would also entail a 50% probability of success for ELAD in FHF, translating into a price target of $102, 363% higher than the 12/15/2014 closing share price. We assign this scenario a 25% probability.

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We are Initiating Coverage of Vital with a Buy Rating and $50 PT

Vital could be the first company to establish a "dialysis for the liver" system. Vital is developing a cellular therapy for liver failure, embodied by the bio-artificial bedside system called ELAD (extracorporeal liver assist device). Unlike the lung, heart, or kidney where function can be replaced (at least temporarily) by artificial systems, the liver performs highly complex biological functions that to date cannot be carried out by any artificial device. For example, patients with kidney failure can survive for many years by means of dialysis (a procedure through which waste is filtered and body levels of salt, potassium and phosphorous are balanced). In contrast, mortality in liver failure patients is about 50%, given the absence of any effective "liver dialysis" devices. Enter ELAD, Vital's device that consists of ~1 pound of functional immortalized human cells, designed to take over hepatic biological functions in a patient with liver failure. Therapy with ELAD (3 to 5 days in duration) is expected to provide the damaged liver temporary respite, as the organ can regenerate and achieve minimal functional liver capacity. This approach capitalizes on the liver's unique ability to regenerate to significant capacity, even when a substantial proportion of the organ is lost due to insult (physical or chemical). Vital's initial focus is on alcohol-induced liver failure, an orphan indication of high unmet need, with no therapies to have demonstrated survival improvement to date. ELAD is being evaluated in the VTI-208 Phase III study in alcohol-induced liver decompensation (AILD), expected to read out in Q2 2015, and a second Phase III study in the AILD subset of acute alcoholic hepatitis (AAH) to report out in 2016 – which could serve as a second shot on goal if VTI-208 fails but has positive trends in this patient population. Beyond AILD, Vital is also focusing on fulminant hepatic failure (FHF) and surgery-induced liver failure (SILF), two ultra orphan rare conditions associated with rapid multi organ failure, coma, and death in the absence of liver transplantation. A Phase II study in FHF and SILF has been enrolling since June 2014, and topline results are expected in 2016.

Data from two randomized controlled studies of ELAD and a meta-analysis of two trials bode well for the VTI-208 Phase III trial. First, ELAD has been evaluated most recently in the randomized VTI-206 Phase II study (U.S. and E.U.), which stratified 62 patients as AILD and non-AILD, to be treated with ELAD or control. The per-protocol analysis (patients that were treated with ELAD for at least 3 days) included an even smaller number of patients (n=45). The study assessed survival at Day 90, whereby it is expected to be 50% or lower. Of the 45 patients, 29 represented the per-protocol, AILD cohort. In these patients, the median survival of those treated with ELAD was >100 days, whereas control patients achieved a median survival of 65 days. However, the improvement was not statistically significant (p=0.27); this observation was not surprising in light of the small number of patients included in this analysis. 9 out of the 13 patients (69.2%) treated with ELAD (who received at least 3 days of ELAD therapy, per protocol analysis) were alive at Day 90, compared with 7 out of the 16 control patients (43.8%). The non-AILD cohort included patients with chronic liver injury, including hepatitis B and C infection, and these patients did not appear to draw benefit from ELAD treatment. In addition, the safety profile of ELAD appeared benign, and serum biomarkers such as bilirubin and sodium levels improved significantly with ELAD therapy. Second, pooled data from two Phase II studies conducted in the U.S. and the U.K. in 26 patients with

fulminant hepatic failure showcased a numerical improvement in survival upon ELAD therapy. As these patients had high priority for transplantation, a sizeable number progressed to liver transplant. A meta-analysis of these results evidenced ELAD as a helpful bridge to transplant system, with a statistically significant improvement in survival in patients who did not get a transplant. Last, a randomized open label Phase II study of ELAD conducted in China demonstrated a statistically significant survival improvement at Day 28 and Day 56, as well as a numerical 20% difference at Day 84 (N=49 patients) per one of two statistical measures. For 23 and 22 patients that agreed to enroll in a 3- and 5-year follow up study, respectively, the survival difference was highly statistically significant with ELAD therapy. At the 5-year mark, 14 out of the 21 patients treated with ELAD were alive (66.6%), compared with 2 out of 7 control patients (28.6%). We believe that the totality of these efficacy signals, as well as the benign safety profile, bode well for ELAD's outlook in the ongoing pivotal trials.

ELAD is tested in two Phase III studies in acute alcohol-induced liver disease, first topline data expected in Q2 2015. The VTI-208 Phase III study is expected to support ELAD's registration. The design of this trial is informed by limitations of the small Phase II trials conducted to date. The pivotal trial conducted by Vital in AILD patients is set to enroll 200 participants, randomized 1:1 to get either up to 5 days of ELAD treatment in addition to the current standard of care, or standard of care alone. The primary endpoint is survival at Day 90. The study is 95% powered to identify a statistically significant difference in survival ($p<0.05$), in line with trends suggestive of a ~20-25% difference observed in the VTI-206 trial. The targeted population for VTI-208 includes patients who are not so sick that they cannot recover (e.g. patients with advanced cirrhosis or extensive hemorrhage), or those who would fare well irrespective of treatment methods (20% or more improvement in bilirubin levels in the 72 hours prior to assessment). The company has provided regular updates on the enrollment status of VTI-208, with 182 patients enrolled at 50 open centers (update as of December 8th). Management noted that enrollment rates have been steady, with ~12 patients entering the trial per month. Accrual completion is expected by YE14, and topline results are anticipated in Q2 2015. This study could be sufficient for ELAD registration, and we believe that in the event of a positive result, Vital could submit a regulatory filing in early 2016, with potential ELAD approval in late 2016. A second Phase III study was designed in collaboration with the EMA, to support registration in this territory. ELAD is expected to be tested in a subset of AILD patients who present with no underlying liver disease (acute alcoholic hepatitis). The study began opening study sites in April 2014, with the goal of enrolling 150 patients. To date, 9 sites have been activated for this trial, and first patient was enrolled in Q4 2014. Given that the study population for VTI-210 is included in the broader AILD (enrolled by VTI-208), the company only expects that significant patient accrual in this study will only occur in 2015.

Beyond alcoholic hepatitis, ELAD is also assessed for fulminant hepatic failure and surgery induced liver failure. Vital is testing ELAD in the VTI-212 Phase II study, a single arm trial slated to enroll 40 patients with FHF or SILF. This design has been agreed upon with the FDA and the EMA, given the difficulty of conducting a controlled trial in this setting. The first patient enrolled in June 2014, and topline results are expected in Q4 2016. We anticipate that potential success in this indication or signs of utility as bridge to transplant could render ELAD a useful "liver support" system for a broader patient population. For example, surgeons undertaking tumor resection of liver

cancer patients could be more "aggressive" in removing metastatic tissue, in the presence of a liver support system. Such an approach is currently not feasible, for fear that the remaining liver tissue is insufficient to carry out normal hepatic function.

Physicians highlight the unmet need in alcoholic hepatitis and the unique potential for ELAD. We spoke with key opinion leading hepatologists and transplant specialists, who highlighted the dire prognosis of patients that presented with acute alcohol liver failure. Our consultants noted that no intervention to date has demonstrated a sustained survival benefit in AILD patients. Several trials, including the STOPAH (consortium-sponsored study assessing the impact of steroids and pentoxifylline) showed that while patients can see some benefit at Day 30, a therapy to demonstrate definitive long term survival has not emerged to date. Artificial systems such as MARS (approved for hepatoencephalopathy, or "clouding" of the brain up to loss of brain function as a result of toxin accumulation) are used sparsely in the U.S. (~10 devices in the entire country). Physicians pointed that investment in devices such as MARS is often not feasible for a practice, given the limited benefit to patients. Our consultants believe that the powering and statistics of the VTI-208 Phase III study of ELAD are "quite good" to ensure that a ~20% survival benefit implied by previous studies would be statistically significant. Consultants also noted the rigorous study endpoint analysis, and enrollment criteria that are "both broad enough and narrow enough". One of our physician consultants served as investigator in the VTI-206 study, and mentioned that his center treated 3 patients on ELAD, while 2 were on control therapy. His overall impression was that "patients who got the machine had a significant change". One AILD patient had been in a coma for 10 days, and awoke after 6-7 hours on the machine and "he was sitting up, talking". This was an impressive achievement, in our consultant's view, given that toxin accumulation in the liver typically leads significant loss of brain function. Given the high rates of encephalopathy in alcoholic hepatitis, one physician mentioned that patients regaining consciousness represents a tremendous benefit, in his opinion.

We Forecast $3.1B in peak revenue for Vital in 2027. In the U.S., ~30K+ patients/year (up to 50K) develop AILD, which includes ~14K patients with AAH and ~16K with non-AAH AILD. In the E.U. we forecast a similar incidence, with ~30-50K patients that are diagnosed with AILD (~up to 23K AAH and ~25K non-AAH). Based on enrollment criteria for the VTI-208 studies, our key opinion leader consultants suggest that the addressable AILD population is ~30K patients in the U.S., split about 50-50 between AAH and non-AAH. We conservatively assume ELAD to be priced at ≥$150K per treatment, at the lower end of the $150K-270K range recommended to Vital by an expert orphan pricing consultant. We model this price for cartridges alone; as we expect that the machine may be loaned or sold for a nominal fee. We anticipate that VTI-208 topline data announcement in Q2 2015 would translate into regulatory filing in early 2016, and potential approval in by year end 2016. We conservatively forecast that that penetration will ramp to 25% at peak in 2027, slightly faster in the AAH versus non-AAH population. Based on annual expected price increases of 2%, we arrive at our peak $1.3B revenue forecast in the U.S. Similarly, we anticipate approval in the E.U. in H2 2017, with penetration increasing to 19% at peak, translating to $1.3B peak sales in 2027. Upside to our estimates may come from 1) China, with ~1.6M liver failures/year in urban areas, mostly due to Hepatitis B, 2) Liver transplant support, with 16.5K patients/year in the U.S. would be candidates, but the number of available livers (6.5K transplants were performed in 2012) is limiting, 3) cancer resection: ~20-100K cancer-related liver resections/year

are performed the U.S. – supporting liver function would allow surgeons to be more aggressive when removing metastatic cancer.

Vital has sufficient cash reserves to fund operations into Q4 2016. At the end of June 2014, Vital held $112.5M in cash and equivalents, including proceeds of $33.4M from a follow-on offering, conducted in October 2014. Management guided that these cash reserves should be sufficient to fund operations into Q4 2016. We model for another equity offering in Q4 2015, to support operations and pre-launch activities for ELAD, of $100M (~2M shares at $50/share).

Valuation

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.

