

## Vital Therapies, Inc. (VTL)

Rating	(from Neutral) <b>OUTPERFORM*</b> [V]
Price (10 Dec 14, US\$)	20.80
Target price (US\$)	25.00 <sup>1</sup>
52-week price range	33.31 - 11.21
Market cap. (US\$ m)	495.98
Enterprise value (US\$ m)	397.48

\*Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.

<sup>1</sup>Target price is for 12 months.

[V] = Stock considered volatile (see Disclosure Appendix).

### Research Analysts

**Bruce Nudell**

212 325 9122

bruce.nudell@credit-suisse.com

**Matthew Keeler**

212 325 9008

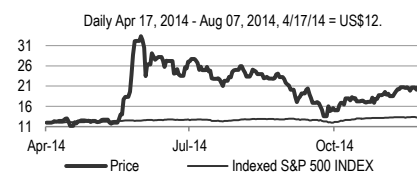
matthew.keeler@credit-suisse.com

### UPGRADE RATING

## Corrected: Proprietary Statistical Analysis Adds to Our Confidence in VTI-208 Success

- **Upgrade to Outperform; Statistical Analysis Supports Our Confidence in VTI-208 Success:** We employed statistical analysis to assess the likelihood of VTI-208 trial success. This analysis adds to our confidence that our original assumption that a 70% likelihood of VTI-208 primary endpoint success is reasonable. As a result, given where VTL currently trades we are revising our rating to Outperform & leaving our price target unchanged (2014 EPS changes below due to change in basis of EPS to be consistent with VTL's reporting, not due to underlying changes).
- **Analysis Supports our View that VTI-208 More Likely than Not to be Successful:** Our analysis relies on data from the VTI-206 Phase 2b alcohol induced liver decompensation (AILD) trial (in a sub-group similar to that enrolling in the ongoing pivotal VTI-208) to assess the plausibility of the 15% absolute survival benefit assumed in the VTI-208 trial & the likelihood of primary endpoint (log-rank difference in 90 day survival at the P < 0.05 level) success of the VTI-208 trial (which we see as the most important driver of VTL valuation). The output of our work suggests that a 10-15% mortality benefit for VTL's extracorporeal liver assist device (ELAD) is plausible (as discussed in detail in this report) which, if achieved, to us implies (based on further statistical analysis), that VTI-208 is more likely than not to hit its primary endpoint. We acknowledge risk remains based on the limited data presented to date, however, this exercise increases our comfort with this risk.
- **Thoughts on the Stock:** Given the large AILD opportunity (60K US/EU patients & ~\$150K ASP implies \$9B opportunity) we see meaningful upside potential on favorable VTI-208 data, however, the risk associated with trial success is likely to weigh on the shares until preliminary results are announced.

### Share price performance



On 08/07/14 the S&P 500 INDEX closed at 2028.04

Quarterly EPS	Q1	Q2	Q3	Q4
2013A	—	—	—	—
2014E	-24.49	-0.91	-0.59	-0.53
2015E	-0.53	-0.53	-0.55	-0.55

### Financial and valuation metrics

Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US\$)	-3.91	-3.48	-2.17	-1.29
Prev. EPS (US\$)	—	-2.99	-2.18	-1.19
P/E (x)	-5.3	-6.0	-9.6	-16.2
P/E rel. (%)	-28.2	-34.1	-59.9	-113.1
Revenue (US\$ m)	—	—	—	—
EBITDA (US\$ m)	-30.6	-47.9	-52.4	-31.4
OCFPS (US\$)	-2.86	-2.77	-2.23	-1.32
P/OCF (x)	—	-7.5	-9.3	-15.7
EV/EBITDA (current)	-13.6	-8.7	-8.0	-13.3
Net debt (US\$ m)	-38	-98	-43	-11
ROIC (%)	-971.60	8,297.92	-2,137.81	-929.53
Number of shares (m)	23.85	—	—	3.23
BV/share (Next Qtr., US\$)	—	—	—	-673.6
Net debt (Next Qtr., US\$ m)	-98.5	—	—	—
Net debt/tot eq (Next Qtr., %)	-100.6	—	—	—
IC (current, US\$ m)	—	—	—	—
EV/IC (x)	—	—	—	—
Dividend (current, US\$)	—	—	—	—
Dividend yield (%)	—	—	—	—

Source: Company data, Credit Suisse estimates.

