VITAL THERAPIES INC
Form 10-Q
August 07, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2018
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 001-36201

Vital Therapies, Inc.
(Exact name of registrant as specified in its charter)

Delaware	56-2358443
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
15010 Avenue of Science, Suite 200, San Diego, CA	92128
(Address of principal executive offices)	(Zip Code)

(858) 673-6840
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ý Yes ¨ No
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer ¨ Accelerated filer ý

Non-accelerated filer ¨ (Do not check if a smaller reporting company) Smaller reporting company ¨

Emerging growth company ý

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ý

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý

The number of shares of common stock outstanding as of the close of business on July 31, 2018:

Class	Number of Shares Outstanding
Common Stock, $0.0001 par value	42,369,394

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VITAL THERAPIES, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$31,116	$ 56,901
Prepaid expenses and other current assets	1,529	1,220
Total current assets	32,645	58,121
Property and equipment, net	2,059	2,155
Other assets	97	108
Total assets	$34,801	$ 60,384
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,075	$ 1,049
Accrued expenses	7,185	9,141
Other current liabilities	39	91
Total current liabilities	8,299	10,281
Long-term liabilities	49	59
Commitments and contingencies (note 4)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized at June 30, 2018 and December 31, 2017; 42,368,998 and 42,368,864 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	4	4
Additional paid-in capital	349,392	345,915
Accumulated other comprehensive income	80	78
Accumulated deficit	(323,023)	(295,953)
Total stockholders' equity	26,453	50,044
Total liabilities and stockholders' equity	$34,801	$ 60,384

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VITAL THERAPIES, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$8,660	$9,834	$18,817	$19,462
General and administrative	4,257	2,715	8,592	5,774
Total operating expenses	12,917	12,549	27,409	25,236
Loss from operations	(12,917)	(12,549)	(27,409)	(25,236)
Other income (expense):				
Interest income	161	169	331	266
Other income (expense), net	74	(27)	8	(39)
Total other income	235	142	339	227
Net loss	$(12,682)	$(12,407)	$(27,070)	$(25,009)
Net loss per share, basic and diluted	$(0.30)	$(0.29)	$(0.64)	$(0.67)
Weighted-average common shares outstanding, basic and diluted	42,368,973	42,207,376	42,368,919	37,452,655

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VITAL THERAPIES, INC.
Condensed Consolidated Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	$(12,682)	$(12,407)	$(27,070)	$(25,009)
Other comprehensive income (loss):				
Unrealized gain (loss) on cash equivalents	5	6	2	7
Total comprehensive loss	$(12,677)	$(12,401)	$(27,068)	$(25,002)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VITAL THERAPIES, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(27,070)	$(25,009)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	424	564
Stock-based compensation	3,360	2,419
Common stock issued for services	115	—
Other	218	3
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(393)	(557)
Accounts payable	31	46
Accrued expenses	(2,052)	1,502
Other liabilities	(62)	(28)
Net cash used in operating activities	(25,429)	(21,060)
Cash flows from investing activities:		
Purchases of property and equipment	(334)	(405)
Proceeds from sale of equipment	2	7
Net cash used in investing activities	(332)	(398)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	—	37,679
Deferred financing costs	(25)	(60)
Proceeds from exercise of stock options	1	1
Net cash (used in) provided by financing activities	(24)	37,620
Net change in cash and cash equivalents	(25,785)	16,162
Cash and cash equivalents, beginning of period	56,901	59,991
Cash and cash equivalents, end of period	$31,116	$76,153
Supplemental disclosure of noncash investing and financing activities:		
Stock issuance costs included in liabilities	$99	$150
Purchases of property and equipment included in liabilities	$10	$130

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VITAL THERAPIES, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of Business and Basis of Financial Statements

Description of Business

We are a clinical-stage biotechnology company focusing on the discovery, development and commercialization of cell-based therapies capable of transforming the management of life-threatening conditions. Our initial product candidate, the ELAD® System, or ELAD, is a human-cell-based, bio-artificial liver which is being developed to improve rates of survival among patients with acute forms of liver failure. Since inception, we have devoted essentially all of our efforts to product development, clinical testing and pilot manufacturing and have not recognized revenues from our planned principal operations. In August 2015, we reported that our VTI-208 phase 3 clinical trial of ELAD in severe alcoholic hepatitis failed to reach its primary or secondary endpoints, although medically pertinent pre-specified subsets based on age and disease severity did show trends toward efficacy. Considering the results of the VTI-208 clinical trial and in an effort to focus our personnel and financial resources, we also discontinued our VTI-210 and VTI-212 clinical trials. In March 2018, we completed enrollment in our phase 3 clinical trial, VTL-308, of 151 subjects with severe alcoholic hepatitis. The trial design of VTL-308, was based on our analysis of the results of the VTI-208 clinical trial. Our business, operating results, financial condition and growth prospects are subject to significant risks and uncertainties including the failure of our clinical trial to meet its endpoint, failure to obtain regulatory approval to commercialize ELAD and failure to secure additional funding to complete the development and commercialization of ELAD.

Liquidity

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $323.0 million through June 30, 2018. Assuming limited activities related to the submission for a biologics license application, or BLA, and that we do not begin building any significant commercial infrastructure, we believe that our existing cash and cash equivalents of $31.1 million as of June 30, 2018 should be sufficient to fund our operations through the first quarter of 2019, past the expected announcement of topline data for the VTL-308 clinical trial, which we currently anticipate to be in the second half of September 2018. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The timing and amount of our actual expenditures will be based on many factors, including, but not limited to, the completion of our VTL-308 clinical trial, the timing of any possible submission of a BLA, decisions with respect to building commercial operations, and any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned. In any case, we will need additional liquidity to fund operations prior to a year from the date of the issuance of our condensed consolidated financial statements for the six months ended June 30, 2018.

Our capital requirements and our ability to fund such requirements are expected to be different based on the outcome of the VTL-308 clinical trial. With successful clinical data, we plan to substantially increase our BLA and commercialization activities and, therefore, our costs. In this event, we would seek to obtain funding through equity or debt financing, and possibly marketing and distribution arrangements or other collaborations, strategic alliances or licensing agreements. Should the VTL-308 clinical trial require additional clinical development or should the trial be unsuccessful, we would attempt to substantially restructure our operations to conserve funds and possibly sell assets or even liquidate the company, depending on the VTL-308 data. In this event, we may also seek funding through similar sources; however, funding in such circumstances would be expected to be more difficult to secure, if at all.

We currently have an effective shelf registration statement on Form S-3 on file with the Securities and Exchange Commission, or SEC, which expires June 2021. The shelf registration statement currently permits the offering, issuance and sale by us of up to an aggregate offering price of $200.0 million of common stock, preferred stock, warrants, debt securities or units in one or more offerings and in any combination, of which $60.0 million may be offered, issued and sold under an “at-the-market” sales agreement with Cantor Fitzgerald & Co. In the event of positive topline results from VTL-308, we plan to raise additional capital.

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There is no assurance that we will be able to obtain additional funding on acceptable terms or at all. If we are not able to secure adequate additional funding, we will be required to make reductions in certain spending to extend current funds. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or we may have to delay, reduce the scope of, or eliminate some or all of our development programs and further clinical development. We may also have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technology that we would otherwise seek to commercialize. Any of these factors could harm our operating results and future prospects. Based on the above, substantial doubt exists over our ability to continue as a going concern for one year from the date of the issuance of our condensed consolidated financial statements for the six months ended June 30, 2018.

Basis of Presentation and Consolidation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles, or GAAP, and the rules and regulations of the SEC related to a quarterly report on Form 10-Q. Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to those rules and regulations. The condensed consolidated balance sheet as of December 31, 2017 included in this report has been derived from the audited consolidated financial statements included in our Annual Report on Form 10-K. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments that are necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. All such adjustments are of a normal and recurring nature.

In addition, our condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The condensed consolidated financial statements for the six months ended June 30, 2018 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that could result from uncertainty related to our ability to continue as a going concern.

Unaudited Interim Financial Information

The results for the six months ended June 30, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018 or any other future interim period or year. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2017, included in our Annual Report on Form 10-K filed with the SEC on March 13, 2018.

The unaudited interim condensed consolidated financial statements include the accounts of Vital Therapies, Inc. and its wholly-owned subsidiaries located in the United Kingdom and China, both of which are currently inactive. All intercompany accounts and transactions have been eliminated in consolidation. We manage our operations as a single reportable segment for the purposes of assessing performance and making operating decisions.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires us to make certain estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates and assumptions.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly-liquid investments with original maturities of three months or less when acquired. Cash equivalents are stated at cost unless they are securities, in which case they are recorded at fair value, which approximates original cost.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants on the measurement date. Accounting guidance establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities. Our Level 1 assets consisted of money market funds for the periods presented. We had no Level 1 liabilities for the periods presented.

Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets with insufficient volume or infrequent transactions (less active markets), or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated with observable market data for substantially the full term of the assets or liabilities. We had no Level 2 assets or liabilities for the periods presented.

Level 3—Unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of assets or liabilities. We had no Level 3 assets or liabilities for the periods presented.

Any transfers into and out of levels within the fair value hierarchy will be recognized at the end of the reporting period in which the actual event or change in circumstances that caused the transfer occurs.

The carrying value of cash and cash equivalents, other current assets and prepaid expenses, accounts payable, accrued expenses and other current liabilities approximates fair value due to the short period of time to maturity.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to five years). Leasehold improvements are stated at cost and depreciated on a straight-line basis over the lesser of the remaining term of the related lease or the estimated useful lives of the assets. Construction in progress is not depreciated until the underlying asset is available to be placed in service. Repairs and maintenance costs are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. We have not recognized any impairment losses in either the six months ended June 30, 2018 or the year ended December 31, 2017.