Investment Risks

The primary investment risks for Vital include the following:

- **Highly binary clinical risk:** More than ~145 patients have been treated with ELAD to date (pre-ongoing trials); 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 50K U.S. (similarly in the E.U.) patients with liver failure can be addressed with ELAD therapy,

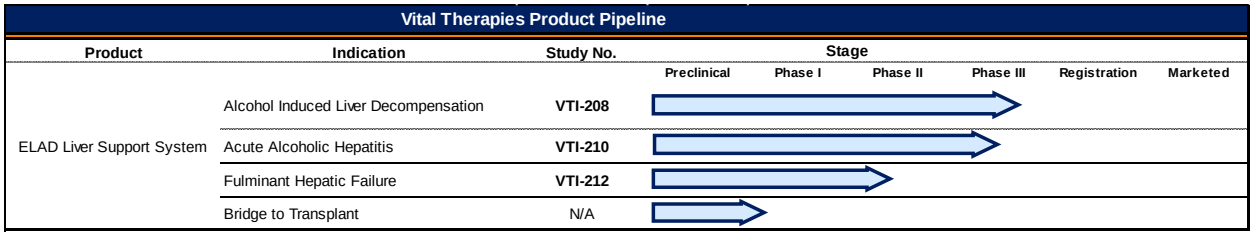
physicians may be reluctant to rapidly refer their patients to this treatment. Should the clinical benefit be marginal (albeit statistically significant and appropriate for approval), physicians may take a "wait and see" approach, treating first a small number of patients and looking for favorable outcomes. There remains a risk that the addressable market is smaller than modeled, penetration ramp is slower, and reimbursement is more burdensome than anticipated.

- **Technical and competition risk:** Given that a number of physical unit components are obtained from different sources, and that other immortalized liver cell lines are available in the public domain, there remains a risk that a competitor may try to undercut Vital.
- **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.

Pipeline Summary

Vital is developing the ELAD system, a cellular therapy incarnated as a bio-artificial liver, operated outside the body (extra-corporeal). The product is currently in two Phase III studies, VTI-208 in Alcohol-Induced Liver Decompensation (AILD), VTI-210 in Acute Alcoholic Hepatitis (AAH), Phase II in the VTI-212 Phase II study in Fulminant Hepatic Failure (FHF) and Surgery Induced Liver Failure (SILF). ELAD could also serve as bridge to transplant, but this option is not currently in clinical testing.

Figure 2: Vital Pipeline



Source: Company filings and STRH analysis

Figure 3: Vital Upcoming Milestones

Product	Indication	Timing	Milestone
ELAD	Alcohol-induced liver decompensation (AILD)	Q4 2014	Phase III VTI-208 enrollment completion
ELAD	**Alcohol-induced liver decompensation (AILD)**	**Q2 2015**	**Phase III VTI-208 data**
ELAD	Alcohol-induced liver decompensation (AILD)	Early 2016	ELAD filing for AILD
ELAD	**Alcohol-induced liver decompensation (AILD)**	**YE 2016**	**U.S. Approval for AILD**
ELAD	**Acute alcoholic hepatitis (AAH)**	**2016**	**Phase III VTI-210 data**
ELAD	Fulminant hepatic failure (FHF) or surgery-induced liver failure (SILF)	2016	Phase II VTI-212 data

Source: Company filings and STRH analysis

Vital is Blazing Trails with the First "Liver Dialysis" Therapy

Vital is focused on the development of cellular therapy for liver diseases. ELAD is a bio-artificial bedside system consisting of a reusable machine and four single-use cartridges filled with ~1 pound of cultured functional liver cells. ELAD is designed to take over hepatic functions for an acutely ill patient that presents with liver failure. Mortality is typically high in most instances of liver failure (~50%), and therapy is mostly palliative (supportive but not disease modifying). While the biological component of ELAD carries out key functions such as toxin clearance, the patient's liver has a chance to regenerate and recover to a point where ELAD support (3-5 days on therapy) is no longer needed. This is akin to dialysis, a procedure that allows a patient with kidney failure to survive, as the procedure filters out waste, and balances levels of sodium, potassium, and phosphorous, key functions carried out by kidneys. However, the liver is a significantly more complex organ, therefore mechanical/adsorbent approaches similar to kidney dialysis have failed to demonstrate a survival benefit to date.

Vital is developing the ELAD system for acute liver failure caused by excessive alcohol intake. The most advanced program is the VTI-208 Phase III study in a type of alcohol liver disease termed "alcohol-induced liver decompensation (AILD)", with pivotal data anticipated in Q2 2015.

A subset of AILD is acute alcoholic hepatitis (AAH), referring to liver failure precipitated by alcohol consumption, excluding any other underlying liver disease. The VTI-210 Phase III study testing ELAD in solely AAH patients is ongoing, with top-line results expected in 2016. This study is slated to support regulatory filing in the E.U., and the results may complement the VTI-208 dataset for U.S. approval (not required for AILD submission). The pivotal programs draw on positive observations and favorable survival trends from several prior studies:

- The randomized, controlled VTI-206 Phase IIb study of ELAD in acute liver failure (AAH and non-AAH cohorts)
- A meta-analysis of two studies of ELAD in fulminant hepatic failure (FHF), that enrolled 26 patients on liver transplant lists
- A randomized controlled study of ELAD in Chinese patients with viral hepatitis B, that demonstrated statistically significant survival benefit for ELAD-treated patients, maintained at 3 and 5 years.

Figure 4: Summary of Vital's Ongoing Studies

Study Identifier	Stage	Indication	Geography	Status	Expected Readout	Clinical Trials Identifier
VTI-208	Phase III	Alcohol Induced Liver Decompensation (AILD)	U.S., U.K., Spain, and Australia	175 out of targeted 200 patients enrolled as of Nov 2014, completion expected by YE14	Q2 2015	NCT01471028
VTI-210	Phase III	Acute Alcoholic Hepatitis (AAH) after steroid failure	U.K., Spain, and the U.S.	9 sites open, targeted enrollment of 150 patients, first patient expected by YE14	2016	NCT01829347
VTI-212	Phase II	Fulminant Hepatic Failure (FHF) and Surgery Induced Liver Failure (SILF)	U.S. (Texas)	Enrollment started Oct 2014	2016	NCT01875874

Source: STRH analysis, Wiesner et al, Gastroenterology, 2003

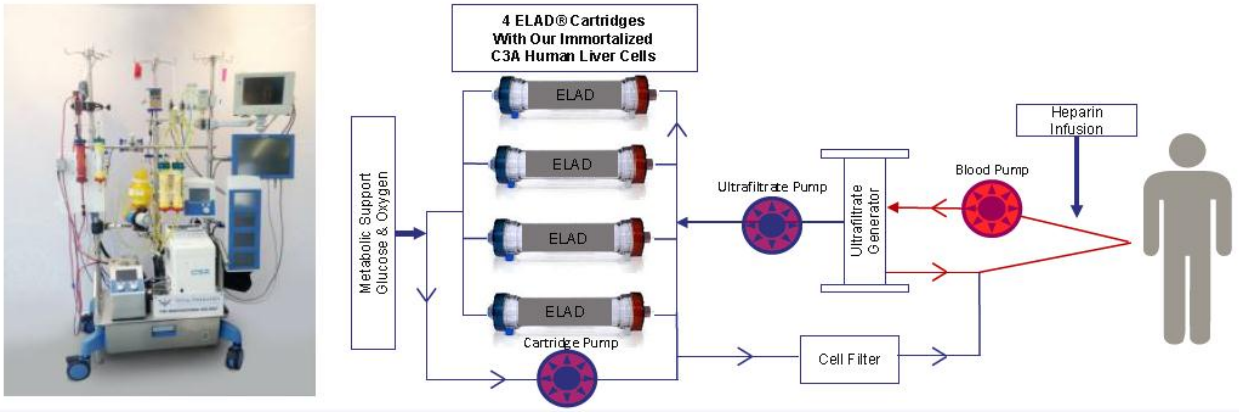
Vital is tackling a relatively broad indication for its first study, alcohol-induced liver decompensation. This is a severe and life-threatening form of liver failure brought on by recent alcohol intake. This can manifest as acute alcoholic hepatitis (AAH), whereby liver failure is caused by high alcohol intake absent underlying liver disease (such as cirrhosis). Separately, alcohol-induced liver decompensation (rapid liver function deterioration) could also be caused by combined toxic exposure to alcohol and toxins such as acetaminophen, known as non-AAH. Liver failure in these conditions is linked to hepatic encephalopathy (confusion, altered consciousness and coma, as the liver no longer removes toxins from the blood), kidney dysfunction, shock and potentially death.

ELAD Could Be the First Approved Bio-Artificial Liver Support System

The human liver has an extraordinary capacity to regenerate, which enables humans to sustain a considerable amount of injury. However, the liver fulfills a vast and complex number of biological functions that can rapidly lead to death should the liver become incapacitated. In our discussions with physician consultants, one theme continuously emerged: there currently exist artificial support options for a number of organs (heart, lungs, kidneys), but not for the liver. This is in spite of decades of clinical attempts to design an artificial adsorbent or filtering device to enable the liver's main function: breakdown and clearance of toxins. Thus, long term artificial maintenance of liver function is still beyond reach; commercial strategies have been instead focused on developing a liver support system to be used temporarily. The goal is not to completely replace the liver, but instead to take over some of its functions, such that the remaining tissue can regenerate and allow the patient to recover. In addition, for patients who do not retain regeneration capability, a liver support system could help "bridge" them to transplantation.

The key components of ELAD are live human hepatic cells. Vital's ELAD consists of two components (See Fig. 5): 1) a reusable bedside unit that includes adequate tubing and 2) four one-time use cartridges containing a proprietary human liver cell line. Vital owns the intellectual property and know-how around the immortalized (can be maintained in culture) hepatic C3A cell lines that function actively to remove exogenous drugs and toxins. The combined product falls under the FDA's Center for Biologics Evaluation and Research jurisdiction, as an allogeneic cellular therapy. The 4 cartridges include 440g (~1 pound) of C3A cells, that represent ~30% liver mass, a portion generally expected to sustain life.

Figure 5: ELAD Depiction and Functional Schema



Source: Vital company presentation

A number of key molecular characteristics showcase C3A cell potency. The most important function carried out by C3A cells in ELAD cartridges is the ability to metabolize toxins. This is achieved through copious amounts of cytochrome p450 present (protein that metabolizes the toxins) in C3A cells. Further, ELAD liver cells produce a number of proteins that regulate response to toxic shock, inflammation, and stimulate growth and regeneration. Given the cultured nature of C3A cells, Vital has extensively studied their biochemical output, with respect to the three functions listed above. ELAD treatment is expected to yield exogenously produced liver proteins that include albumin, anti-thrombin (modulator of blood clotting), alpha-fetoprotein, but also C3 complement protein, macrophage migration inhibitory factor, apolipoproteins, as well as growth factors. Nevertheless, C3A cells do not behave identically to primary liver cells. One of the key differences is the lower efficiency in processing ammonia; however, we note that regular dialysis could resolve any abnormal ammonia accumulation.