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## Statistical Analysis Supports Our View that VTI-208 Likely to Hit Primary Endpoint (this note corrects & replaces previous version to include corrected Exhibit 3, no changes to any other text or exhibits)

### Background on VTL's Extracorporeal Liver Assist Device (ELAD) Therapy

A Phase 2b study (VTI-206), as well as pre-clinical work suggests that ELAD may be used as a bridging therapy (5 days) for patients suffering from acute alcohol induced liver decompensation (AILD). ELAD harnesses extra-corporeal activated liver cells to 1) help reestablish overall physiological hemostasis and 2) off-load the "shocked" liver while providing a more favorable environment for liver regeneration. Key in patient selection is the requirement that the liver is sufficiently viable to regenerate. The ELAD hypothesis is formally being tested in a US pivotal trial – VTI-208 – which is enrolling 200 AILD patients (randomized 1:1 versus standard of care) with MELD liver risk scores of 18-35, with the mid-point score of 26.5 connoting just around 50% 90 day mortality risk.

The 4 ELAD bio-canisters contain the equivalent mass of around 30% of a normal liver, with each cell performing around 80% of the functions of a native liver cell. Pre-clinical work has demonstrated that the ELAD cells likely contribute to plasma detoxification (cytochrome P-450 enzyme systems), osmotic balance / protein clearance (albumin, alpha fetoprotein, transferrin), coagulation factors (FV, FVII, fibrinogen, etc.), immunological balance (alpha-1-antitrypsin, alpha-1-antichymotrypsin, antithrombin III, complement C3, gelsolin), and liver regeneration (hepatocyte growth factor, gelsolin, alpha-fetoprotein).

### Proprietary Statistical Analysis Supports Greater than 50/50 Likelihood of VTI-208 Success

In this note, we use data from the VTI-206 Phase 2b AILD trial (in a sub-group similar to that enrolling in the ongoing pivotal VTI-208) to estimate the likely impact of ELAD on survivorship in severely compromised AILD patients. Specifically, we feed the changes in key biochemical markers (creatinine and bilirubin) that were observed in ELAD treated patients in VTI-206 - which are the key elements of the MELD risk score (Model for End-Stage Liver Disease, a scoring system for assessing the severity of chronic liver disease) - to predict the anticipated impact on 90 day mortality. This exercise suggested that a 90 day survivorship benefit of 10-15% is indeed feasible (the trial assumed a 15% absolute benefit as the expected case).

We then analyzed whether survival benefits of this magnitude would yield a statistical significant difference (log-rank difference at the  $P < 0.05$  level) between exponentially declining survivorship curves (across control survival rates of 40% to 60% at 90 days) and for the circumstance in which ELAD survivorship flattens after 30 days with controls continuing to decline in an exponential manner. For the more stringent case of exponential decline in both arms, probability of trial success was about 50% for a 10% absolute benefit (with control mortality at the expected 50% at 90 days) but rose to around 85% with a 15% absolute benefit, with a mean probability of trial success of around 70% across this range of benefit. When invoking an early flattening in ELAD survivorship (actually observed in the small VTI-206, but perhaps favorably biased), a survival benefit of even 5% at 90 days would very likely result in a statistically significant trial outcome. **Given the small size (and sub-selection) of the VTI-206 pilot data (n=29), which provided the grist for this analysis, and uncertainties with regards to the exact mechanism of action of ELAD, we continue to see risk to approval, however, our statistical analysis adds to our confidence that our original assumption that the assumption of a 70% likelihood of VTI-208 primary endpoint success remains reasonable.**