Clinical Trial Accruals

As part of the process of preparing our condensed consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process seeks to account for expenses resulting from our obligations under agreements with clinical sites, clinical research organizations, or CROs, vendors, and consultants in connection with conducting our clinical trials. We account for these expenses according to the progress of each trial as measured by subject enrollment, the timing of various aspects of the trial and if available, information from our service providers. During the course of a clinical trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary, and could result in us reporting amounts that may later be determined to be higher or lower than our estimates for a particular period and adjustments to our research and development expenses may be necessary in future periods.

Research and Development

Research and development costs consist primarily of employee-related expenses, costs of contractors, clinical trial sites and CROs engaged in the development of ELAD, costs related to our investigation of the mechanism of action of ELAD, expenses associated with obtaining regulatory approvals, and the cost of acquiring and manufacturing clinical trial materials. All research and development costs are expensed as incurred.

Stock-Based Compensation

We measure and recognize compensation expense for all stock-based compensation for employees and directors based on the estimated fair value at the date of grant, and to consultants based on the ongoing estimated fair value. Currently, our stock-based awards consist only of stock options; however, future grants under our equity compensation plan may also consist of shares of restricted stock, restricted stock units, stock appreciation rights, performance awards and performance units. We estimate the fair value of stock options using the Black-Scholes-Merton, or BSM, option pricing model, which requires the use of estimates.

We recognize stock-based compensation cost for employees and directors for ratably vesting stock options on a straight-line basis over the requisite service period of the award. For performance-based stock options to employees and directors, we record stock-based compensation expense only when the performance-based milestone is deemed probable of achievement. We utilize both quantitative and qualitative criteria to judge whether milestones are probable of achievement.

The fair value of options granted to consultants is estimated using the BSM option pricing model and is re-measured at each reporting date with changes in fair value prior to vesting recognized as expense in the condensed consolidated statements of operations across the applicable vesting period. For performance-based stock options held by consultants, we record stock-based compensation expense only when the performance-based milestone is achieved unless there is a performance commitment.

The BSM option pricing model requires the input of highly-subjective assumptions, including the risk-free interest rate, the expected dividend yield of our common stock, the expected volatility of the price of our common stock, and the expected term of the option. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

Risk-free Interest Rate

We base the risk-free interest rate assumption on zero-coupon U.S. treasury instruments appropriate for the expected term of the stock option grants.

Expected Dividend Yield

We base the expected dividend yield assumption on the fact that we have never paid cash dividends and have no present intention to pay cash dividends. Consequently, we used an expected dividend yield of zero.

Expected Volatility

The expected stock price volatility for our common stock is estimated based on volatilities of a peer group of similar publicly-traded, biotechnology companies by taking the average historic price volatility for the peers for a period equivalent to the expected term of the stock option grants. We do not use our average historical price volatility as we have only been a publicly-traded company since April 2014.

Expected Term

The expected term represents the period of time that options are expected to be outstanding. As we do not have sufficient historical experience for determining the expected term of the stock option awards granted, we have determined the expected life assumption for employee and director stock options using the comparable average expected term utilizing those companies in the peer group as noted above. For consultant stock options, we estimate the expected term based on the period we expect each consultant to provide services to us.

Leases

We lease all of our research, manufacturing and office space and enter into various other operating lease agreements in conducting our business. At the inception of each lease, we evaluate the lease agreement to determine whether the lease is an operating or capital lease. Some of our lease agreements may contain renewal options, tenant improvement allowances, rent holidays or rent escalation clauses. When such items are included in a lease agreement, we record a deferred rent asset or liability equal to the difference between the rent expense and future minimum lease payments due. The rent expense related to operating leases is recognized on a straight-line basis in the statements of operations over the term of each lease. In cases where our lessor grants us leasehold improvement allowances that reduce our rent expense, we capitalize the improvements as incurred and recognize deferred rent, which is amortized over the shorter of the lease term or the expected useful life of the improvements.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Accumulated other comprehensive income has been reflected as a separate component of stockholders' equity in the accompanying condensed consolidated balance sheets.

Foreign Currency Translation and Transactions

The functional currency of each of our subsidiaries in the United Kingdom and China, both of which are currently inactive, is the local currency. Assets and liabilities of the subsidiaries are translated at the rate of exchange at the balance sheet date. Expenses are translated at the average exchange rates in effect during the reporting period. Gains and losses resulting from foreign currency translation are included in accumulated other comprehensive income in the accompanying condensed consolidated balance sheets. Gains and losses resulting from foreign currency transactions are included in the condensed consolidated statements of operations, which to date have not been significant.

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the condensed consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

We recognize net deferred tax assets to the extent we believe these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that we would be able to realize our deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. As of June 30, 2018 and December 31, 2017, we maintained a full valuation allowance against our entire balance of deferred tax assets.

We record uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. We recognize interest and penalties related to unrecognized tax benefits, if any, within income tax expense, and any accrued interest and penalties are included within the related tax liability line.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of common shares and, if dilutive, common stock equivalents outstanding for the period determined using the treasury-stock method. Common stock equivalents are comprised of options outstanding under our stock option plan and warrants for the purchase of common stock. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to our net loss position.

Potentially dilutive securities not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive are as follows:

	As of June 30,	
	2018	2017
Options to purchase common stock	8,499,150	6,068,395
Warrants to purchase common stock	240,620	240,620

Recently Issued and/or Adopted Accounting Standards

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-02, "Leases," or ASU 2016-02. ASU 2016-02 will require that lease arrangements longer than 12 months result in an entity recognizing an asset and liability equal to the present value of the lease payments in the statement of financial position. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods therein. This standard requires a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. We expect to adopt ASU 2016-02 in 2019. The adoption of this guidance is expected to result in a significant increase in the total assets and liabilities reported on our consolidated balance sheets.

In November 2016, the FASB issued ASU No. 2016-18, "Statement of Cash Flows: Restricted Cash," or ASU 2016-18. ASU 2016-18 provides guidance on the classification of restricted cash in the statements of cash flows. This ASU requires that our statements of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. We adopted this standard in the first quarter of 2018, and the adoption did not have any impact on our condensed consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, “Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting,” or ASU 2017-09. The amendments in this update provide guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. We adopted this standard in the first quarter of 2018, and the adoption did not have a significant impact on our condensed consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Improvements to Non-employee Share-Based Payment Accounting," or ASU 2018-07. ASU 2018-07, which simplifies the accounting for non-employee share-based payment transactions, specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, and early adoption is permitted. We plan to early adopt this standard effective July 1, 2018 to simplify our accounting for share-based payments to consultants and to make it more consistent with our accounting for share-based payments to employees and directors. As provided by the standard, we will apply ASU 2018-07 on a modified retrospective basis through a cumulative-effect adjustment, which we do not expect to be material, to retained earnings as of the beginning of fiscal 2018. We will calculate the cumulative-effect adjustment using a measurement date of July 1, 2018 for our awards for which a measurement date had not been established as of such date.

3. Other Financial Information

Property and Equipment

Property and equipment, leasehold improvements, and related accumulated depreciation and amortization were as follows (in thousands):

	June 30, 2018	December 31, 2017
Manufacturing, clinical and laboratory equipment	$7,660	$ 7,500
Leasehold improvements	4,795	4,727
Office furniture and equipment	263	234
Construction in progress	84	17
	12,802	12,478
Less: accumulated depreciation and amortization	(10,743)	(10,323)
Total	$2,059	$ 2,155

Depreciation and amortization expense was $200,000 and $229,000 for the three months ended June 30, 2018 and 2017, respectively, and $424,000 and $564,000 for the six months ended June 30, 2018 and 2017, respectively.

Accrued Expenses

Accrued expenses consist of (in thousands):

	June 30, 2018	December 31, 2017
Accrued clinical and related costs	$4,503	$ 5,377
Accrued compensation and related taxes	2,272	3,591
Accrued other	410	173
Total	$7,185	$ 9,141

4. Commitments and Contingencies

Operating Leases

We lease office, manufacturing and research and development facilities and equipment under various non-cancellable operating lease agreements with expiration dates into 2022. Our facility leases generally provide for periodic rent increases and many contain escalation clauses.

We recognize rent expense for our facility operating leases on a straight-line basis. We account for the difference between the minimum lease payments and the straight-line amount as deferred rent. Total rent, property taxes and routine maintenance expense under our operating leases was $276,000 and $229,000 for the three months ended June 30, 2018 and 2017, respectively and $574,000 and $483,000 for the six months ended June 30, 2018 and 2017, respectively. Current and long-term deferred rent totaled $39,000 and $49,000 at June 30, 2018, and $91,000 and $59,000 at December 31, 2017, respectively.

Legal Proceedings

We are not currently a party to any litigation, nor are we aware of any pending or threatened litigation against us, that we believe would materially affect our business, operating results, financial condition or cash flows. However, our industry is characterized by frequent claims and litigation including securities litigation, claims regarding patent and other intellectual property rights and claims for product liability. As a result, in the future, we may be involved in various legal proceedings from time to time.

5. Fair Value

The following fair value hierarchy tables present information about each major category of our financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	Fair Value Measurement at June 30, 2018			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$29,444	$29,444	$—	$—

	Fair Value Measurement at December 31, 2017			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$55,245	$55,245	$—	$—

There were no liabilities measured at fair value on a recurring basis as of June 30, 2018 or as of December 31, 2017. The carrying amounts of other current assets and prepaid expenses, accounts payable, accrued expenses, and other current liabilities approximate their fair values due to their short-term nature.