C3A cells benefit from commercial scalability. Vital has optimized culture conditions for C3A cells, such that they can be expanded and production scaled up for commercial purposes. C3A cells are produced at a GMP-production plant in San Diego, and the production process takes ~ 6 weeks. Unlike primary liver cells that would not survive longer than their natural lifespan, C3A cells are "immortalized" and can survive for ~50 days. A number of biochemical sensors enable the company to measure the viability of cartridge-enclosed C3A cells. These provide ample notice to the technician operating the machine to obtain new cartridges and replace "used" ones. For transportation, C3A cells are maintained into a "dormant" state which allows survival for ~60 hours.

For patients whose liver retains regenerative potential, ELAD could be a less invasive option compared to transplantation. While liver transplant is the only procedure demonstrated to provide a survival benefit to patients with acute liver failure, it entails a highly invasive process and surgery. Temporary use of ELAD, as the patient's liver recovers, may circumvent the need for liver transplantation. Furthermore, our physician consultants point to the shortage of organs for transplantation: there are currently ~16.5K patients listed for a transplant, and only 6.8-7K organs available in the U.S. They estimate that annual mortality while waiting for a transplant is 16-20%. In

addition, patients need to continue lifetime therapy with immunosuppressants following liver transplantation.

ELAD could provide patients with a bridge to transplant alternative. In light of the high mortality rates while waiting for an organ to become available, treatment with ELAD could enable maintenance of liver function. Some of the clinical data generated to date by Vital suggests that ELAD therapy may indeed provide such benefit.

ELAD's Clinical Outlook is Supported by a Number of Completed Trials

A Phase IIb Study of ELAD Conducted in the U.S. and E.U. Supports Efficacy.

Supporting data for the ELAD efficacy stem from the VTI-206 Phase IIb trial. The open label study enrolled 62 patients with acute liver failure or acute-on-chronic hepatitis, and was conducted at 26 sites in the U.S. and the U.K between 2009 and 2011. Enrollment criteria included Model for End-Stage Liver Disease (MELD) score between 18 and 35, acute decompensation of chronic liver disease over the preceding 30 days, and age greater than 18. The exclusion criteria were designed to prevent participation of patients with systemic disease, who would have been unlikely to improve with ELAD therapy: chronic renal failure, septic shock, major hemorrhage, liver cancer, seizures, or who harbored evidence of acute myocardial infarction, stroke, or brain death. The study also excluded patients who previously received liver transplantation.

The primary endpoint was time to progression, evaluated as a 5-point or greater increase in MELD score compared to baseline, or death, up to study Day 91. Secondary endpoints included overall survival (OS) analysis at Day 30 and Day 90, as well as the proportion of progression-free survivors at Day 90.

The MELD score is a measure of liver damage initially used to predict chance of survival within three months from surgery, and currently used to determine prognosis and enable transplant decisions. The MELD score provides a clear cut framework to evaluate liver failure, given the varied manifestations of this indication and the multitude of molecular markers that can be measured in this context. MELD measures patient serum levels of bilirubin, creatinine, and blood clotting tendency (named the "international normalized ratio of prothrombin time"). For hospitalized patients, MELD scores typically result in the following mortality estimates:

Figure 6: MELD Score Interpretation

MELD score	Est. 3-month mortality
>40	71.30%
30-39	52.60%
20-29	19.60%
10-19	6%
<9	1.90%

Source: STRH analysis, Wiesner et al, Gastroenterology, 2003

62 patients were randomized to get either standard of care therapy (including treatment with pentoxifylline, corticosteroids, abdominal paracentesis (i.e. fluid removal), and nutritional therapy) or standard of care in addition to up to 6 days of ELAD treatment.

Results from the VTI-206 Phase IIb study reflect relatively small patient numbers in the intent-to-treat and per-protocol analyses. Participants in the study were stratified to alcohol-induced liver damage and non- alcoholic hepatitis. Of note, the study did not require baseline biopsy analysis, such that the academic definition of acute alcoholic hepatitis is not technically applicable to these patients. Given that these patients most likely may also have presented with some degree of steatosis, fibrosis, or scarring, Vital termed the indication alcohol-induced liver damage (AILD), to include both "pure" AAH patients (no trace of preceding liver disease) as well as patients with some preceding liver disease that presented with alcohol liver failure. Data discussed below refers to "AAH" patients, although enrollment criteria correspond to the AILD population addressed by the VTI-208 study.

Patients were therefore randomized independently into four cohorts. Patients characterized as "baseline failures" were not treated following randomization either due to death, transplantation, or systemic toxicity. The following populations were analyzed:

- Modified intent-to-treat (mITT), namely patients who received treatment (thus excluding baseline failures) and for whom 90 days follow up data were available (N=51).
- Per-protocol, namely patients who were treated with ELAD for at least 3 days (N=45)

Patient disposition in this study, including breakdown of each cohort, is detailed in Fig 7:

Figure 7: Patient Disposition in the VTI-206 Study

	Acute alcoholic hepatitis (AAH)		Non-acute alcoholic hepatitis (non-AAH)		Total	
	ELAD	Control	ELAD	Control	ELAD	Control
Randomized	16	21	13	12	29	33
Baseline failure	0	2	4	0	4	2
Withdrew consent/Lost to follow up	1	3	0	1	1	4
Modified ITT	**15**	**16**	**9**	**11**	**24**	**27**
<72 hrs of therapy	2	0	3	1	5	1
Per protocol	13	16	6	10	19	26
Reasons for Baseline Failures						
Death	0	0	1	0	1	0
Transplant	0	0	1	0	1	0
Ineligible	0	2*	2**	0	2	2
Total	0	2	4	0	4	2

*DNR, portal vein thrombosis

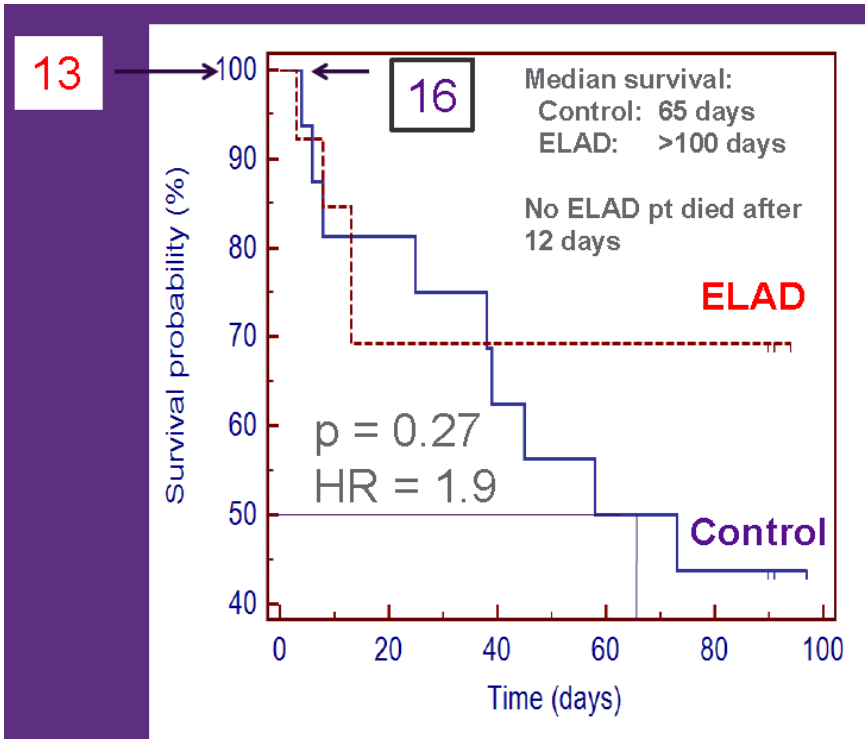
**hemodynamic instability, systemic fungal infection

Source: STRH analysis, Vital company presentation

The "non-AAH"/non-AILD patient cohort of VTI-206 did not appear to benefit from ELAD therapy. The non-AAH patient cohort consisted of 25 patients, of whom 12 had chronic alcoholic liver disease, but 13 presented with liver failure not caused by alcohol (including HCV, HBV, non-alcoholic steatohepatitis and autoimmune cholangitis). Vital disclosed that in January 2011, the Data Safety and Monitoring Board (DSMB) for VTI-206 recommended that the non-AILD cohort be closed. This recommendation was based on the low likelihood that these patients would draw any benefit from ELAD therapy. Per discussions with the FDA, the statistical analysis of the entire trial would have been impacted, and the dataset could not have been used. Thus, Vital terminated this study early and designed the VTI-208 Phase III study to serve as registrational trial in the U.S.

Results from the AAH/AILD cohort of VTI-206 were suggestive of ELAD activity. In the 29 patient, per protocol, AAH cohort of the VTI-206 study, the median survival of patients treated with ELAD was >100 days, whereas control patients achieved a median survival of 65 days (Fig. 8). However, the improvement was not statistically significant (p=0.27); this observation was not surprising in light of the small number of patients included in this analysis.

Figure 8: VTI-206 Phase IIb Study Survival Analyses Highlight ELAD Activity Signal



Source: Vital company presentation

9 out of the 13 patients (69.2%) treated with ELAD (who received at least 3 days of ELAD therapy, per protocol analysis) were alive at Day 90, compared with 7 out of the 16 control patients (43.8%), as illustrated in Fig. 9. One out of the 13 ELAD patients (8%) went on to pursue liver transplantation, whereas none of the control patients achieved this outcome.

Figure 9: ELAD Treatment Resulted in Numerical Survival Superiority in the AILD Cohort

	MITT		PP	
	ELAD n = 15	Control n = 16	ELAD n = 13	Control n = 16
OS through Day 90	9 (60%)	7 (43.8%)	**9 (69.2%)**	**7 (43.8%)**
Median survival, days	>100	73	>100	65

Source: Vital company presentation

There was no improvement upon ELAD therapy in the non-AAH patient cohort. 1 out of the 6, or 17% (per protocol analysis) ELAD treated patients in the non-AAH cohort were alive at Day 90, versus 6 out of 10 (60%) control patients. The survival differences

were not statistically significant. 1 out of 6 (17%) ELAD treated and 4 out of 10 (40%) control patients were transplanted by Day 90.