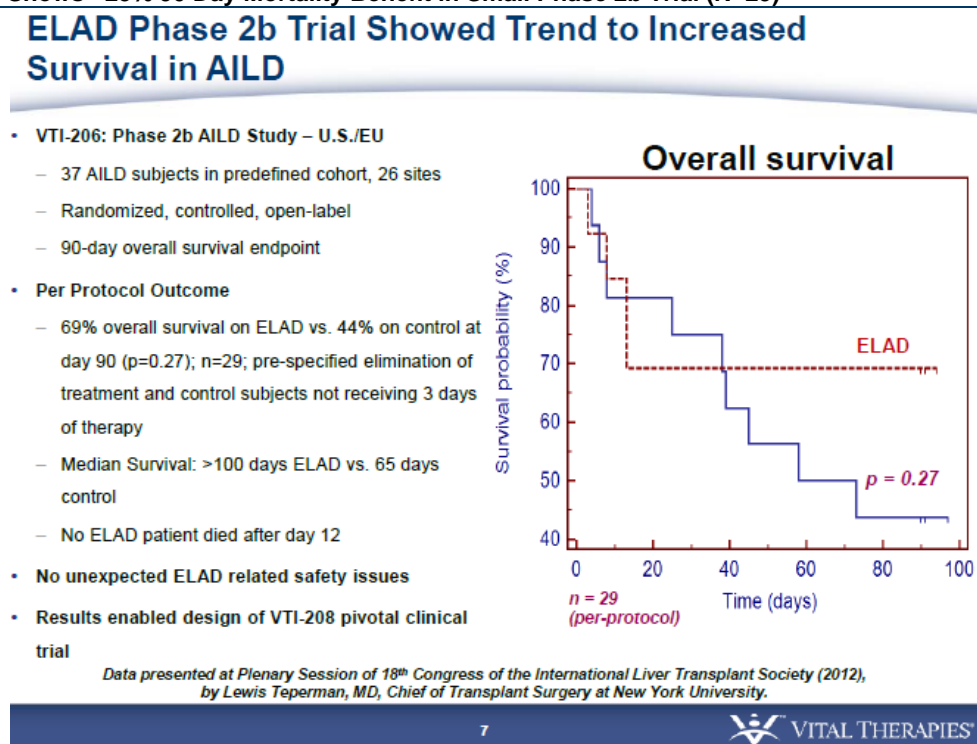
### Upgrade to Outperform

(Market uncertainty as to the pace of adoption even with a successful outcome remains a factor as well.) As we previously articulated, a 70% chance of success supports a price target of \$25 (EV/Sales of ~3X 2020 sales estimate of \$300M discounted back at ~11%). Given where the stock trades currently, we are therefore revising our rating to Outperform and leaving our price target unchanged.

### VTI-206 Suggests a Big Survivorship Benefit is Possible

Exhibit 1 shows the Kaplan-Meier survival curves for the very small (n=29) per-protocol Phase 2b test of ELAD in a group of severely ill AILD patients who had a MELD score (in both arms) of 29. A MELD score of 29 implies around 58% 90 day mortality and the observed death rate in the control arm was in fact around 55%, whereas the treatment arm showed a 30% death rate (with survival curve flattening beyond 10 days).

**Exhibit 1: ELAD Shows ~25% 90 Day Mortality Benefit in Small Phase 2b Trial (N=29)**



Source: Company presentation

The MELD algorithm provides a validated risk score for mortality at 90 days for AILD patients and uses bilirubin, creatine, and INR levels as prognostic indicators of global liver function and disruptions in overall physiological hemostasis driven by liver dysfunction. Given the broad range of biochemical support seemingly bestowed by ELAD cells (outlined in the introductory paragraphs), we felt that we could use calculated changes in MELD scores seen in ELAD patients in VTI-206 to gauge the likely impact upon mortality at 90 days.

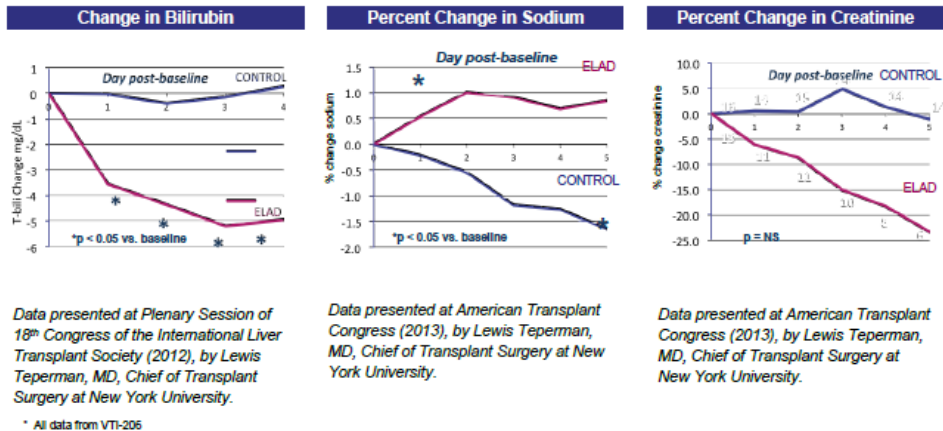
Exhibit 2 shows the changes in key metabolites for treatment and controls in VTI-206. Treatment arm patients enjoyed about a 23-25% decline in creatinine and bilirubin, and an increase in plasma sodium (which is deemed an important prognostic indicator, but which isn't included in the standard MELD score). Control patients, showed constant or worsening levels of these analytes. As ELAD patients are anti-coagulated while hooked up to the extra-corporeal ELAD circuit, we discounted the about 0.5 increases in INR that were seen during the five days of therapy. We reasoned that the small increase in INR was not reflective of underlying liver function / hemostasis (ELAD in fact results in an increase in circulating coagulation factors), and we also reasoned that a brief period (5

days) of elevated INR in a carefully monitored patient was unlikely to significantly influence the 90 day death rate.