For our money market funds, unrealized gains and losses are reported as accumulated other comprehensive income (loss), and realized gains and losses are included in interest income on the condensed consolidated statements of operations. There were no transfers between Level 1, Level 2 or Level 3 for our assets during the periods presented.

6. Common Stock and Stock Warrants

Shelf Registration Statement

In May 2018 we filed a shelf registration statement on Form S-3, or the 2018 Shelf Registration Statement, which became effective in June 2018. The 2018 Shelf Registration Statement permits: (i) the offering, issuance and sale by us of up to a maximum aggregate offering price of $200.0 million of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination; (ii) sales of up to 2.5 million shares of common stock by certain selling stockholders; and (iii) the offering, issuance and sale by us of up to a maximum aggregate offering price of $60.0 million of our common stock that may be issued and sold under an “at-the-market” sales agreement, or ATM, with Cantor Fitzgerald & Co. No shares have been sold under the 2018 Shelf Registration Statement.

Under our prior registration statement filed on Form S-3 in May 2015, or the 2015 Shelf Registration Statement, we completed a follow-on public offering raising gross proceeds of $40.3 million in March 2017 with net proceeds to us of $37.5 million. We did not sell any shares under the 2015 Shelf Registration Statement during the six months ended June 30, 2018. The 2015 Shelf Registration Statement was replaced by the 2018 Shelf Registration Statement in June 2018.

Common Stock Issued for Services

In October 2017, we entered into an independent consulting agreement, or the Consulting Agreement, with two consulting groups, or the Consultants, pursuant to which we issued 60,000 restricted shares of our common stock to the Consultants as partial consideration for investor relations services to be rendered. The restricted shares have not been registered based on a specific exemption from the registration requirements of the Securities Act. The terms of the Consulting Agreement state that we have the right to terminate the Consulting Agreement at any time, upon providing written notice. We had the right to terminate this agreement for any reason within 180 days following the effective date, whereby each of the Consultants would have been required to promptly surrender to us 40% of the number of restricted shares issued to it. In connection with this transaction, we valued 36,000 shares, or 60% of the shares, at the quoted market price of $207,000, or $5.75, per share, on the date of the agreement. The remaining 24,000 shares are being adjusted to fair value based on the closing price at the end of the reporting period with the expense being recorded ratably over the 180-day period. We recognized expense in connection with these consulting shares of $27,000 and $115,000 during the three and six months ended June 30, 2018, respectively, in general and administrative expenses.

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Stock Warrants

We issued warrants in connection with financing activities and for consulting services prior to our initial public offering. As of June 30, 2018, warrants for 240,620 shares of common stock were outstanding and exercisable at an exercise price of $92.99 and expire in September 2019.

Stock Reserved for Future Issuance

Shares reserved for future issuance at June 30, 2018 are as follows:

	Number of Shares
Common stock options outstanding	8,499,150
Common stock options available for future grant:	
2014 Equity Incentive Plan	590,556
2017 Inducement Equity Incentive Plan	168,642
Common stock warrants	240,620
Total common shares reserved for future issuance	9,498,968

7. Stock Compensation Plans

Equity Incentive Plans

Our 2014 Equity Incentive Plan, or the 2014 Plan, became effective in April 2014 and replaced our 2012 Stock Option Plan, or the 2012 Plan, with respect to future awards. The 2014 Plan provides for the grant of stock options, restricted stock, restricted stock units, stock appreciation rights, performance awards and performance units to employees, directors and consultants. The 2012 Plan provided for the grant of stock options, restricted stock, restricted stock units, stock purchase rights and performance awards to employees, directors and consultants. Option grants under our 2012 Plan were exercisable immediately and subject to repurchase rights, all of which have lapsed.

Shares available for grant under the 2014 Plan include any shares remaining available or becoming available in the future under the 2012 Plan due to cancellation or forfeiture. In addition, the 2014 Plan provides for annual increases in the number of shares available for issuance thereunder beginning upon its effective date in April 2014, and on each annual anniversary, equal to the lower of:

- 1,200,000 shares of our common stock;
- 3% of the outstanding shares of our common stock on the second-to-the-last day prior to each anniversary date of the effectiveness date of our initial public offering; or
- an amount as our board of directors may determine.

Shares available for grant under the 2014 Plan totaled 590,556 shares as of June 30, 2018. In addition, pursuant to the above provisions, the number of shares available for issuance under the 2014 Plan was increased by 1,200,000 shares effective April 16, 2018.

In September 2017, our board of directors approved the 2017 Inducement Equity Incentive Plan and amended and restated the plan in November 2017, or the Inducement Plan, which has terms and conditions substantially similar to our 2014 Plan. Under the Inducement Plan, 1,850,000 shares of our common stock were reserved to be used exclusively for non-qualified grants to individuals who were not previously our employees or directors, as an inducement material to the individual’s entry into employment with us within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. During the six months ended June 30, 2018, we granted options to purchase 1,681,358 shares of our common stock under the Inducement Plan leaving 168,642 shares available for grant under this plan.

Option grants made under the 2014 Plan and the 2012 Plan generally vest over one year or ratably over four years except for performance-based stock options. Our performance-based stock options will fully vest and become exercisable only on achievement of the performance conditions while the participant is a continuing service provider. Options currently outstanding under the Inducement Plan become 25% vested on the one year anniversary of the grant date and then vest ratably over an

additional three years or ratably over four years. Options generally expire ten years from the grant date or earlier in accordance with the terms of the plans and the related stock option agreement.

In 2015, our board of directors (the "Board") approved grants for performance-based stock options to certain employees and consultants under the 2014 Plan. Performance-based stock options for 644,952 shares remain outstanding at June 30, 2018. Performance-based stock options that have not been forfeited will fully vest on the third anniversary of the grant date if (i) our VTL-308 clinical trial has achieved statistical significance in its primary efficacy endpoint and (ii) the participant is a continuing service provider through the third anniversary of the grant date (as such terms are defined in the 2014 Plan). Vesting of the performance-based stock options will not be accelerated if the performance goal is achieved in less than three years. Since the grant date, we have deemed the performance condition as being probable and are recording stock-based compensation expense over the requisite service period for all performance-based stock options held by employees. The performance-based stock options have exercise prices ranging from $4.57 to $7.69 per share, the closing sales price of our common stock on the grant dates, and expire ten years from the grant date (or earlier in accordance with the terms of the 2014 Plan and the related stock option agreement).

The following table summarizes stock option activity under the 2012 Plan, the 2014 Plan and the Inducement Plan:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2018	6,083,482	$ 6.76		
Granted	2,459,728	$ 6.01		
Exercised	(134)	$ 5.80		
Forfeited or expired	(43,926)	$ 6.74		
Outstanding as of June 30, 2018	8,499,150	$ 6.54	7.35	$10,957,292
Options vested and expected to vest as of June 30, 2018	8,180,579	$ 6.58	7.28	$10,531,284
Options exercisable as of June 30, 2018	4,297,119	$ 7.38	5.77	$5,095,729

Stock-Based Compensation Expense

The weighted-average grant date fair value of stock options granted during the six months ended June 30, 2018 and 2017 was $4.17 and $2.30, respectively. The following are the ranges of underlying assumptions used in the BSM option pricing model to determine the fair value of stock options granted to employees and to non-employees under all stock plans:

	Six Months Ended June 30,	
	2018	2017
Employees:		
Risk-free interest rate	2.0% - 2.3%	1.5% - 1.7%
Expected dividend yield	0%	0%
Expected volatility	79.8% - 82.0%	83.4% - 85.4%
Expected term of options (years)	5.9 - 6.2	5.9 - 6.1
Fair value of common stock	$5.00 - $6.45	$3.20 - $5.05
Non-employees:		
Risk-free interest rate	2.1% - 2.8%	1.0% - 1.9%
Expected dividend yield	0%	0%
Expected volatility	72.6% - 82.3%	72.1% - 83.9%
Expected term of options (years)	0.2 - 9.3	1.0 - 4.5
Fair value of common stock	$5.00 - $6.85	$2.90 - $4.00

Total stock-based compensation expense for all stock awards recognized in our condensed consolidated statements of operations is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Employees:				
Research and development	$384	$370	$773	$830
General and administrative	1,315	779	2,359	1,566
Total	$1,699	$1,149	$3,132	$2,396
Non-employees:				
Research and development	$40	$7	$91	$23
General and administrative	68	—	137	—
Total	$108	$7	$228	$23

As of June 30, 2018, there was $12.6 million and $1.3 million of total compensation cost related to unvested employee and non-employee stock option awards, respectively, not yet recognized. The fair value of the non-employee stock options is re-measured at each reporting date and, accordingly, the expense to be recognized will change, primarily with changes in the market value of our common stock. Stock-based compensation expense for employee and non-employee stock option awards is expected to be recognized over a remaining weighted-average vesting period of 2.6 years and 1.8 years, respectively.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and notes thereto included in Item 1 “Financial Statements” in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, for the year ended December 31, 2017. As used in this report, unless the context suggests otherwise, “we,” “us,” “our,” “the Company” or “Vital Therapies” refer to Vital Therapies, Inc. and its subsidiaries.

Forward-Looking Statements

In addition to historical information, this Quarterly Report on Form 10-Q, or Quarterly Report, includes forward-looking statements within the meaning of federal securities laws. Forward-looking statements, are subject to certain risks and uncertainties, many of which are beyond our control, particularly those inherent in the process of discovering, developing and commercializing biologics and devices that are safe and effective for use as human therapeutic products. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words, “believe,” “may,” “might,” “can,” “could,” “will,” “would,” “should,” “estimate,” “continue,” “ar “intend,” “seek,” “plan,” “project,” “expect,” "potential," "predicts," or similar expressions and the negatives of those terms. Forward-looking statements discuss matters that are not historical facts. Our forward-looking statements involve assumptions that, if they never materialize or prove correct, could cause our results to differ materially from those expressed or implied by such forward-looking statements. In this Quarterly Report, for example, we make forward-looking statements, among others, regarding: the strategy, timing and conduct of our clinical trials, regulatory requirements and markets for the ELAD® System; financial estimates and projections; and the sufficiency of our capital resources to fund our operations.