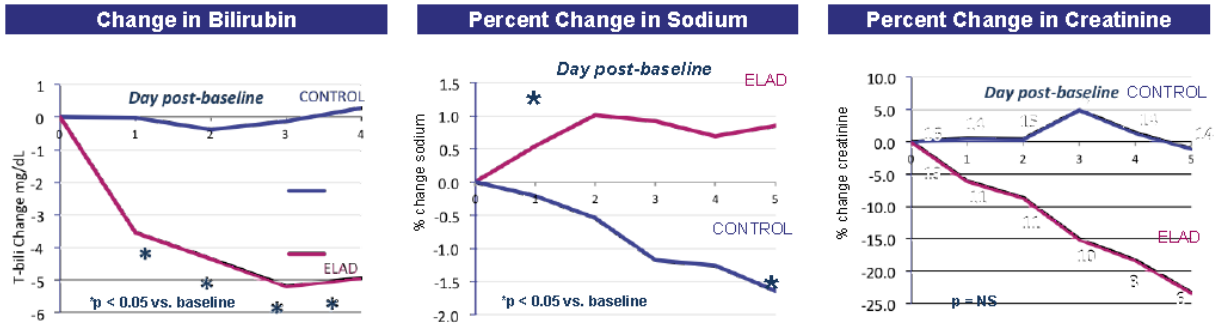
Figure 10: ELAD Showed no Benefit in the non-AILD Liver Failure Patients

	MITT		PP	
	ELAD n = 9	Control n = 11	ELAD n = 6	Control n = 10
OS through Day 90	2 (22.2%)	6 (54.5%)	1 (17%)	6 (60%)

Source: Vital company presentation

Serum biomarkers such as bilirubin, creatinine, and sodium, were suggestive of benefit with ELAD therapy. Vital also conducted a number of analyses of patient biomarker data in VTI-206, to assess other potential measures of benefit of ELAD therapy (given the need to replace a large number of complex functions fulfilled by the liver in these hepatic failure patients). Retrospective analyses of these markers revealed that ELAD treatment resulted in a statistically significant reduction in bilirubin and creatinine levels, and an increase in sodium. Interestingly, the reduction in bilirubin in ELAD versus control treated patients was evident both in AAH and non-AAH patient cohorts.

Figure 11: ELAD Therapy Was Associated with Positive Impact on Serum Biomarkers



Source: Vital company presentation

Physicians we have spoken with highlight that improvement in bilirubin and creatinine are key. One of our physician consultants noted that reduction in these biomarkers was not directly attributable to ELAD C3A cells taking up protein. Rather, this reduction suggests that the patient's liver is managing to recover normal function and begins to "clear" up the blood.

ELAD therapy was associated with a benign safety profile. Safety analyses were in line with expectations, and the DSMB did not identify any differences between rates of serious adverse events (SAEs) experienced by ELAD and control treated patients. There were 28 SAEs reported in 17 ELAD patients, and 40 SAEs recorded for 20 control

patients. Six reported events may have been related to ELAD therapy, each recorded in one patient (gastrointestinal bleeding, vomiting blood, worsening kidney failure, sepsis, vaginal bleeding, and hemolysis (breakdown of red blood cells).

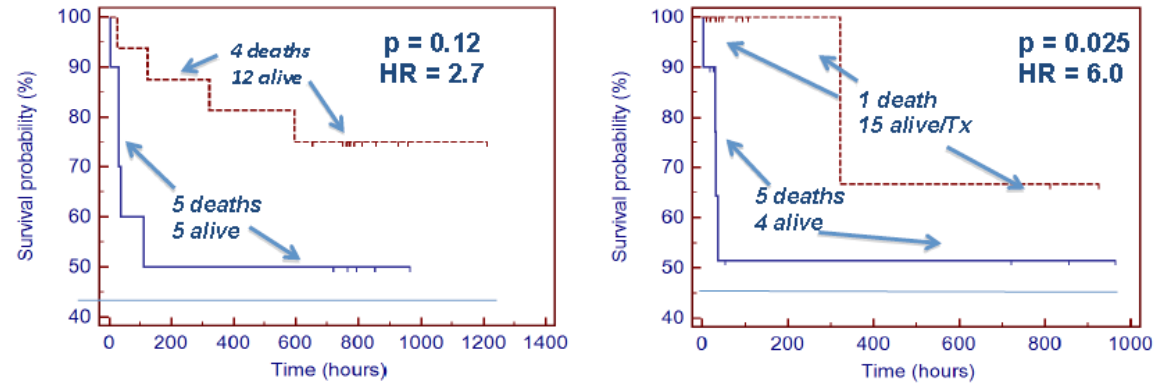
Data from a Meta-Analysis of Two Studies in Fulminant Hepatic Failure (FHF) Provide Hints of Survival Benefit

Fulminant hepatic failure represents a small subset of acute liver failure (accounting for ~2K cases per year in the U.S.), with rapid disease progression typically triggered by acetaminophen poisoning, injury from other drugs or viral hepatitis, in patients without any underlying liver disease. These patients have a high mortality rate (~50%), as patients present with general symptoms such as fatigue, abdominal pain, fever, and jaundice, and develop encephalopathy and coma that lead to multi-organ failure. Similar to AILD, liver transplantation is the only intervention demonstrated to improve patient survival.

Vital conducted two randomized controlled studies in FHF, with pooled data providing evidence of ELAD benefit. In the two studies, 26 U.S. and U.K. fulminant hepatic failure patients were enrolled, based on high expected mortality rates and listing for transplant. Patients were treated with either 2 or 4 cartridges of cells, based on body weight, and each cartridge contained 80-100 grams of C3A hepatic cells.

The primary endpoint in both studies was 30-day overall survival. The overall outcome of these studies was confounded by a high rate of transplantation that occurred on average in less than 3 days from therapy, and some unexpected post-transplant mortality. 3 patients treated with ELAD died after transplantation; in total, there had been 4 deaths in the ELAD arm, and 5 deaths in the control arm of this study. At the end of the 30 day analysis period, 12 patients treated with ELAD were still alive, compared with 5 patients given the standard of care. The numerical difference in survival was not statistically significant (p=0.12), which is expected given this small patient group.

Figure 12: Meta-Analysis of Fulminant Hepatic Failure Studies of ELAD Was Suggestive of Survival Benefit



Subject disposition at 30-day end of study:

p = 0.006	BTT/R	Death w/o Transplant
ELAD	15	1
Control	5	5

Source: Vital company presentation

In a second analysis, events of transplantation were censored (i.e. only deaths without transplant were counted as events), and ELAD use as bridge-to-transplant was evaluated. At the end of 30 days of follow-up, 15 patients treated with ELAD achieved recovery or were successfully bridged to transplant, versus 5 in the control arm.

Comparison of pooled patient data from these trials suggested of an increase in 30-day survival benefit, associated with ELAD therapy. This improvement, however, was not statistically significant.

Long Term Follow Up from an ELAD Study Conducted in China Provides Statistically Significant Evidence

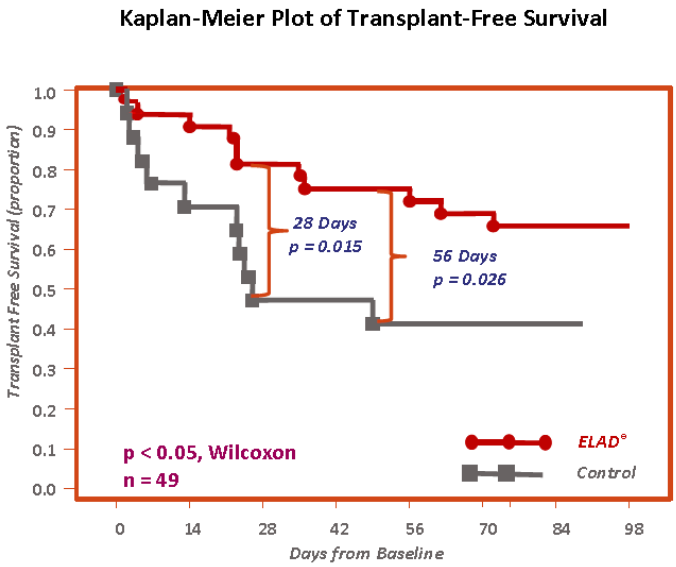
In 2004, Vital received an invitation to conduct a randomized, open label Phase II (called VTIC-301) at two hospitals in Beijing, China. The trial was started in March 2006, and was designed to treat patients with acute flare hepatitis B with ELAD. The targeted enrollment was 120, and patients were randomized 2:1 to receive continuous ELAD therapy for 3 days or standard of care supportive therapy alone. Patient eligibility was pegged to a 50% expected probability of death by 84 days, therefore most participants presented with acute flares or viral hepatitis. The study outcome was transplant-free survival. While this study was not meant to support approval in the U.S. or the E.U., we believe that these clinical datapoints (taken with the appropriate caveats) may provide yet another tidbit of evidence that ELAD therapy could aid acute liver failure patients.

Following the enrollment of the first 49 patients, the study protocol was amended to enable enrollment of patients with less severe disease. However, this change resulted in fewer deaths or transplantations conducted in the second cohort of 19 enrolled patients. Thus, two separate analyses were designed to account for these differences, one that would take into account the entire 68 patient dataset, while a

second analysis would be restricted to the first 49 patients. Enrollment in the study was stopped early (limited to the 68 patients) as investigators deemed continued therapy with the standard of care unethical due to ELAD benefit.

Data from the first 49 patients showcased statistically significant differences in 28 and 56-day survival (logrank test p=0.015 and 0.026, for the two timepoints, respectively). While the logrank test analysis carried out at Day 84 no longer demonstrated a statistically significant benefit, another survival test (Wilcoxon), showed that the survival difference between ELAD and control treated patients was statistically significant (p=0.049). Analysis of the entire dataset revealed statistically significant survival improvement upon ELAD therapy at Day 28, but no significant differences at Day 56 and 84. There was a ~20% difference in survival favoring ELAD at Day 84. Given the higher sensitivity/stringency of the logrank test, Vital anticipates that future analyses will be conducted using this statistical approach.

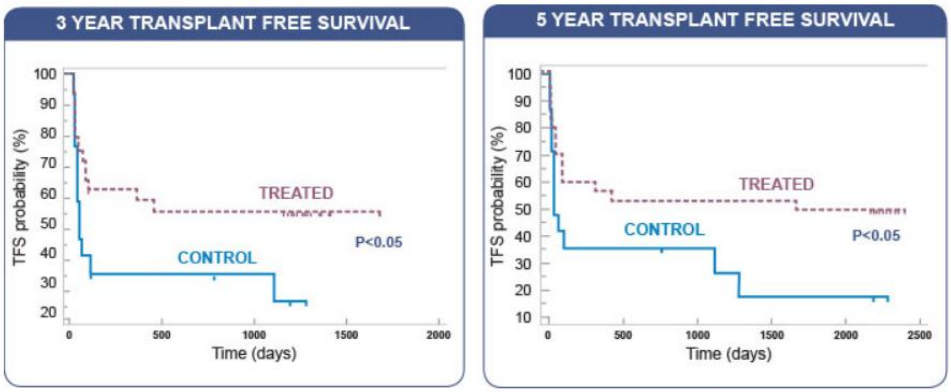
Figure 13: ELAD Therapy Demonstrated Statistically Significant Transplant-Free Survival Benefit in VTIC-301



Source: Vital company presentation

ELAD survival benefit was maintained at 3 and 5 years in the China study. Long term analyses of VTIC-301 data suggest that the ELAD benefit is maintained 3 and 5 years following therapy. 23 and 22 patients from the original patient cohort presented for follow up at 3 and 5 years, respectively, following initial randomization. Of note, these analyses were not prospectively defined in the VTIC-301 protocol. At the 5-year mark, 14 out of the 21 patients treated with ELAD were alive (66.6%), compared with 2 out of 7 control patients (28.6%).