#### Exhibit 2: Changes in Key Metabolites for Treatment & Controls in VTI-206

### Favorable Trends for Key Biomarkers Support Activity of C3A Cells

- Bilirubin, sodium, creatinine and International Normalized Ratio (INR) correlate with survival
  - INR (coagulation efficiency) is excluded due to use of heparin during treatment



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VITAL THERAPIES

Source: Company presentation

Exhibit 3 shows a calculation of the expected impact on 90 day survivorship for ELAD patients in VTI-206 based on observed changes in creatinine and bilirubin. The MELD changes following ELAD therapy suggest a reduction in 90 day mortality from 58% to 43%, a 15% absolute difference, or a 26% reduction in the 90 day event rate. In fact, observed mortality in the ELAD arm was 30% (a 28% absolute survival benefit relative to that predicted by MELD), but because the per protocol VTI-206 was so small and involved sub-selection of patients meeting the selection criteria employed in the follow-on VTI-208, we've elected to explore the statistical consequences of a smaller treatment effect. A 26% treatment effect for patients with a background risk of death of 40% at 90 days, would amount to a 10% absolute benefit, it would be about 13% for patients with a 50% risk of death, and 15.6% for patients with a risk of death of 60%. We've therefore elected to explore a range of 10-15% absolute benefit across control death rates of 40% to 60% at 90 days (all conceivable given the enrollment criteria of the trial).

#### Exhibit 3: MELD Score Changes in Treatment Arm of VTI-206

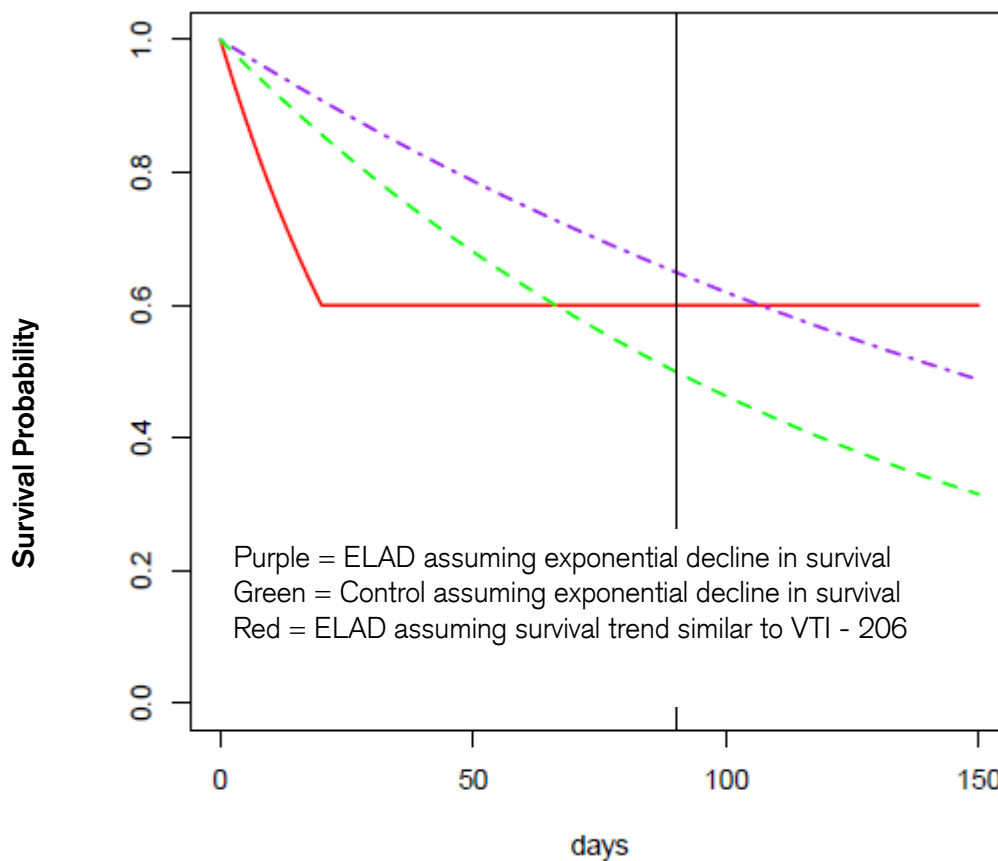
	Pre-ELAD	Post-ELAD	Delta
Creatinine	1.95	1.50	-0.45 (-23%)
Bilirubin	20.4	15.4	-5.0 (-24.5%)
INR	1.5	1.5	0 (0%)
MELD	29	25	-4 (-14%)
Predicted 90 day Mortality	58%	43%	-15% (-26%)
Observed Mortality		30%	