The inclusion of any forward-looking statements in this Quarterly Report should not be regarded as a representation that any of our plans will be achieved. Our actual results may differ from those anticipated in our forward-looking statements as a result of various factors, including those set forth below under the caption “Part II, Item 1A—Risk Factors,” and the differences may be material. These risk factors include, but are not limited to: the cost and timing of our clinical programs for the ELAD System; the timing of, and our ability to obtain and maintain regulatory approvals for the ELAD System; the performance of third parties in connection with the development of the ELAD System including, but not limited to, third parties involved in our clinical trials and third-party suppliers; our ability to reliably manufacture ELAD cartridges and ELAD bedside units in sufficient quantities and in compliance with regulatory requirements for clinical trials and commercialization; the outcomes of clinical trials; regulatory developments in the U.S. and foreign countries; our ability to obtain funding for our operations; and our ability to maintain effective

internal control over financial reporting.

Although our forward-looking statements reflect the good faith judgment of our management, these statements are based only on facts and factors currently known by us. As a result, you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update such statements to reflect events or circumstances after the date hereof, except as required by law.

Overview

We are a clinical-stage biotechnology company focusing on the discovery, development and commercialization of cell-based therapies capable of transforming the management of life-threatening conditions. Our initial product candidate, the ELAD® System, or ELAD, is a human-cell based, bio-artificial liver which is being developed to improve rates of survival among patients with acute forms of liver failure.

We believe that the ELAD System may improve rates of overall survival and transform the management of acute forms of liver failure. Therapy with ELAD consists of a single, up to five-day treatment session, during which a patient's blood plasma is passed continuously through four cartridges containing approximately one pound of VTL C3A cells. We believe these cells, which have been shown to retain a large number of the liver's synthetic and metabolic functions, may infuse the patient's plasma with beneficial proteins, including growth factors, cell survival proteins, and anti-inflammatory proteins, and may also remove certain harmful substances. This may better allow the patient's own liver to recover and regenerate, thereby potentially improving patient survival.

The ELAD System has been granted orphan drug designation by the U.S. Food and Drug Administration, or FDA, and the European Commission, for the treatment of patients with acute liver failure, including alcoholic hepatitis. This designation provides tax credits for qualified clinical testing, seven years of market exclusivity in the U.S. and ten years of market exclusivity in Europe for the first orphan drug approved for a given indication. However, orphan designation does not alter the standard regulatory requirements or the process for obtaining marketing approval.

In May 2016, we commenced our phase 3 VTL-308 clinical study. This is a randomized, open label, multicenter, controlled study comparing the efficacy and safety of the ELAD System plus standard-of-care to standard-of-care alone in adults, under the age of 50 and without secondary organ failure, with liver failure from severe alcoholic hepatitis, or sAH. VTL-308 was designed to enroll at least 150 subjects, and the study's primary endpoint is overall survival after the last subject to be enrolled has been followed for at least ninety days. In March 2018, we completed enrollment in VTL-308, and we expect to announce topline data in the third quarter of 2018, likely September. If the data is positive, these results are expected to form the basis for a marketing application to the FDA and other global health regulatory authorities for the approval of the ELAD System for the treatment of sAH.

Results from a prior phase 3 study, VTI-208, informed the design of the VTL-308 study and guided its focus on subjects under the age of 50 without secondary organ failure. The VTI-208 study enrolled 203 subjects between 2013 and January 2015 with alcohol-induced liver decompensation, most of whom were experiencing liver failure as a result of sAH. In August 2015, we learned that an analysis of overall survival was not statistically different between treated and control groups. Although VTI-208 failed to reach either its primary or secondary endpoints, pre-specified and post-hoc analyses identified criteria for a group of subjects in which favorable survival trends were observed. While the VTL-308 phase 3 clinical trial has been designed to show statistical significance based on these pre-specified and post-hoc analyses of the VTI-208 trial, there can be no assurance that the data from the trial or that a single trial will be sufficient to support a marketing application in any country.

During 2014, we also initiated enrollment in VTI-210, a second phase 3 clinical trial for subjects with sAH, and a phase 2 clinical trial, VTI-212, for subjects with post-surgical liver failure and fulminant hepatic failure. The VTI-210 trial was suggested by the European regulatory authority and was intended to include subjects who had failed conventional therapy and were therefore a sicker population than the VTI-208 subjects. Considering the results of the VTI-208 clinical trial and in an effort to focus our personnel and financial resources, we discontinued the VTI-210 and VTI-212 clinical trials, postponed most activities associated with the preparation for submitting a marketing application to the FDA, and reduced our workforce in late 2015.

We have incurred net losses since inception of $323.0 million through June 30, 2018. We anticipate that we will continue to incur losses for at least the next several years. Due to the uncertainties involved with biological product development and the clinical trial process, we cannot predict the timing or level of future expenses with certainty,

when product approval for the ELAD System might occur, if ever, or when profitability may be achieved or sustained.

Results of Operations

Research and Development Expenses

Research and development expenses relate to the development of the ELAD System and are expensed as incurred. Our research and development expenses consist primarily of:

- expenses incurred under agreements with clinical sites, clinical research organizations, or CROs, and statistical, regulatory and other consultants that assist us with our clinical trials;
- employee-related expenses, which include salaries, benefits, travel and stock-based compensation;
- the cost of acquiring and manufacturing clinical trial materials;
- facilities, depreciation, and other allocated expenses, which include direct and allocated expenses for rent, information systems, maintenance of facilities and equipment, and depreciation of fixed assets; and
- other costs associated with research, the preparation for a potential biologics license application, or BLA, submission and other regulatory activities.

We do not track our employee and facility-related research and development costs by clinical trial, as we have used our employee and infrastructure resources across multiple clinical trials, and we believe the allocation of such costs would be arbitrary and would not provide a meaningful assessment.

The costs of clinical trials may vary significantly over the life of a project as a result of a variety of factors including, but not limited to, the following:

- per subject trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the number of subjects that participate in the trials;
- continuing quality assurance activities and standards consistent with the U.S. Food and Drug Administration, or FDA, and other regulatory requirements;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the number of events that occur in our event driven VTL-308 clinical trial; and
- the frequency and duration of subject follow-up visits.

A change in any of these variables could result in a significant change in the costs and timing associated with the development of the ELAD System. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond what we currently anticipate will be required for the completion of clinical development of the ELAD System, we could be required to expend significant additional financial resources and time on the completion of the clinical development of the ELAD System. We also expect to incur an increase in operating costs related to certain tasks associated with the preparation of a BLA prior to the release of the results for the VTL-308 clinical trial. If we have a successful outcome from the VTL-308 clinical trial, we would expect to incur a significant increase in our operating costs related to the preparation of a BLA and the possible commercialization of the ELAD System.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, information technology, marketing and legal functions. Other general and administrative expenses include but are not limited to related facility costs, stock-based compensation, professional fees for legal, consulting, accounting and tax services and insurance costs. If we have a successful outcome from the VTL-308 clinical trial, we expect to incur additional costs related to planning and preparing for the possible commercialization of the ELAD System.

Other Income

Interest Income

Our cash and cash equivalents are or have been invested primarily in money market funds, which in our opinion, provide liquidity and protection from loss of principal. We expect to continue to make similar investments with any additional financing proceeds while the funds await use in operations.

Comparison of the Three Months Ended June 30, 2018 and 2017

The following table summarizes our operating expenses for the three months ended June 30, 2018 and 2017:

	Three Months Ended June 30,		Change	
	2018	2017	$	%
(dollars in thousands)	(unaudited)			
Operating expenses:				
Research and development	$8,660	$9,834	$(1,174)	(12)%
General and administrative	4,257	2,715	1,542	57 %
Total operating expenses	$12,917	$12,549	$368	3 %

The $1.2 million decrease in research and development expense during the three months ended June 30, 2018 as compared to the three months ended June 30, 2017 principally reflects a reduction in clinical trial costs of $1.5 million due to the completion of enrollment in VTL-308 in the first quarter of 2018. There were 25 subjects enrolled in the VTL-308 clinical trial in the second quarter of 2017, while no subjects were enrolled in the second quarter of 2018 due to the completion of enrollment. Costs for conferences and sponsorships were also lower by $370,000 in the 2018 quarter as activity decreased with the completion of enrollment. These decreases were partially offset by higher costs of $378,000 for compensation and benefits, primarily driven by an increase in headcount, and of $207,000 for BLA and technical consultants and services.

Total general and administrative expenses during the three months ended June 30, 2018 increased by $1.5 million as compared to the three months ended June 30, 2017. The increase reflects an increase in compensation costs of $721,000 primarily due to an increase in stock-based compensation related to the hiring of a new chief executive officer in January 2018 and additional stock option grants made in the first half of 2018. We also incurred higher costs of $298,000 for patent and other legal costs and of $427,000 for corporate, investor relations and marketing consultants and services in the three months ended June 30, 2018 as compared to the corresponding period in 2017.