Figure 14: Long Term Benefit with ELAD in the VTIC-301 Study



Source: Vital company presentation

Vital will likely utilize this dataset for ELAD approval in China. The completed VTIC-301 was slated to serve as registrational study in China, as of the completion of this trial in 2007. However, the current regulations require that a foreign sponsor have the therapy approved in their country of origin before requesting approval with the Chinese sFDA. Vital intends to apply for ELAD registration following potential approval in the U.S., likely in 2016.

The VTI-208 Phase III Study is Ongoing, Data Expected Q2/15

The Pivotal VTI-208 Study Incorporates Robust Powering and a Number of Lessons Learned from VTI-206

Two key aspects of the VTI-206 design may have prevented achievement of a clear survival benefit. First, the number of AILD patients in the per-protocol analysis in the 206 study was very small. Although mathematically, survival was longer in the ELAD arm, and a higher proportion of patients in this cohort achieved the primary endpoint of survival at Day 90, our physician consultants suggest that the number of patients (n=29) is unlikely to have helped attain a statistically significant result. Second, some non-AILD patients enrolled in the trial may not have benefitted from this therapy, as their livers were highly cirrhotic and unlikely to regenerate (i.e. the chronic liver failure population in the non-AAH cohort).

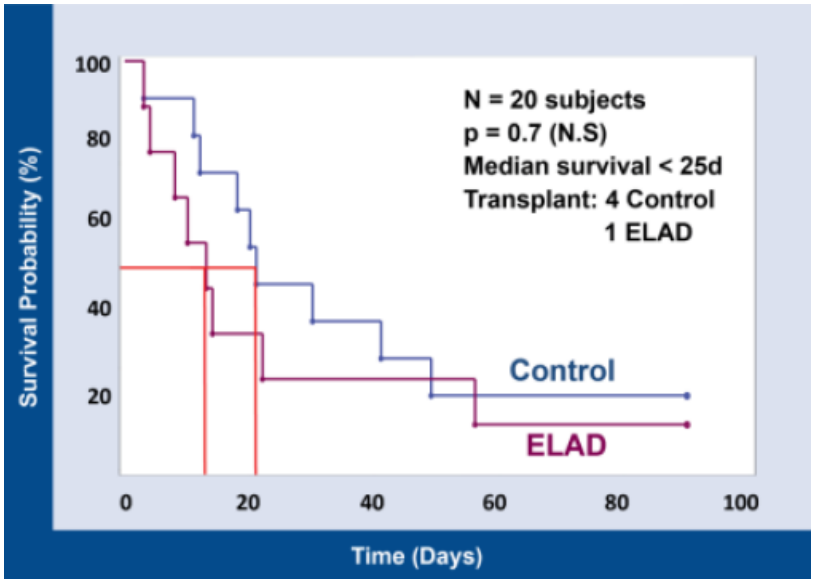
The VTI-208 study is slated to enroll a substantially larger number of patients than VTI-206. The pivotal trial conducted by Vital in AILD patients is set to enroll 200 participants, randomized 1:1 to receive either up to 5 days of ELAD treatment in addition to the current standard of care (includes nutrition support, N-Acetyl Cysteine, steroids, pentoxifylline, etc), or standard of care alone. There are 51 study sites currently open and actively enrolling patients, in the U.S., Australia, and the E.U. The primary endpoint is survival at Day 90. The study is 95% powered to identify a statistically significant

difference in survival (p<0.05), in line with trends suggestive of a ~20% difference in the VTI-206 trial. Secondary endpoints include time to progression of disease, set to measure the ability of ELAD to stabilize hepatic function.

VTI-208 is designed to exclude patients not expected to recover from liver failure. The 20 patients in the non-AAH modified intend-to-treat population harbored significant cirrhosis and likely presented with non-regenerable liver. As illustrated in the figure below, and there appeared to be no survival benefit associated with ELAD treatment in these patients, and there was no opportunity for patient improvement absent a liver transplant. This observation corroborated long-held assumptions that cirrhotic livers have a limited capacity to regenerate, and therefore transferring liver function to ELAD alone was unlikely to aid patient recovery.

Thus, the VTI-208 study is slated to exclude patients with advanced cirrhosis, or who are likely to die imminently irrespective of therapy (elevated liver enzyme AST greater than 500 IU/L, suggestive high inflammation levels, systolic blood pressure below 90mm Hg or arterial pressure below 60 mm Hg, or hemorrhage requiring transfusion on 2 units of red blood cells.

Figure 15: ELAD Therapy is Likely not Suitable for Patients With Cirrhotic, Non-Regenerable Liver



Source: Vital company presentation

Enrollment criteria for VTI-208 exclude patients with very good prognosis. The VTI-208 trial is also set to exclude patients who are expected to recover irrespective of treatment, for example those who experience a 20% or more improvement in bilirubin levels just before treatment with ELAD.

The trial design includes robust powering, drawing on the survival benefit seen in the VTI-206 trial. Based on the ~25% more patients on ELAD in the VTI-206 per protocol population who achieved survival at Day 90, VTI-208 incorporate adequate powering to

detect a 15-20% difference in survival between ELAD and control treated patients. The trial is 99% powered to detect a statistically significant improvement of 25% in survival, 95% powered to detect a 20% difference, and 80% powered to detect a 15% change.

Figure 16: Summary of Key Changes in Design Between VTI-206 and VTI-208

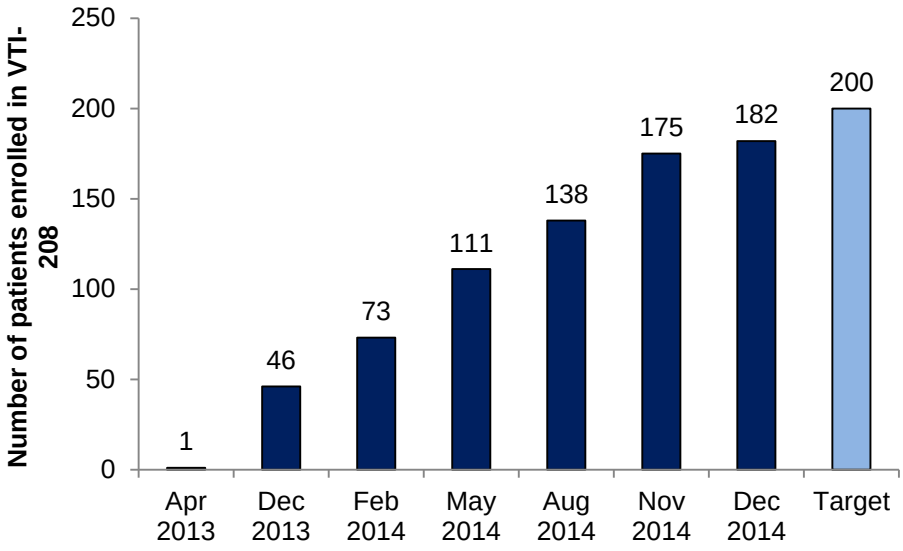
- Patient number of 200 enables 99% powering to detect a statistically significant improvement of 25% in survival
- Patients with end-stage cirrhosis are excluded
- Patients whose bilirubin has improved 20% or more in prior 72 hours are excluded
- Patients with poor prognosis are excluded:
  - AST greater than 500 IU/L
  - Systolic blood pressure <90mm Hg, or mean arterial pressure <60mm Hg
  - Hemorrhage requiring 2 units of red blood cell transfusion

Source: Vital company presentation

The VTI-208 Study Has Been Enrolling Steadily, on Path to Readout in Q2/15

Patient accrual began in April 2013, Vital expects that enrollment completion will occur by year end 2014. The company has provided regular updates on the enrollment status of VTI-208, with 175 patients enrolled at 39 of the 51 open centers (update as of November 14th), with ~12 patients enrolling steadily per month.

Figure 17: Patient Enrollment Updates in VTI-208 Provided by the Company



Source: Vital company presentation

While the study is open label, extra steps have been taken to ensure comparable treatment and follow up during therapy and post-therapy. Management has described that there are two distinct steps in the treatment of each study participant: the first involves bedside use of ELAD (typically in the intensive care hospital unit) for up to 5 days, while the second entails patient follow up care. While blinding of the first portion is not possible, physicians providing follow up care are blinded to ELAD/standard of care treatment in the first step. Thus, the study is designed to prevent any bias in follow up care and in observations. We note that the overall survival outcome provides an undisputable measure of clinical benefit.

Alcohol recidivism is expected to impact the control and ELAD arms in similar fashion. Some patients may regress, once released from the hospital, and resume alcohol consumption. In fact, at least 30% of the alcoholic hepatitis patients regress, according to management (our consultants suggest that as many as 40%). Management anticipates that deaths potentially attributable to resumption of alcohol consumption will be proportionally distributed between the control and the ELAD arm. Correlation of the cause of death and alcohol consumption could be carried out in a post-hoc fashion. The study follow up protocol requires that patient blood samples are taken at regular intervals post ELAD therapy, enabling measurement of blood alcohol content. We anticipate that any imbalances in the number of recidivism-caused deaths could be clearly identified and accounted for in the final data analysis.

With topline data expected in Q2 2015, we believe ELAD could reach the market in 2016. The company has disclosed that VTI-208 could be sufficient for ELAD registration. Should the 208 study reach its primary endpoint, we believe that the company could submit a regulatory filing in 2H 2015 and the product could be approved in 2016.

VTI-210 is a Second Ongoing Phase III Study, to Evaluate a More Stringently Defined AAH Population

A second pivotal trial was designed in collaboration with the EMA, to evaluate ELAD in a subset of AILD patients, acute alcoholic hepatitis that does not present with any underlying liver disease. These patients are not likely to receive liver transplantation, and therefore survival analyses are unlikely to be confounded by this procedure. The specific population to be enrolled includes patients who failed 7 days of steroid therapy, and who are expected to have a higher mortality rate than AILD all-comers.

The study began opening study sites in April 2014, with the goal of enrolling 150 patients. To date 9 sites have been activated for this trial, and first patient enrolled in December. Given that the study population for VTI-210 is included in the broader AILD (enrolled by VTI-208), the company only expects that significant patient accrual in this study will only occur in 2015.