Source: Credit Suisse estimates

### Assessing Likelihood of VTI-208 Success

VTI-208 trial success has been defined as a statistically significant survivorship advantage using a log rank test (with  $P < 0.05$ ) across the period of observation, with a minimum patient follow-up of 90 days. We used publicly available information on the pace of enrollment to define the period of observation. In Exhibit 4, we show the shapes of the survival curves that we exercised. The purple and green lines reflect an exponential decline in survivorship for both treatment (purple) and control (green) arms, with an absolute difference of 15% at 90 days. The red line depicts a hypothetical survivorship curve for ELAD patients with a steep initial decline, followed by a flattening at around 20 days. This pattern more closely resembles that seen in VTI-206 (Exhibit 1) and results in a higher likelihood of trial success (given the play of chance) at any given absolute survivorship benefit at 90 days. As noted above, given the uncertainties in ELAD mechanism of action, and the small size of the predicate VTI-206 trial, we've elected to base our assumption of success on the more conservative exponential survivorship curve analysis.

**Exhibit 4: Potential VTI-208 Kaplan Meier Curves Assuming Exponential Survival Declines & VTI-206-Like ELAD Survival Trend**



Source: Credit Suisse estimates

Exhibit 5 shows the probability for statistical success for various absolute survival benefits at 90 days, across control survivorship of 40% to 60% (with 50% being the expected case given the mid-point of the MELD enrollment range), while assuming exponentially shaped survival curves for both treatment and control. The relative risk reduction (RRR) columns reflect the calculated diminution in daily risk (assuming exponential curves) for treatment relative to control. Focusing on the expected case for 50% survival in the control arm, this

analysis suggests an around 50% chance of trial success if the survival benefit is really 10%, which rises to an 85% chance of success if the survival benefit is really 15% (yellowed region). The reason success is defined as a probability is because of the play of chance in clinical trials in which observed survival can deviate from true survival if assessed with an infinitely large sample size. Focusing on the yellowed region in Exhibit 5 which spans the likely range of absolute benefit consistent with the MELD analysis, the probability of success seems centered around 70%, consistent with our prior valuation assumption. Of note, for any given absolute benefit, the probability of trial success increases with relative risk reduction; e.g., a 10% risk reduction represents a bigger treatment effect and bestows a higher likelihood of trial success against a 40% background death rate versus the impact seen when the background death rate is 60% in the control arm.

**Exhibit 5: Probability of VTI 208 Success on Primary Endpoint Given Varying Levels of ELAD Absolute Benefit in Survival Assuming Exponentially Shaped Survival Curves for ELAD & Control**

Absolute Survival Versus Probability of Success						
Exponential Survival Curves						
Absolute ELAD Survival Benefit	40% Control Survival		50% Control Survival		60% Control Survival	
	RRR	Probability of Trial Success	RRR	Probability of Trial Success	RRR	Probability of Trial Success
5.0%	13.0%	14.9%	13.8%	15.9%	15.6%	18.1%
6.0%	15.4%	19.6%	16.1%	20.4%	19.0%	24.5%
7.0%	17.9%	25.5%	19.1%	25.9%	21.5%	32.0%
8.0%	20.1%	31.9%	21.5%	33.8%	24.5%	40.2%
9.0%	22.4%	38.9%	23.8%	41.8%	27.3%	49.3%
10.0%	24.5%	44.6%	26.4%	50.5%	30.3%	59.5%
11.0%	26.6%	51.9%	28.8%	58.3%	33.1%	68.0%
12.0%	28.9%	60.7%	31.0%	66.2%	35.7%	76.9%
13.0%	30.9%	67.3%	33.6%	73.1%	38.4%	82.9%
14.0%	32.7%	74.5%	35.7%	80.0%	41.1%	88.7%
15.0%	34.8%	80.1%	38.2%	84.9%	43.7%	92.6%