Comparison of the Six Months Ended June 30, 2018 and 2017

The following table summarizes our operating expenses for the six months ended June 30, 2018 and 2017:

	Six Months Ended June 30, 2018		Change	
	2018	2017	$	%
(dollars in thousands)	(unaudited)			
Operating expenses:				
Research and development	$18,817	$19,462	$(645)	(3)%
General and administrative	8,592	5,774	2,818	49 %
Total operating expenses	$27,409	$25,236	$2,173	9 %

The $645,000 decrease in research and development expense during the six months ended June 30, 2018 as compared to the six months ended June 30, 2017 principally reflects a reduction in clinical trial costs of $2.1 million due to the completion of enrollment in VTL-308 in the first quarter of 2018. There were 49 subjects enrolled in the VTL-308 clinical trial in the first half of 2017, while there were 19 subjects enrolled in the first half of 2018 due to the completion of enrollment. Costs for conferences and sponsorships were also lower by $371,000 in the 2018 period as activity decreased with the completion of enrollment. These decreases were partially offset by higher costs of $830,000 for compensation and benefits, primarily driven by an increase in headcount of $767,000, for BLA and technical consultants and services and $469,000 for manufacturing and laboratory supplies. Upon the completion of enrollment, the manufacturing, quality and regulatory functions began focusing their efforts and resources on

preparing for a potential BLA submission as opposed to clinical development.

Total general and administrative expenses during the six months ended June 30, 2018 increased by $2.8 million as compared to the six months ended June 30, 2017. The increase reflects an increase in compensation costs of $1.4 million due primarily to the payment of a signing bonus and an increase in stock-based compensation related to the hiring of our new chief executive officer, plus additional stock-based compensation related to stock option grants made in the first half of 2018. In addition, we incurred higher costs of $492,000 for patent and other legal costs and $756,000 for corporate, investor relations and marketing consultants and services, which included $115,000 in stock issued for services, in the six months ended June 30, 2018 as compared to the corresponding period in 2017.
We expect to continue to incur significant research and development costs in support of BLA activities. We also expect general and administrative costs to remain relatively constant for the remainder of 2018 compared to 2017 except for increases in stock-based compensation and costs associated with hiring our new chief executive officer in January 2018. In addition, with successful topline results from our VTL-308 clinical trial, we would expect to increase our research and development costs to support a BLA submission and our general and administrative costs as we begin to prepare for the potential commercialization of the ELAD System.

Liquidity and Capital Resources

Overview

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $323.0 million through June 30, 2018. Assuming limited activities related to the submission for a biologics license application, or BLA, and that we do not begin building any significant commercial infrastructure, we believe that our existing cash and cash equivalents of $31.1 million as of June 30, 2018 should be sufficient to fund our operations through the first quarter of 2019, past the expected announcement of topline data for the VTL-308 clinical trial, which we currently anticipate to be in the second half of September 2018. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. As a result of the above, there exists substantial doubt about our ability to continue as a going concern for a year from the date of the issuance of our condensed consolidated financial statements for the six months ended June 30, 2018.
The timing and amount of our actual expenditures will be based on many factors, including, but not limited to, the timing of any possible submission of a BLA, decisions with respect to building commercial operations, and any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned. In addition, our operating plans may change and we may need additional funds earlier to meet operational needs and capital requirements for product development, BLA-related activities and building for commercialization. In addition, we will need additional liquidity to fund operations subsequent to the first quarter of 2019.

Our capital requirements and our ability to fund such requirements is expected to be different based on the outcome of the VTL-308 clinical trial. With successful clinical data, we plan to substantially increase our BLA and commercialization activities and, therefore, our costs. In this event, we would expect to obtain funding through equity or debt financing, and possibly marketing and distribution arrangements or other collaborations, strategic alliances or licensing agreements. Should the VTL-308 clinical trial require additional clinical development or should the trial be unsuccessful, we would expect to substantially restructure our operations to conserve funds and possibly sell assets or even liquidate the company, depending on the VTL-308 data. In this event, we may also seek funding through similar sources; however, such funding would be expected to be more difficult to secure, if at all.

We currently have an effective shelf registration statement on Form S-3 on file with the SEC, which expires in June 2021. The shelf registration statement currently permits the offering, issuance and sale by us of up to an aggregate offering price of $200.0 million of common stock, preferred stock, warrants, debt securities or units in one or more offerings and in any combination, of which $60.0 million may be offered, issued and sold under an “at-the-market” sales agreement with Cantor Fitzgerald & Co. In the event of positive topline results from VTL-308, we plan to raise additional capital.

There is no assurance that we will be able to obtain additional funding on acceptable terms or at all. If we are not able to secure adequate additional funding, we will be required to make reductions in certain spending to extend current

funds. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or we may have to delay, reduce the scope of, or eliminate some or all of our development programs or clinical trials. We may also have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technology that we would otherwise seek to commercialize. Any of these factors could harm our operating results and future prospects.

Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with an intent to maximize liquidity and preserve capital. As of June 30, 2018, such funds were held in cash and money market funds.

Cash Flows

The following table shows a summary of our cash flows for the six months ended June 30, 2018 and 2017:

	Six Months Ended June 30,	
	2018	2017
(in thousands)	(unaudited)	
Cash (used in) provided by:		
Operating activities	$(25,429)	$(21,060)
Investing activities	(332)	(398)
Financing activities	(24)	37,620

Net cash used in operating activities

During the six months ended June 30, 2018, operating activities used $25.4 million of cash. The use of cash primarily related to our net loss of $27.1 million adjusted for non-cash charges of $3.4 million related to stock-based compensation and $424,000 related to depreciation and amortization, and a $2.5 million change in our operating assets and liabilities. Changes in our operating assets and liabilities during the six months ended June 30, 2018 consisted primarily of a decrease of $2.0 million in accrued expenses and accounts payable and of an increase of $393,000 in other current assets and prepaid expenses. The decrease in accrued expenses and accounts payable was primarily attributable to the payout of the 2017 bonuses during the period and a decrease in the amounts due for our VTL-308 clinical trial. The increase in the current assets and prepaid expenses is principally related to an increase in our prepaid liability insurance.

During the six months ended June 30, 2017, operating activities used $21.1 million of cash. The use of cash primarily related to our net loss of $25.0 million adjusted for non-cash charges of $2.4 million related to stock-based compensation, $564,000 related to depreciation and amortization and a $963,000 change in our operating assets and liabilities. Changes in our operating assets and liabilities during the six months ended June 30, 2017 consisted primarily of an increase of $1.5 million in accrued expenses and accounts payable, partially offset by an increase of $557,000 in other current assets and prepaid expenses. The increase in accrued expenses and accounts payable was primarily attributable to the increase in the amounts due for our VTL-308 clinical trial partially offset by the payout of 2016 bonuses and the reduction in amounts due to clinical sites for our prior clinical trials. The increase in the current assets and prepaid expenses is related to an increase in our prepaid liability insurance.

Investing Activities

During the six months ended June 30, 2018, net investing activities used $332,000 of cash due primarily to capital expenditures for facilities improvements and purchases of equipment for manufacturing and research and development. During the six months ended June 30, 2017, net investing activities used $398,000 of cash, primarily due to capital expenditures of $405,000 for facilities improvements and purchases of equipment for manufacturing and research and development.

Financing Activities

During the six months ended June 30, 2018, financing activities used $24,000 of cash primarily related to deferred financing costs. During the six months ended June 30, 2017, financing activities provided $37.7 million of cash related to net cash proceeds after underwriters' commissions and cash payments for offering costs from the follow-on offering completed in March 2017.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Our future capital requirements are difficult to forecast and will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of research and development and clinical trials related to the ELAD System or any future product candidates;

- the cost and timing of a potential BLA submission;

- the cost and timing of scaling up and validating the manufacturing process for the ELAD System or any other product candidates for commercialization;
- the cost and timing of commercialization activities, including reimbursement, marketing, sales and distribution costs, both before and after product approval (if any);
- our ability to establish new collaborations, licensing or other arrangements and the financial terms of such agreements;
- the number and characteristics of any future product candidates we pursue;
- the costs involved with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties, if any, on the ELAD System and any future product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of stock offerings, debt financings, collaborations and licensing arrangements. We do not expect to achieve revenue from product sales prior to the use of the net proceeds from our public and private offerings to date. We do not have any committed external source of funds. Additional funds may not be available on acceptable terms, if at all. To the extent that we raise additional capital through the sale of equity securities, the ownership interest of our stockholders will be diluted and may be on terms that are not favorable to us or our stockholders. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt or other terms that are not favorable to us or our stockholders. If we raise additional funds through collaborations and licensing arrangements with third parties, which we have no prior experience in, we may have to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or we may have to delay, reduce the scope of, or eliminate some or all of our development programs or clinical trials. We may also have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technology that we would otherwise seek to commercialize. Any of these factors could harm our operating results.

Off-Balance Sheet Arrangements

Through June 30, 2018, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

Contractual Obligations

There were no material changes during the six months ended June 30, 2018 outside the ordinary course of business in our specified contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 13, 2018.

Critical Accounting Policies and Estimates

The preparation of condensed consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires us to make estimates and assumptions that affect amounts reported in the accompanying condensed consolidated financial statements and related notes. In preparing our condensed consolidated financial statements, we make assumptions and estimates about future events and apply judgments that affect the reported amounts of assets, liabilities, revenue, expenses and the related disclosures. We base our assumptions, estimates and judgments on historical experience, current trends and other factors that management considers relevant. Because future events and their effects cannot be determined with certainty, actual results could differ materially from our assumptions and estimates. We have reviewed these critical accounting policies and related disclosures with the Audit Committee of our Board of Directors.