The primary endpoint is survival at Day 90, and topline results are expected in 2016.

Beyond Alcoholic Hepatitis, ELAD Will Also Be Tested in A Phase II Study in FHF/SILF

A Phase II program is also evaluating ELAD in patients with FHF, based on the activity signals seen in the meta-analysis discussed above. In addition, ELAD could provide benefit to patients with surgery-induced liver failure (SILF), e.g. patients that failed a cancer resection. However, the company faces a number of difficulties in designing a randomized controlled study in this indication, chief among them the ultra-orphan nature of this type of liver failure. Furthermore, these patients are the first ones that have priority on the liver transplant lists, and may be subject to this procedure in as little as 3-5 days. The outcome for these patients is rapid onset of multiorgan failure which typically occurs within one week. We believe ELAD could be used in this disease as a bridge to transplant system, in a similar fashion that a ventilator or a dialysis machine would enable patient survival ahead of a lung or kidney transplant.

Vital reached concurrence with regulatory agencies to conduct a single arm study. Following discussions with the FDA and EMA, the company designed the single arm VTI-212 study, to enroll 40 patients with FHF or SILF. The primary endpoint is 28-day overall survival, to be compared with historical databases. The first patient enrolled in June 2014, and topline results are expected in Q4 2016.

Physician Feedback Highlights Unmet Need and Optimism with ELAD Promise

Anecdotal example bodes well for ELAD's outlook. One of our physician consultants has served as investigator in the prior VTI-206 study, and mentioned that his center treated 3 patients on ELAD, while 2 were on control therapy. His overall impression was that "patients who got the machine had a significant change". One AILD patient had been in a coma for 10 days, and awoke after 6-7 hours on the machine, "he was sitting up, talking". This is an impressive achievement, given that toxin accumulation in the liver typically leads to hepatoencephalopathy ("clouding" of the brain up to loss of brain function). Given the high rates of encephalopathy in alcoholic hepatitis, he mentioned that patients regaining consciousness represents a tremendous benefit, in his opinion. Consultants also highlighted the lack of SAEs related to machine treatment.

Acute alcoholic liver disease represents a great unmet need. Our consultants noted that no intervention to date has demonstrated a sustained survival benefit in AILD patients. While 30 day clinical data in several trials, including the STOPAH (consortium-sponsored study assessing the impact of steroids and pentoxifylline) show that patients can see some benefit at early timepoints, a therapy to demonstrate definitive long term survival has not emerged to date. Artificial support systems such as MARS are being used sparsely (10 estimated devices are in use in the entire U.S.), given their high cost (~$30,000), lack of long term survival improvement demonstrated in clinical trials, and marginal benefit (according to the few practitioners who have used this machine).

Hepatology key opinion leaders are comfortable with the study design. The physicians we spoke with noted that a survival benefit is difficult to gauge based on 20-30 patient trials. The 200-participant number in VT-208 provides Vital with a better chance to assess ELAD-associated survival benefit. Further, our consultants believe that the powering and statistics are "quite good" to ensure that a ~20% survival benefit implied by

previous studies would be statistically significant in VT-208. A physician who participated in VTI-206 alluded to a number of technical upgrades that the company instated prior to pivotal testing launch. Consultants also noted the rigorous study endpoint analysis, of survival at 90 days. While "many things" maintain survival in the first month after hospitalization, long term impact has not been demonstrated to date by any intervention, save for liver transplantation.

Our physician consultants view the VTI-208 enrollment criteria as suitable to establish clinical benefit for ELAD. One of the investigators in the prior VTI-206 study noted "months" of discussions among physicians and Vital coordinators, to best define the patient population appropriate for VTI-208 enrollment. He believes that the process has been very thorough, and current enrollment criteria "are both broad enough and narrow enough": eligibility criteria currently exclude patients that would recover anyway, as well as patients who have such a small liver volume (namely because of high proportion of cirrhotic tissue) who have a small chance of survival. Thus, the desired patient population is alcohol-induced liver failures with poor prognosis, who are unlikely to respond to intensive therapeutic support with N-Acetyl Cysteine, nutrition, or steroids.

Physicians are encouraged by the steady pace of enrollment. Our consultants noted the steady pace of patient enrollment in VTI-208, month after month. These trends represent a good indicator, in their opinion, that enrollment criteria are appropriate for this patient population.

Relapse and drinking are unlikely to confound study data. Following hospital release, study participants continue to be followed in an out-patient setting. While one of the consultants we have spoken with noted the high alcohol recidivism rate (~40%) at the 1-year mark, he noted that relapse typically occurs in the 6-12 month window. A physician who has treated hundreds of alcoholic patients alluded that a person who "almost died in the hospital" due to binge alcohol drinking typically has an "almost religious experience" that motivates abstaining from alcohol. Further, the 40% patients who do relapse are typically those without a social support network.

Alcohol-Induced Liver Disease Represents an Area of High Unmet Need

Liver failure has two main incarnations: acute and chronic. Acute liver failure refers to a decline of liver function over a period of hours or days, in a patient who does not present with any other underlying liver disease. This is typically caused by ingestion of unsustainable levels of alcohol or other toxic substances, including but not limited to acetaminophen, narcotics, or mushrooms. Other types of acute liver injury entail sepsis (rapidly progressing infection). Chronic liver failure is defined by existing liver disease.

Of note, underlying liver disease can range from fatty liver (steatosis), hepatitis (liver inflammation), fibrosis (accumulation of scar tissue interspersed with normal cells), to cirrhosis (predominant presence of scar tissue to the detriment of normal tissue). The

milder presentations of steatosis and some types of hepatitis are associated with liver compensation (i.e. the liver retains a majority of its normal function). Acute-on-chronic liver failure is typically precipitated by an event such as those described above, on a background of advanced hepatitis, fibrosis, or cirrhosis.

Acute liver failure is an orphan disorder with poor prognosis. There are about 50K incident cases of acute liver failure in the U.S., and the numbers are similar in the E.U. Three different subsets of acute liver failure are alcohol-induced failure, fulminant hepatic failure, and surgery-induced liver failure. Jaundice (yellowing of the skin and the eyes) is a common symptom of liver failure, as the liver fails to clear out accumulated toxins and waste. Encephalopathy refers to mental status changes induced by this toxin buildup, and liver failure patients can often slip into a coma. Left untreated, between 60% and 90% of the patients eventually succumb to the disease.

Alcohol-induced liver decompensation (AILD) refers to a relatively broad spectrum of acute liver disease. Acute liver injury induced by alcohol consumption can occur on a background of steatosis or inflammation caused by sustained alcohol abuse. However, a number of AILD patients present with no underlying liver disease, and liver failure caused by binge drinking (acute alcoholic hepatitis, AAH). About 90% of alcoholics harbor fatty liver, about 25% progress to alcoholic hepatitis, and 15% of these patients develop cirrhosis. Hospital-admitted patients due to acute alcoholic hepatitis are generally in their 40s and have high mortality rates. To qualify for a liver transplant these patients had to historically abstain from alcohol consumption for 6 months. According to our consultants, the timelines are less strict nowadays, with 3 months of abstinence being sufficient to enable a patient to qualify for liver transplantation.

Fulminant hepatic failure is a rare type of acute liver failure. Approximately 2K U.S. patients are expected to be hospitalized with this disorder over one year. FHF refers to rapidly progressing loss of liver function, in patients with a previously healthy liver that suffered hepatic shock induced by severe drug-induced injury or viral hepatitis. Patients progress rapidly to encephalopathy, present with fever, fatigue, malaise, nausea, abdominal pain, and can develop multiorgan failure, coma, and death.

Surgery-induced liver failure (SILF) results from a failed transplant or inappropriate resection. Acute graft non-function refers to a failed surgical transplantation procedure, while failed resection describes a patient with liver cancer who undergoes surgery for tumor removal but retains insufficient functional liver tissue. There are currently no artificial support systems for these patients, and our physician consultants note that many surgeons are reluctant to address patients with primary liver cancer or with liver metastases, for fear of SILF.

A Number of Approaches to Date Including Artificial Liver Support Have Failed to Provide Clinical Benefit

Therapy with steroids or pentoxifylline does not result in survival benefit. For liver failure patients the standard of care is nutritional support, as well as steroids (such as prednisone) and pentoxifylline. Steroids are expected to manage inflammation associated with acute liver crises, while pentoxifylline is approved for management of chronic

occlusive arterial disease of the limbs. The rationale for its use in liver failure patients is the expectation that blood flow would be enhanced. At the American Association for the Study of Liver Diseases (AASLD) meeting in Nov 2014, a Late Breaker Oral presentation showcased data from a large study (N=1103 patients) conducted through a collaborative effort of 16 institutes in the U.K. The so called STOPAH trial demonstrated that, in spite of benefit exhibited by either steroids, pentoxifylline, or the combination, there was no survival benefit at Day 90 for any of the three treatment arms, compared with placebo.

Figure 18: STOPAH Trial Results

Factors influencing 28 day mortality (Multivariate analysis)		
Variable	Odds ratio (95% CI)	p - value
Prednisolone vs no prednisolone	0.61 (0.41-0.90)	0.014
PTX vs no PTX	1.09 (0.74-1.63)	0.66
Prothrombin ratio	1.39 (1.13-1.70)	0.002
Bilirubin	1.002 (1.001 – 1.003)	0.003
Age	1.05 (1.03 - 1.07)	<0.001
WBC	1.03 (1.001-1.06)	0.04
Urea	1.06 (1.01-1.12)	0.012
Creatinine	1.59 (1.07 - 2.39)	0.023
Encephalopathy	1.05 (1.03-1.07)	<0.001

Source: STRH analysis of AASLD presentation

Molecular adsorbents recirculating system (MARS) was designed to bridge patients to transplant. This artificial liver support device developed by Gambro entailed two circuits designed to remove a patient's albumin-bound toxins such as bilirubin and bile acids, and filter out cytokines such as TNF-alpha, and IL-6, to quell inflammation. The MARS system transfers patient blood through a dialysis module, filtered through an albumin-impregnated polysulfone membrane. Thus, the system should "clear" the patient's albumin and enable it to fulfill purification functions in the patient's liver. A Phase III trial for MARS called RELIEF evaluated the device versus standard of care. The transplant free survival rate at Day 28 was 60.7% for MARS versus 58.9% standard of care treated patients. Although the device is approved in the U.S. for hepatic encephalopathy, it is only used for ~200 cases/year.

Fresenius' Prometheus was similarly designed to help recycle the patient's albumin. Unlike MARS, however, patient plasma was passed through two different columns, and bound toxins were retained by high affinity adsorbing material. Nevertheless, Prometheus also failed to demonstrate a survival benefit in pivotal testing, with a Day 28 survival rate of 66% in the active therapy group, and 63% survival in the control group.