Source: Company data, Credit Suisse estimates

Exhibit 6 shows a similar probability of success analysis under the circumstance in which the survival curve for the ELAD arm flattens after about 20 days whereas the control arm remains on a constant exponential trajectory. As Exhibit 6 indicates, much smaller absolute survival benefits will result in a high probability of statistical success; e.g., with a control death rate of 50% at 90 days; e.g., a 5% absolute ELAD benefit will be associated with a 98% chance of trial success. As noted above, a flattening in ELAD survival was in fact noted in VTI-206, but the trial was very small, the sub-analysis retrospective, ELAD's mechanism of action remains incompletely defined and the pace of market adoption is hard to predict. Hence, at the risk of being overly conservative, we are retaining our \$25 price target which we believe is roughly consistent with a 70% chance of success in ELAD approval and which implies an EV/Sales ratio of 3X \$300M in 2020 sales discounted back to today at a WACC of 11%.



**Exhibit 6: Probability of VTI 208 Success on Primary Endpoint Given Varying Levels of ELAD Absolute Benefit in Survival Assuming VTI-206-Like Survival Curve for ELAD**

Absolute Survival Versus Probability of Success					
Flattened Treatment Arm Survivorship					
Absolute ELAD Survival Benefit	40% Control Survival		50% Control Survival		
	RRR	Probability of Trial Success	RRR	Probability of Trial Success	
5.0%	39.1%	79.0%	53.2%	97.7%	
6.0%	41.3%	84.3%	54.9%	98.5%	
7.0%	43.4%	87.7%	56.7%	99.2%	
8.0%	45.5%	91.3%	58.4%	99.4%	
9.0%	47.6%	93.6%	60.0%	99.7%	
10.0%	49.5%	95.9%	61.8%	99.8%	
11.0%	51.3%	97.4%	63.4%	99.9%	
12.0%	53.4%	98.3%	64.9%	99.9%	
13.0%	54.9%	98.9%	66.5%	99.9%	
14.0%	57.0%	99.5%	68.1%	99.9%	
15.0%	58.6%	99.6%	69.6%	99.9%	

Source: Credit Suisse estimates

**Companies Mentioned** (Price as of 10-Dec-2014)

**Vital Therapies, Inc.** (VTL.OQ, \$20.8, OUTPERFORM[V], TP \$25.0)

## Disclosure Appendix

**Important Global Disclosures**

I, Bruce Nudell, certify that (1) the views expressed in this report accurately reflect my personal views about all of the subject companies and securities and (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this report.

**3-Year Price and Rating History for Vital Therapies, Inc. (VTL.OQ)**

VTL.OQ	Closing Price	Target Price	
Date	(US\$)	(US\$)	Rating
07-Apr-14			R
12-May-14	12.49	16.00	O *
30-Sep-14	20.41		R
13-Oct-14	16.00	25.00	N

\* Asterisk signifies initiation or assumption of coverage.



The analyst(s) responsible for preparing this research report received Compensation that is based upon various factors including Credit Suisse's total revenues, a portion of which are generated by Credit Suisse's investment banking activities

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Neutral/Hold*	38%	(50% banking clients)
Underperform/Sell*	14%	(44% banking clients)
Restricted	2%	

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**Price Target: (12 months) for Vital Therapies, Inc. (VTL.OQ)**

**Method:** Our \$25 DCF-derived price target is based on an ~11% WACC and a 2% terminal growth rate.

**Risk:** Risks to our \$25 price target are: (1) a large, clean dataset does not yet exist, and while early data are encouraging, the ultimate clinical benefit of the ELAD system is yet to be proven; (2) ultimate pricing of the system is likely dependent on the mortality benefit demonstrated in VTL's ongoing phase 3 trial; (3) VTL will likely need additional financing prior to commercialization; (4) approval process in China is opaque; and (5) VTL's IP could ultimately afford exclusivity for a shorter period of time than we anticipate.



Please refer to the firm's disclosure website at <https://rave.credit-suisse.com/disclosures> for the definitions of abbreviations typically used in the target price method and risk sections.

*See the Companies Mentioned section for full company names*

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