During the first six months of 2018, there were no significant changes in our critical accounting policies or in the methodology used for estimates. Please refer to Management’s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 13, 2018 for a more complete discussion of our critical accounting policies and estimates.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

There has been no material change in our assessment of sensitivity to market risk since our presentation set forth in "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K filed with the SEC on March 13, 2018.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Management, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures during the six months ended June 30, 2018. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures during the six months ended June 30, 2018, our Chief Executive Officer and Chief Financial Officer have concluded that, as of June 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the six months ended June 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II - OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any litigation, nor are we aware of any pending or threatened litigation against us, that we believe would materially affect our business, operating results, financial condition or cash flows. Our industry is characterized by frequent claims and litigation including securities litigation, claims regarding patent and other intellectual property rights and claims for product liability. As a result, in the future, we may be involved in various legal proceedings from time to time.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before deciding to invest in our company or deciding to maintain or increase your investment, you should consider carefully the risks and uncertainties described below. The risks and uncertainties described below and in our other filings with the Securities and Exchange Commission, or SEC, are not the only ones we face. If one or more of the following risks are realized, our business, financial condition and results of operations and prospects could be materially and adversely affected. In that event, the market price for our common stock could decline, and you may lose your entire investment.

Risks Related to Our Business

We have designed our current phase 3 clinical trial for ELAD® based on the results of pre-specified and post-hoc analyses of our VTI-208 trial. There is no assurance of success, and the current trial may fail. Since ELAD is our sole product candidate, failure of this new trial could result in failure of the company.

In August 2015, we announced that the ELAD System, our sole product candidate, failed to meet its primary and secondary endpoints in our VTI-208 phase 3 clinical trial. Following this announcement, we discontinued our VTI-210 and VTI-212 clinical trials and began a series of pre-specified and post-hoc analyses of the VTI-208 data to determine if there was a basis for continuing the development of the ELAD System. Based on these analyses, we prepared a preliminary protocol for a new clinical trial, VTL-308, incorporating changes based on clinically relevant trends we observed in subset data from the VTI-208 clinical trial, including limits on subjects' age, Model for End-stage Liver Disease, or MELD, score and the three components of the MELD score associated with kidney dysfunction (creatinine), blood clotting dysfunction defined as international normalization ratio, or INR, and liver function (bilirubin). In November 2015, we received written responses from the U.S. Food and Drug Administration, or the FDA, to our Type C meeting request on the VTL-308 phase 3 clinical trial. At the FDA's suggestion, we incorporated an event-driven feature into the trial design consistent with the primary endpoint of overall survival. Under the modified design, we enrolled 151 subjects before ending enrollment at the end of March 2018.

The design of and the assumptions underlying our VTL-308 clinical trial, including the inclusion and exclusion criteria, may prove to be incorrect or may not ultimately demonstrate statistical significance in overall survival over a control group. Further, even if statistical significance in overall survival is achieved, the results may not be accepted without a confirmatory study as the basis for the submission of a biologics license application, or BLA, to the FDA or for a similar filing with any other regulatory authority. For example, even if the VTL-308 clinical trial were to meet its primary endpoint, the FDA or other regulatory authorities may still require an additional pivotal trial before granting market approval, which would require substantial additional time and funds in order to complete clinical development. If we are unsuccessful in our clinical development program, we will need to undertake a review of potential business alternatives, which may include, but are not limited to, a merger or sale of the company or ceasing operations and winding down the business.

We may not be able to complete the development of, successfully obtain regulatory or marketing approval for, or successfully commercialize, the ELAD System.

To date, we have expended significant time, resources and effort on the development of the ELAD System. The unfavorable VTI-208 outcome has caused a significant delay in our plans to commercialize the ELAD System. In order to complete the development of the ELAD System, we will need to have completed one or more additional clinical trials that successfully demonstrate statistical significance in overall survival over a control group, manage clinical and manufacturing activities, obtain necessary regulatory approvals from the FDA in the U.S., from the European Medicines Agency, or EMA, in the European Economic Area, and from foreign regulatory authorities in other jurisdictions, obtain commercial manufacturing supply, build a commercial marketing organization or enter into a commercial marketing collaboration with a third party, and in some jurisdictions, obtain reimbursement authorization, among other things. If we do not successfully complete the necessary clinical trials, do not have sufficient commercial manufacturing supply for the ELAD System, encounter additional difficulties in the development of the ELAD System due to any of the factors discussed in this “Risk Factors” section or otherwise, we do not seek or receive regulatory approval or are unable to successfully commercialize the ELAD System, if approved, then we will not be able to continue our business, and we would need to undertake a review of the potential business alternatives discussed above.

We are a clinical-stage company with no approved products, which makes assessment of our future viability and performance difficult.

We are a clinical-stage company, and we have no approved products or revenues from the sale of products. Our operations to date have been limited to organizing, staffing and financing our company, applying for patent rights, manufacturing on a clinical scale, undertaking clinical trials of our product candidate, and engaging in research and development. Our VTI-208, VTI 210 and VTI-212 trials failed to reach both their primary and secondary endpoints or were terminated. We have not yet demonstrated an ability to obtain regulatory approval, manufacture products on a

commercial scale, or conduct the sales and marketing activities necessary for successful product commercialization. As a result, there is limited information about us for investors to use when assessing our future viability and our potential to successfully develop product candidates, conduct clinical trials, manufacture our products on a commercial scale, obtain regulatory approval and profitably commercialize any approved products.

We are totally dependent upon the success of the ELAD System, our sole product candidate.

The ELAD System is designed to improve survival rates of patients with certain forms of liver failure resulting from hepatocellular insult. The ELAD System is a novel product candidate whose safety, efficacy and other attributes have not been demonstrated in well-designed, large scale, clinical trials and are not fully understood. As a cell-based therapy, the ELAD System's mechanism of action is complex, and we cannot be certain that our currently-targeted indication of severe alcoholic hepatitis, or sAH, in the U.S. and Europe, and viral hepatitis (predominantly hepatitis B) in China represent suitable applications for the ELAD System, or even ones where the ELAD System therapy can or will ultimately be shown to be safe and effective in well-designed phase 3 clinical trials necessary to support regulatory approval in any jurisdiction. For example, our VTI-208 phase 3 trial in alcohol-induced liver decompensation, or AILD, which included many subjects with sAH, failed to reach both its primary and secondary endpoints. Finally, even if the ELAD System is proven to be safe and effective and ultimately receives regulatory approval, there is no guarantee that its commercialization will be successful. If the ELAD System fails at any stage in our clinical trials or at the marketing stage, our business and operating results and financial condition will be materially and adversely affected.

We cannot give any assurance that we will successfully complete the ELAD System's clinical development, or that the ELAD System will receive regulatory approval in a timely fashion or at all.

We are subject to all of the uncertainties and complexities affecting a clinical-stage, combination product, biologic and medical device company. We have not successfully completed clinical development for any of the ELAD System's potential indications in the U.S. or Europe where the ELAD System is regulated as a combination biologic and medical device, and as a combined somatic cell Advanced Therapy Medicinal Product, respectively. In March 2018, we completed enrollment in our phase 3 clinical trial, referred to as VTL-308, designed to establish the safety and efficacy of the ELAD System and to support approval in the U.S. and Europe. This clinical trial was performed in certain subjects with sAH. Any additional indications we elect to pursue will require the initiation and completion of additional phase 3 clinical trials demonstrating safety and efficacy for each such indication. For example, even prior to our VTI-208 clinical trial, the FDA had noted its view that preliminary clinical evidence did not indicate that the ELAD System may demonstrate a substantial improvement over standard of care. Since then, our VTI-208 clinical trial failed to meet both its primary and secondary endpoints. There is no guarantee that any future clinical trials will be completed in a timely fashion or will succeed. Our ability ultimately to reach profitability is critically dependent on our future success in obtaining regulatory approval for the ELAD System. However, there can be no assurance that any future clinical trials will be timely, successful, or that regulators will approve the ELAD System in a timely manner, or at all.

If we fail to obtain regulatory approval in the U.S. and Europe, our business would be harmed.

We require regulatory approval for each indication we are seeking before we can market and sell the ELAD System in a particular jurisdiction for such indication. To date, we have not applied for or received the regulatory approvals required for the commercial sale of the ELAD System for any indication in the United States or the EU. Our ability to obtain regulatory approval of the ELAD System depends on, among other things, successful completion of phase 3 clinical trials, and demonstrating efficacy with statistical significance and acceptable safety in humans. The results of our VTL-308 clinical trial or future clinical trials may not meet the FDA, the EMA or other regulatory agencies' requirements to approve the ELAD System for marketing under any specific indication, and these regulatory agencies may also determine that our manufacturing processes or facilities are insufficient to support approval. For example, the FDA had previously noted its view that preliminary clinical evidence available prior to our VTI-208 clinical trial did not indicate that the ELAD System may demonstrate a substantial improvement over standard of care. Additionally, the negative results of VTI-208 may bias the FDA, EMA and other regulatory authorities against the ELAD System. As such, we may need to conduct more clinical trials than we currently anticipate and upgrade our manufacturing processes and facilities, which may require significant additional time and expense and which could delay or prevent approval. Furthermore, the timing of final FDA review and action varies greatly, but can take years in some cases and may involve the input of an FDA advisory committee of outside experts. Sales of the ELAD System in the United States may commence only when our BLA is approved. In addition, a BLA filing may take longer and may be more expensive than we currently expect. If we fail to obtain such regulatory approval in a timely manner, our

commercialization of the ELAD System would be further delayed and our business would be harmed.

If we are able to secure marketing approval, our commercial success will be determined by our ability to obtain acceptable pricing and reimbursement for the ELAD System.