Data from HepatAssist suggests that live liver cells are required to take over complex liver function. HepatAssist was developed by Circe Biomedical (no longer operating). The patient plasma separated from large proteins and blood cells was first filtered through charcoal and then oxygenated. In the final step, patient plasma was passed through the bioreactor where porcine (pig) liver cells resided. While HepatAssist demonstrated a numerical improvement in 30-day survival rates in a trial of 147 patients with FHF (73% survival for patients on HepatAssist, versus 59% compared to placebo), this benefit was not statistically significant (p=0.1). Nevertheless, we believe that the small number of porcine cells (~30g compared to 440g of C3A liver cells included in ELAD) may have provided insufficient support for patient liver regeneration.

Live Transplantation is the Only Procedure with Demonstrated Survival Benefit

Liver transplantation has been successfully used for patients with end-stage cirrhosis, acute liver failure or liver cancer, with about 4 in 5 patients surviving at the 1 year mark:

Figure 19: Survival Outcomes of Liver Transplantation

Diagnosis	1 year survival	3 year survival	5 year survival	10 year survival
Cirrhosis	87%	78%	72%	59%
Acute Liver Failure	77%	71%	61%	51%
Cancer	88%	78%	56%	32%

(European Liver Transplant Registry, 2012)

Source: Vital company presentation

Liver transplantation has a number of drawbacks and therefore not all patients can benefit from the procedure. To qualify for a transplant, patients need to generally demonstrate 6 months of alcohol abstinence. While physicians we spoke to note that in practice this period is more flexible, the number of patients with acute alcohol liver failure that actually get transplanted is significantly lower (2-3 patients in Vital's previous studies). Further, the procedure is highly invasive, and patients with co-morbidities may not qualify. Of 16-17K patients on annual waiting lists for transplant less than half (~6.5K) actually proceed to transplantation. For those who do, the average billed cost is ~$570K, in addition to the cost of life-long immunosuppressants.

We Forecast $3.1B in Vital Revenue in 2027

In the U.S., ~30K+ patients/year (up to 50K) develop AILD, which includes ~14K patients with AAH and ~16K with non-AAH AILD, with similar incidence numbers in the E.U.

Based on enrollment criteria for the VTI-208 studies, our key opinion leader consultants suggest that the addressable AILD population is ~30K patients in the U.S., split about 50-50 between AAH and non-AAH. We expect ELAD to be priced at ≥$150K per treatment (cartridges only; machine may be loaned or sold for a nominal fee). We anticipate that VTI-208 topline data announcement in Q2 2015 would translate into regulatory filing in early 2016, and potential approval by the end of 2016. We believe that penetration will ramp to 24-26% at peak in 2027, based on annual expected price increases of 2%, we arrive at our peak $1.3B revenue forecast in the U.S. Similarly, we anticipate approval in the E.U. in H2 2017, with penetration increasing to 19% at peak, translating to $1.3B peak sales in 2027.

Vital has a >$4.5B opportunity in the U.S. alone. Upside may come from:

- China: ~1.6M liver failures/year in urban areas, mostly due to Hepatitis B
- Liver transplant support: 16.5K patients/year in the U.S. would be candidates, but the number of available livers (6.5K transplants were performed in 2012) is limiting
- Cancer resection: ~20-100K cancer-related liver resections/year are performed the U.S. – supporting liver function would allow surgeons to be more aggressive to remove metastatic cancer

Intellectual Property

Vital Owns a Broad IP Estate Related to the C3A Cell Line

The company has a key U.S. patent 8,105,491, that covers the use of the C3A cell line in the ELAD system, to treat liver failure. This patent is set to expire in 2027. A separate key patent issued in 2013 has been extended to May 2025, it covers the bedside unit.

ELAD was also granted Orphan Designation of acute liver failure, which consists of 7 years of market exclusivity in the U.S. and 10 years in the E.U. In line with Patient Protection and Affordable Care Act, ELAD benefits from 12 years of data exclusivity following FDA approval, effectively barring biosimilar competition.

Financials

Vital reported Q3 2014 results, with a net loss of $12.8M or $(0.59) per share. The company had 21.7M shares outstanding, and ended the quarter with $79.1 in cash and equivalents. Additional proceeds from a follow-on offering conducted in October 2014 brought Vital's cash reserves to $112.5M. Management has guided that its current cash balance is sufficient to fund operations through Q4 2016, at the current spend levels of ~4M/month. We model for an equity offering in Q4 2015, to support the ELAD launch and ongoing operations. We anticipate that Vital could issue ~2M shares at $50/share, totaling $100M. We forecast that Vital will achieve profitability in 2018, and we model for increasing revenue through 2027 as we do not expect ELAD to lose existing patients to competitors (should any arise on the horizon).

Management Compensation

Vital's executive compensation is determined by a compensation committee comprised of independent advisors (i.e. who have not served during the previous three years as officers or employees of the company). A summary of compensation for 2013 is included in the table below.

Figure 20: Management Compensation Summary

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)(5)	Total ($)
Terence E. Winters, Ph.D.(2)	2013	418,125	110,719	—	17,946	546,790
Co-Chairman and Chief Executive Officer	2012	325,000	—	266,174	—	591,174
Michael V. Swanson(3)	2013	94,791	20,854	657,900	3,260	776,805
Chief Financial Officer						
Andrew Henry(4)	2013	201,875	35,076	281,554	84,139	602,644
Vice President, Clinical Operations						

Source: SEC filings

In conjunction with the October 2014 follow on offering, all Vital's executive officers, directors and a number of stockholders (including the largest shareholder) entered a lock-up agreement. These individuals agreed not to sell any VTL shares ahead of the date of the press release announcement of Phase III VTI-208 topline data.

Vital Therapies, Inc

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Revenue Model

Alcohol-induced liver decompensation (AILD) market

U.S.

		FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E
Total U.S. population ('000)	1%	320,396	323,600	326,836	330,104	333,405	336,739	340,106	343,507	346,942	350,412	353,916	357,455	361,030	364,640
Incidence of AAH		*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*
Rate of AAH as the primary diagnosis		*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*
Total number of eligible new cases of AAH		14,292	14,407	14,551	14,696	14,843	14,992	15,142	15,293	15,446	15,600	15,756	15,914	16,073	16,234
Incidence of non-AAH AILD		*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*
Rate of non-AAH AILD as the primary diagnosis		*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*
Total number of eligible new cases of non-AAH AILD		15,440	15,564	15,719	15,877	16,035	16,196	16,358	16,521	16,687	16,853	17,022	17,192	17,364	17,538
Market penetration into AAH population		*0.0%*	*0.0%*	*0.0%*	*1.8%*	*2.6%*	*3.8%*	*5.0%*	*6.5%*	*11.0%*	*13.8%*	*17.8%*	*20.1%*	*23.9%*	*26.0%*
Market penetration into non-AAH AILD population		*0.0%*	*0.0%*	*0.0%*	*1.2%*	*2.4%*	*3.4%*	*4.5%*	*6.0%*	*8.5%*	*11.0%*	*13.0%*	*17.0%*	*21.0%*	*24.0%*
Total number of AAH patients on ELAD		-	-	-	455	771	1,120	1,493	1,985	3,117	4,007	5,017	6,113	7,488	8,430
Total number of non-AAH patients on ELAD		-	-	-	191	385	551	736	991	1,418	1,854	2,213	2,923	3,646	4,209
Gross cost per treatment per patient		$ -	$ -	$ -	$ 150,000	$ 153,000	$ 156,060	$ 159,181	$ 162,365	$ 165,612	$ 168,924	$ 172,303	$ 175,749	$ 179,264	$ 182,849
Net cost per treatment per patient		$ -	$ -	$ -	$ 127,500	$ 130,050	$ 132,651	$ 135,304	$ 138,010	$ 140,770	$ 143,586	$ 146,457	$ 149,387	$ 152,374	$ 155,422
Total U.S. AAH AILD sales ($ '000s)		$ -	$ -	$ -	$ 33,728	$ 50,189	$ 75,569	$ 102,436	$ 137,188	$ 239,175	$ 309,118	$ 410,759	$ 476,653	$ 585,339	$ 656,001
Total U.S. non-AAH AILD sales ($ '000s)		$ -	$ -	$ -	$ 24,291	$ 50,050	$ 73,045	$ 99,597	$ 136,807	$ 199,662	$ 266,190	$ 324,089	$ 436,607	$ 555,627	$ 654,179
Total U.S. AILD sales ($'000)		**$ -**	**$ -**	**$ -**	**$ 58,019**	**$ 100,239**	**$ 148,614**	**$ 202,033**	**$ 273,994**	**$ 438,838**	**$ 575,308**	**$ 734,847**	**$ 913,261**	**$ 1,140,966**	**$ 1,310,180**

E.U.

		FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E
Total E.U. population ('000)	1%	523,237	528,470	533,754	539,092	544,483	549,928	555,427	560,981	566,591	572,257	577,980	583,759	589,597	595,493
Incidence of AAH		*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*
Rate of AAH as the primary diagnosis		*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*
Total number of eligible new cases of AAH		23,341	23,527	23,763	24,000	24,240	24,483	24,728	24,975	25,225	25,477	25,732	25,989	26,249	26,511
Incidence of non-AAH AILD		*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*
Rate of non-AAH AILD as the primary diagnosis		*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*
Total number of eligible new cases of non-AAH AILD		25,216	25,417	25,671	25,928	26,187	26,449	26,714	26,981	27,251	27,523	27,799	28,076	28,357	28,641
Market penetration into AAH population		*0.0%*	*0.0%*	*0.0%*	*0.0%*	*1.0%*	*3.0%*	*5.0%*	*7.3%*	*9.0%*	*11.7%*	*14.2%*	*16.3%*	*18.0%*	*19.1%*
Market penetration into non-AAH AILD population		*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.8%*	*2.5%*	*4.5%*	*6.0%*	*8.0%*	*10.5%*	*12.0%*	*14.2%*	*16.0%*	*18.0%*
Total number of AAH patients on ELAD		-	-	-	-	452	1,396	2,439	3,442	4,450	5,871	6,990	8,223	9,262	10,219
Total number of non-AAH patients on ELAD		-	-	-	-	209	661	1,202	1,619	2,180	2,890	3,336	3,987	4,537	5,155
Gross cost per treatment per patient		$ -	$ -	$ -	$ -	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000
Net cost per treatment per patient		$ -	$ -	$ -	$ -	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500
Total E.U. AAH AILD sales ($ '000s)		$ -	$ -	$ -	$ -	$ 30,906	$ 93,647	$ 157,639	$ 232,454	$ 289,453	$ 380,051	$ 465,872	$ 540,116	$ 602,411	$ 645,618
Total E.U. non-AAH AILD sales ($ '000s)		$ -	$ -	$ -	$ -	$ 26,711	$ 84,307	$ 153,271	$ 206,404	$ 277,958	$ 368,468	$ 425,317	$ 508,325	$ 578,488	$ 657,307
Total E.U. AILD sales ($'000)		**$ -**	**$ -**	**$ -**	**$ -**	**$ 57,618**	**$ 177,954**	**$ 310,909**	**$ 438,858**	**$ 567,410**	**$ 748,519**	**$ 891,189**	**$ 1,048,441**	**$ 1,180,899**	**$ 1,302,925**