Therapies such as the ELAD System are paid for primarily by private and government insurance, although in some markets payment may be made by private individuals and their families. Reimbursement policies and decisions for medical products is a highly bureaucratic, politicized and regulated process that includes consideration of factors such as cost effectiveness and meaningful patient benefit. Government and third-party payors are under great pressure to reduce costs. Furthermore, there are no therapies approved to restore liver function and the lack of an established reimbursement structure introduces additional uncertainty with regard to reimbursement for the ELAD System. Although we commissioned a report in 2013 from pricing study and reimbursement specialists that concluded we should target a commercial price between $150,000 and $275,000 for ELAD therapy in the U.S., we do not know whether this price is achievable or sustainable. Further, this report was prepared prior to the failure of the VTI-208 clinical trial, the discontinuation of our VTI-210 and VTI-212 clinical trials and prior to the commencement of our VTL-308 phase 3 trial, all of which may result in a lower target commercial price if the report was recreated based on the additional information known to us. Although we do not expect to determine a target commercial price for ELAD therapy either within or outside of the U.S. until after completion of a successful clinical trial, we believe it may be difficult to sustain a commercial price outside of the U.S. at or above the commercial price in the U.S. In addition, we will have no control over the reimbursement or conditions that may be set by the government or private insurers, if any, assuming we are able to secure marketing approval for the ELAD System. In markets where payment will be made by private individuals and their families, such private payors may not be prepared to pay an acceptable price.

If we are unable to implement our sales, marketing, distribution, training and support strategies in the U.S. and Europe or enter into agreements with third parties to perform these functions in markets outside of the U.S. and Europe, we will not be able to effectively commercialize the ELAD System and may not reach profitability.

Our technology is new and complex, and potential customers will have limited knowledge of, or experience with, the ELAD System. In addition, we have no ELAD System-related sales and marketing experience either domestically or abroad. We have not commercialized the ELAD System anywhere. Our commercial success will depend on our ability to market and receive adequate reimbursement for the ELAD System. This success will also depend on our ability to obtain and maintain adequate pricing for the ELAD System.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of biologic products and medical devices. To achieve commercial success for the ELAD System, if and when we obtain marketing approval, we will need to establish a sales and marketing organization, and we are unable to predict how we will market the ELAD System. In the future, we expect to build a targeted sales, marketing, training and support infrastructure to market the ELAD System in the U.S. and Europe and to establish collaborations with third parties to market, distribute and support the ELAD System outside of the U.S. and Europe. There are risks involved with establishing our own sales, marketing, distribution, training and support capabilities. For example, recruiting and training sales and marketing personnel and personnel necessary to initially provide on-site device support and later device training to end-users is expensive and time consuming and could delay any product launch. If the commercial launch of the ELAD System is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales, marketing, training and support personnel.

Factors that may inhibit our efforts to commercialize the ELAD System on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, training and support personnel;
- the inability of sales personnel to obtain access to physicians, including key opinion leaders, or to persuade adequate numbers of physicians to use the ELAD System;
- our inability to properly support the ELAD System therapy with our own qualified personnel at each customer site or our inability to properly train and support our customers to use the ELAD System effectively on their own;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive or integrated product offerings; and
-

unforeseen costs and expenses associated with creating an independent sales, marketing, training and support organization.

If we are unable to establish our own sales, marketing, distribution, training and support capabilities and instead enter into arrangements with third parties to perform these services, our product revenues, gross margins and our profitability, if any, are likely to be lower than if we were to market, sell and distribute the ELAD System ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute the ELAD System, or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to commercialize the ELAD System effectively. If we do not establish sales, marketing, distribution, training and support capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing the ELAD System and achieving profitability, and our business would be harmed.

We have incurred losses since our inception and expect to incur significant losses in the foreseeable future and may never become profitable. Even if we ultimately achieve profitability, it may not be sustained, and we may require additional capital.

We are a clinical-stage company, and clinical development of a novel therapy is a highly speculative undertaking. We have incurred significant losses in each fiscal year since our inception, including net losses of $27.1 million for the six months ended June 30, 2018 and $52.1 million, $41.0 million and $52.0 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of June 30, 2018, we had an accumulated deficit of $323.0 million. We expect to spend a considerable amount of our resources on the completion of our clinical programs and the work necessary to submit and gain approval of our ELAD System, including costs related to a potential BLA submission, on the production of the ELAD cartridges and bedside units, on investment in production facilities, and on the commercial launch and sales and marketing of the ELAD System. We also expect to expend considerable resources on research and development to develop new and improved products and to understand the mechanism of action of the ELAD System. Even if we succeed in commercializing the ELAD System, we expect to continue to incur substantial research and development and other expenditures to develop and market additional potential product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. To date, we have not generated significant revenues, and we anticipate incurring additional losses and negative cash flow from operations for at least the next several years. Even if we do achieve profitability in the future, there is no guarantee that we will be able to sustain this profitability in subsequent periods, and we may need to raise additional capital.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2017, we had net operating loss, or NOL, carryforwards of approximately $167.7 million and $200.8 million (prior to our adjustments for uncertain tax positions), net of estimated limitations caused by certain ownership changes under Section 382 of the Internal Revenue Code, for federal and state income tax purposes, respectively. In general, under Section 382, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs and its tax credit carryforwards. We believe our existing NOLs and tax credit carryforwards are subject to limitations arising from previous ownership changes, and if we undergo any further ownership changes, our ability to utilize NOLs and tax credit carryforwards could be further limited. Future changes in our stock ownership, some of which are outside of our control, could also result in additional ownership changes under Section 382. Furthermore, our ability to utilize NOLs and tax credit carryforwards of companies that we may acquire in the future may be subject to limitations. In addition, in 2013, California adopted a single factor, sales, for apportioning income and losses to the state. Although completely offset by our valuation allowance, we had recognized NOL carryforwards from 2013 through 2017 based on a multiple factor apportionment based on salaries, property and sales in the state. This position was based on prior court rulings supporting the use of the multiple factor apportionment. This ruling was overturned by the California Supreme Court in December 2015, and, in October 2016, the U.S. Supreme Court declined to hear the case. California has no regulations or guidance nor have there been any rulings addressing how a company with no sales should apportion losses to California. As most of our operations are in California, we intend to file our tax returns using a multiple factor apportionment until such time as California provides a ruling or guidance on such an apportionment. For these reasons, we may not be able to utilize a material

portion of the NOLs and tax credit carryforwards, even if we attain profitability.

We conduct business and file income tax returns in various tax jurisdictions. Our tax position could be adversely affected by several factors, many of which are outside of our control. For example, in the U.S., recently enacted U.S. tax reform in December 2017 commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act, may have a negative impact on our business. In addition, it is possible that further changes to the U.S. tax code and the tax rules in the other jurisdictions could occur in the near future. Although we monitor these developments, it is not possible to assess to what extent changes may be implemented in the U.S. and other jurisdictions in which we conduct our business or may impact the way in which we conduct our business or our effective tax rate due to the unpredictability and interdependency of these potential changes. Even though we maintain a full valuation allowance to offset our NOLs and tax credit carryforwards, changes in tax laws and related regulations and practices could have a material adverse effect on our business operations, cash flows, effective tax rate, financial position and results of operations.

Our internal computer systems, cloud-based systems and those used by our clinical investigators, contract research organizations or other contractors or consultants may fail or suffer security breaches, which could result in a material disruption of our development programs for the ELAD System.

We rely on information technology systems to keep financial records, maintain laboratory information, clinical data and corporate records, communicate with staff and external parties and operate other critical functions. Despite the implementation of security measures, our internal computer systems, cloud-based systems and those used by our clinical investigators, clinical research organizations, or CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, cyber-attacks, terrorism, war, and telecommunication and electrical failures. The techniques that could be used to attack these computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these risks proactively or implement adequate preventative measures. While, to our knowledge, we have not experienced any significant system failure, theft of information, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our clinical development or manufacturing activities. For example, the loss of clinical trial data could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption, theft of information, or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the clinical development and any future development of the ELAD System could be delayed.

In the recent past, we have been involved in securities litigation, and defending against such litigation or an adverse resolution of such litigation may adversely affect our business, financial condition, results of operations and cash flows.

Our industry is characterized by frequent claims and litigation, including claims regarding patent or other intellectual property rights, as well as product liability. Following our announcement that the ELAD System, our sole product candidate, failed to meet its primary and secondary endpoints in our VTI-208 phase 3 clinical trial, we became the subject of a lawsuit alleging securities law violations. Although this litigation was dismissed, this type of litigation can be expensive and disruptive to normal business operations and divert management's attention, and the outcome can be difficult to predict regardless of the facts involved. An unfavorable outcome with respect to a lawsuit could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Risks Related to the ELAD System’s Clinical Development

We have limited experience in conducting pivotal clinical trials used to support regulatory approval, and our prior clinical trials of the ELAD System did not demonstrate a statistically significant improvement in survival, the primary endpoint that is needed to support regulatory approval.

Our VTI-208 phase 3 randomized, controlled, open-label trial evaluating the ELAD System in subjects primarily with sAH failed to meet the primary endpoint of overall survival through at least 91 days assessed using the Kaplan Meier statistical method. Our protocol for our clinical trial in sAH, VTL-308, incorporates limits on subjects' age, MELD score and its three components. While the endpoints and populations for VTL-308 are derived from results of our prior studies, including the results of VTI-208, and based on medical literature, in none of those prior studies have we demonstrated a statistically significant effect on the population based on the endpoints prospectively described in the study plan. Our prior clinical trials of the ELAD System in sAH did not demonstrate statistically significant

improvement over standard of care in the primary endpoint of survival through at least study day ninety-one. Similarly, our prior clinical trials of the ELAD System in fulminant hepatic failure, or FHF, did not demonstrate statistically significant improvement in the primary endpoint of 28-day survival. The lack of statistical significance could be attributed to various factors, including the lack of power to demonstrate significance, the design of the studies or the lack of an ELAD System treatment benefit.

Any positive results from previous clinical trials may not be predictive of future results.