ROW

		FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E
Total ROW population ('000)	0%	358,842	362,431	366,055	369,715	373,413	377,147	380,918	384,727	388,575	392,460	396,385	400,349	404,352	408,396
Incidence of AAH		*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*	*0.032%*
Rate of AAH as the primary diagnosis		*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*	*14%*
Total number of eligible new cases of AAH		16,007	16,135	16,297	16,460	16,624	16,791	16,958	17,128	17,299	17,472	17,647	17,824	18,002	18,182
Incidence of non-AAH AILD		*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*	*0.096%*
Rate of non-AAH AILD as the primary diagnosis		*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*
Total number of eligible new cases of non-AAH AILD		14,411	14,526	14,671	14,818	14,966	15,116	15,267	15,420	15,574	15,730	15,887	16,046	16,206	16,369
Market penetration into AAH population		*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.1%*	*1.8%*	*2.3%*	*3.7%*	*5.0%*	*6.2%*	*7.0%*	*8.0%*	*9.0%*
Market penetration into non-AAH AILD population		*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.1%*	*1.8%*	*2.3%*	*3.7%*	*5.0%*	*6.2%*	*7.0%*	*8.0%*	*9.0%*
Total number of AAH patients on ELAD		-	-	-	-	-	32	580	749	1,216	1,660	2,079	2,371	2,737	3,110
Total number of non-AAH patients on ELAD		-	-	-	-	-	15	275	355	576	786	985	1,123	1,297	1,473
Gross cost per treatment per patient			$ -	$ -	$ -	$ -	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000
Net cost per treatment per patient		$ -	$ -	$ -	$ -	$ -	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500
Total ROW AAH AILD sales ($ '000s)		$ -	$ -	$ -	$ -	$ -	$ 2,141	$ 38,920	$ 50,228	$ 81,610	$ 111,386	$ 139,500	$ 159,075	$ 183,618	$ 208,636
Total ROW non-AAH AILD sales ($ '000s)		$ -	$ -	$ -	$ -	$ -	$ 1,927	$ 35,038	$ 45,219	$ 73,471	$ 100,278	$ 125,588	$ 143,210	$ 165,306	$ 187,829
Total ROW AILD sales ($'000)		**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 4,068**	**$ 73,958**	**$ 95,447**	**$ 155,080**	**$ 211,664**	**$ 265,088**	**$ 302,285**	**$ 348,924**	**$ 396,465**

Total AILD (AAH) sales - WW ('000s)	$ -	$ -	$ -	$ 33,728	$ 81,096	$ 171,356	$ 298,994	$ 419,870	$ 610,238	$ 800,556	$ 1,016,130	$ 1,175,844	$ 1,371,369	$ 1,510,255
Total AILD (non-AAH) sales - WW ('000s)	$ -	$ -	$ -	$ 24,291	$ 76,761	$ 159,280	$ 287,906	$ 388,430	$ 551,091	$ 734,935	$ 874,993	$ 1,088,143	$ 1,299,420	$ 1,499,314
TOTAL AILD sales - WW ($'000)	**$ -**	**$ -**	**$ -**	**$ 58,019**	**$ 157,857**	**$ 330,636**	**$ 586,900**	**$ 808,299**	**$ 1,161,329**	**$ 1,535,491**	**$ 1,891,124**	**$ 2,263,987**	**$ 2,670,789**	**$ 3,009,569**

Source: STRH Research, Company Reports

Vital Therapies, Inc

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Fulminant hepatic failure (FHF) market

U.S.

	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E
Total U.S. population ('000)	320,396	323,600	326,836	330,104	333,405	336,739	340,106	343,507	346,942	350,412	353,916	357,455	361,030	364,640
Incidence of FHF	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*
Rate of eligible FHF	*100%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*
Total number of eligible new cases of FHF	2,055	1,553	1,569	1,584	1,600	1,616	1,633	1,649	1,665	1,682	1,699	1,716	1,733	1,750
Market penetration into FHF population	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.8%*	*5.0%*	*10.5%*	*13.0%*	*15.5%*	*18.5%*	*22.0%*	*23.0%*
Total number of FHF patients on ELAD	-	-	-	-	-	-	12	82	175	219	263	317	381	403
Gross cost per treatment per patient	$ -	$ -	$ -	$ 150,000	$ 153,000	$ 156,060	$ 159,181	$ 162,365	$ 165,612	$ 168,924	$ 172,303	$ 175,749	$ 179,264	$ 182,849
Net cost per treatment per patient	$ -	$ -	$ -	$ 127,500	$ 130,050	$ 132,651	$ 135,304	$ 138,010	$ 140,770	$ 143,586	$ 146,457	$ 149,387	$ 152,374	$ 155,422
Total U.S. FHF sales ($'000)	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 1,657**	**$ 11,378**	**$ 24,615**	**$ 31,396**	**$ 38,564**	**$ 47,418**	**$ 58,092**	**$ 62,567**

E.U.

	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E
Total E.U. population ('000)	523,237	528,470	533,754	539,092	544,483	549,928	555,427	560,981	566,591	572,257	577,980	583,759	589,597	595,493
Incidence of FHF	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*
Rate of eligible FHF	*100%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*
Total number of eligible new cases of FHF	3,355	2,537	2,562	2,588	2,614	2,640	2,666	2,693	2,720	2,747	2,774	2,802	2,830	2,858
Market penetration into FHF population	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.5%*	*4.0%*	*6.5%*	*8.5%*	*10.0%*	*12.0%*	*13.5%*
Total number of FHF patients on ELAD	-	-	-	-	-	-	-	13	109	179	236	280	340	386
Gross cost per treatment per patient	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000
Net cost per treatment per patient	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500
Total E.U. FHF sales ($'000)	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 1,717**	**$ 13,870**	**$ 22,764**	**$ 30,066**	**$ 35,726**	**$ 43,300**	**$ 49,200**

ROW

	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E
Total ROW population ('000)	358,842	362,431	366,055	369,715	373,413	377,147	380,918	384,727	388,575	392,460	396,385	400,349	404,352	408,396
Incidence of FHF	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*	*0.0006%*
Rate of eligible FHF	*100%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*
Total number of eligible new cases of FHF	2,301	1,740	1,757	1,775	1,792	1,810	1,828	1,847	1,865	1,884	1,903	1,922	1,941	1,960
Market penetration into FHF population	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.4%*	*3.5%*	*6.5%*	*8.0%*	*9.0%*	*10.0%*
Total number of FHF patients on ELAD	-	-	-	-	-	-	-	-	7	66	124	154	175	196
Gross cost per treatment per patient	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000
Net cost per treatment per patient	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500	$ 127,500
Total ROW FHF sales ($'000)	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 951**	**$ 8,407**	**$ 15,768**	**$ 19,601**	**$ 22,272**	**$ 24,994**

TOTAL FHF sales - WW ($'000)	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 1,657**	**$ 13,094**	**$ 39,436**	**$ 62,567**	**$ 84,399**	**$ 102,745**	**$ 123,664**	**$ 136,760**
TOTAL product sales - WW ($'000)	**$ -**	**$ -**	**$ -**	**$ 58,019**	**$ 157,857**	**$ 330,636**	**$ 588,556**	**$ 821,394**	**$ 1,200,765**	**$ 1,598,058**	**$ 1,975,523**	**$ 2,366,732**	**$ 2,794,453**	**$ 3,146,330**

Source: STRH Research, Company Reports

Vital Therapies, Inc

(NASDAQ: VTL)

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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, $22.00, 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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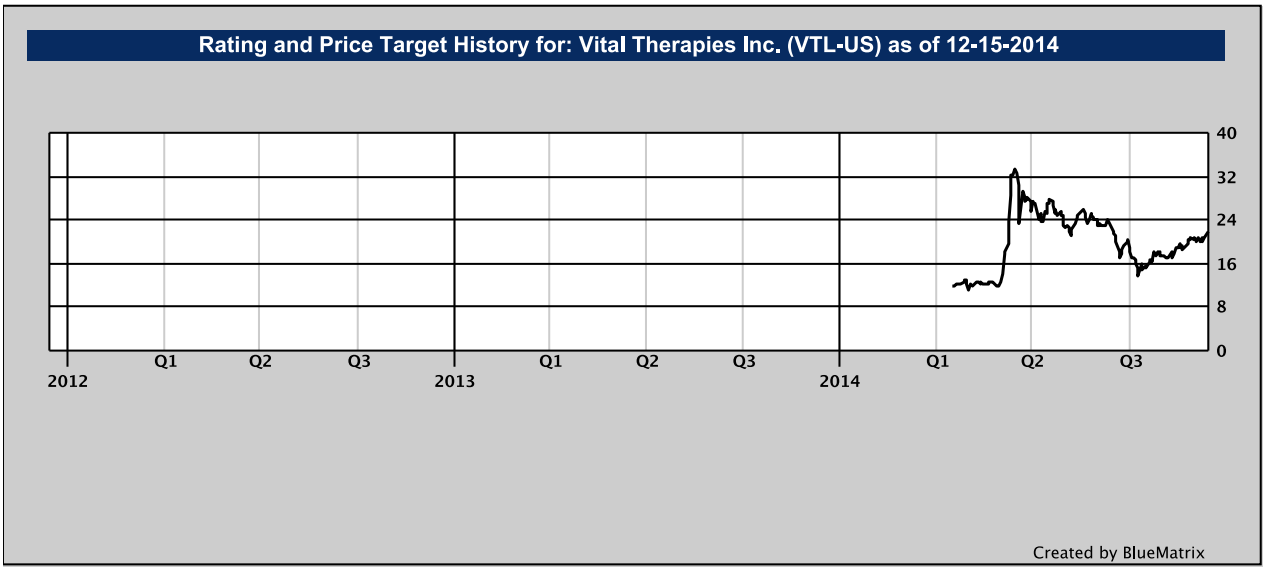

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- **Reduce** – total return ≤ negative 10% (5% for low Beta securities)
- **Neutral** – total return is within the bounds above
- **NR** – NOT RATED, STRH does not provide equity research coverage
- **CS** – Coverage Suspended

*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

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Sell/Reduce	7	1.30%	Sell/Reduce	0	0.00%

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