Any positive results from our prior clinical trials, including either statistical significance in some endpoints or trends towards statistical significance in other endpoints, should not be relied upon as evidence that our current or future clinical trials will necessarily succeed. While we believe that we have learned valuable lessons from the results of prior trials and have attempted to use these lessons to guide our design of VTL-308, there can be no guarantee that these lessons are correct or that we have effectively incorporated them into the design of VTL-308. For example, our primary endpoint in VTI-208 was based on the results of a subset of subjects in our VTI-206 clinical trial. Although that subset showed a trend toward increased survival up to at least study day ninety-one, it consisted of only 29 subjects. The FDA has noted its belief that this preliminary clinical evidence did not indicate that our product may demonstrate a substantial improvement over standard of care. We cannot provide any guarantee that our potential future clinical trials will provide statistically significant data sufficient to support regulatory approval.

If we fail to select appropriate subjects for our phase 3 clinical trials or if these subjects do not progress as expected, it will be difficult for us to demonstrate the statistically significant efficacy of the ELAD System therapy necessary to gain approval.

We designed VTI-208 and VTI-210 in accordance with input provided by regulatory authorities that we must demonstrate a statistically significant improvement in a survival endpoint. VTI-208 and VTI-210 included concurrent control subjects in a 1:1 ratio with treated subjects, and all subjects were to be included in the statistical analysis. Each study was designed to enroll subjects with an expected death rate of about 50% in 90 days without the ELAD System therapy. It was and is necessary to select subjects with high expected death rates in order to be able to determine whether the ELAD System has an effect on treated subjects and to help determine the number of subjects to enroll in a clinical trial in order to be able to achieve statistical significance. When conducting clinical trials, we monitor certain baseline characteristics of the subjects we are enrolling (such as age and MELD scores) to assess that the population characteristics are similar to prior studies in which death rates were in the target range. Although we have incorporated limits on age, MELD scores, creatinine, INR and bilirubin for VTL-308, there is no assurance that the revised parameters will be sufficient to predict survival. Additionally, there is no assurance that the inclusion and exclusion criteria for VTL-308, which will have the same primary and secondary endpoints as the VTI-208 clinical trial, will help the study show statistical significance. Moreover, if the subjects we have selected do not progress as expected, we may not be able to demonstrate statistically significant efficacy of the ELAD System therapy necessary to gain approval.

Random variation or changes in standard of care could cause our clinical trials to be delayed and/or fail.

Regulatory authorities worldwide have adopted the standard that, to gain marketing approval, clinical trials should produce a result that has less than a 5% probability of being due to random variation. There is no assurance that our current or any of our potential future clinical trials will meet that standard. In addition, we have designed all of our clinical trials to be judged by a survival primary endpoint, which may be difficult to achieve for many reasons, including unanticipated survival rates of control subjects due to random variations, deficiencies in our exclusion and inclusion criteria, and the standard of care of the subjects, which may vary from site to site and country to country and is continuously evolving. For example, the FDA had expressed concern that the VTI-208 study may not have been adequately designed to provide convincing evidence of efficacy if there were significant differences in how the ELAD System subjects and controls were treated during the treatment period and after hospital discharge. VTL-308 will bear the same risk. Variations in length of hospital stay, rates of hospital re-admission, alcohol recidivism rates, nutritional support, and concomitant medications, all of which are not within our control, could significantly confound the study results and call into question whether any difference in survival is due to the ELAD System or these factors. Moreover, evolution in the standard of care for the treatment of patients with acute forms of liver failure could make our trials difficult to enroll and interpret. For instance, the results of the Steroids or Pentoxifylline for Alcoholic Hepatitis, or STOPAH, study funded by the United Kingdom National Institute for Health Research failed to demonstrate any significant benefit in the primary analysis of overall survival for subjects treated with either steroids, Pentoxifylline or a combination of the two at one, three or twelve months, as compared with placebo. Any of these factors, which are beyond our control, could materially and adversely affect the results of any of our phase 3 clinical trials and prevent us from gaining regulatory approval of our ELAD System therapy. In addition, even if the results of

our clinical programs are positive, our inability to control or adequately account for these factors between treatment arms could cause the FDA or other regulatory authorities to determine that the results are not adequate, or must be reproduced in a confirmatory study, to support marketing approval.

The ELAD System treatment could result in significant clinical risks to the patient, including death.

The ELAD System therapy is targeted toward very sick patients who are likely to die if left untreated. Patients with liver failure resulting from acute hepatocellular insult quickly develop failure of other organs including lungs, kidney, brain, and blood coagulation systems. Patients who receive the ELAD System therapy may die due to other serious health problems even if the ELAD System is effective.

All extracorporeal therapy systems, including the ELAD System, cause a decline in blood platelets, which can lead to coagulation problems and uncontrolled bleeding because platelets are critical to clot formation. Patients with liver failure generally have serious blood clotting problems since the liver produces almost all of the body's blood clotting proteins. These patients therefore have wide variations in their ability to coagulate their blood. To minimize blood clotting issues during ELAD treatment, some subjects require an infusion of anti-coagulants, which can aggravate bleeding. Because every subject is different, the need for anti-coagulant therapy is variable and must be closely monitored during ELAD System therapy. The risk of uncontrolled bleeding may be treated during the ELAD System therapy by administering platelet transfusions or by administering blood coagulation factors. However, there have been cases of uncontrolled bleeding during and after the ELAD System therapy. Additionally, some patients have abnormal red blood cells, which have weakened cell walls subject to rupture by physical force, a process known as hemolysis. The physical force exerted on the red blood cells by the ultrafiltrate generator in the ELAD System line can, in some cases, be enough to cause overt mechanical hemolysis that resolves after ELAD treatment is stopped, but can result in death if it continues too long. The incidence of hemolysis was less than 0.5% in subjects enrolled in our prior clinical trials, and one patient died in our China trial as a result of hemolysis.

Data from our clinical trials suggest that ELAD treatment should not be used in subjects with acute kidney injury (defined as a serum creatinine level of greater than or equal to 1.5 mg/dL). The use of extracorporeal systems such as ELAD may cause harm in patients with pre-existing kidney injury because these subjects are at an increased risk to develop fluid overload due to the renal impairment. Furthermore, ELAD treatment should be stopped if a patient develops any indication for renal replacement therapy, because patients with renal impairment are less likely to be able to tolerate the increased stresses associated with two extracorporeal devices requiring high venous flow rates.

Similarly, data from our prior clinical trials suggest that ELAD treatment should not be used in subjects with severe coagulopathy (problems with blood clotting, defined as an INR of greater than 2.5). The use of extracorporeal systems such as ELAD may cause harm in patients with pre-existing severe coagulopathy because the circulation of blood outside the body can cause a depletion in circulating factors associated with the blood clotting cascade, and reductions in the number of circulating platelets in the blood which are required for the blood to clot properly. As a result, subjects on extracorporeal systems such as ELAD are at an increased risk to develop bleeding issues.

Human liver-derived C3A cells have been shown in animal studies to have the capacity to grow into a tumor mass under certain conditions. While it is possible that some VTL C3A cells could escape from the ELAD cartridges and cause tumors in patients or produce substances that could lead to the development of malignant tumors, it is expected within the natural medical history of this population of patients with chronic liver disease (whether caused by hepatitis B or alcohol) that a certain incidence of cancer will be reported. There was no evidence that the incidence or type of cancer was different between the ELAD and control group in the China study. There have been two reported cancers (rectal cancer and squamous cell carcinoma) in our extended follow-up of ELAD-treated subjects from the VTI-208 study. Long term follow up of the subjects in the VTI-208, VTI-210, VTI-212 and VTL-308 clinical studies, as required by the regulatory authorities, is ongoing, and will provide more information. These or other adverse events, even those that are currently unforeseen, could significantly affect our development and commercialization efforts, cause the regulatory authorities to place any clinical trials on hold or to refuse to grant or maintain the marketing approval or result in withdrawal of the ELAD System from the market.

Ethical considerations require us to conduct open-label clinical trials of the ELAD System where control subjects do not receive a sham treatment and this could introduce unacceptable bias into our trial results.

We are not conducting any of our clinical trials with a sham control extracorporeal circuit that includes empty cartridges. This is due to the potential harm that the extracorporeal circuit can cause to control subjects without the potential for any benefit, which makes it unethical to subject the controls to a sham. Although regulatory agencies agree that, due to the nature of the ELAD System therapy, it is not possible to conduct a blinded study, they have expressed concern that the open-label nature of the study may introduce significant bias in the treatment of the ELAD System or control subjects, since the study subject, physicians and caregivers know who has and has not received the ELAD System therapy. We have developed a protocol that attempts to minimize this bias to the extent possible, including defining a protocol-specific standard of care, specifying steroid treatment, standardizing the discharge criteria for both the ELAD System and control subjects, requiring that follow-up visits are conducted by a blinded reviewer, ensuring home healthcare nurses and other clinical personnel are unaware of treatment assignment, educating subjects not to reveal treatment assignment to their caregivers and monitoring concomitant medications, alcohol recidivism and interaction with the healthcare system to provide evidence that there is no meaningful difference between the groups that could significantly confound the trial data. However, there is no guarantee that bias will not enter into the trial, affect the results or cause regulatory agencies to refuse marketing approval of the ELAD System.

If we encounter difficulties enrolling subjects in our clinical trials, any future clinical trials could be delayed or otherwise adversely affected.

Clinical trials for the ELAD System require us to identify and enroll a large number of subjects that meet all of the entry criteria set forth in our protocols, including having the disease under investigation. We may not be able to enroll a sufficient number of subjects who meet our protocol requirements in a timely manner. Subject enrollment is affected by numerous factors, many of which fall outside of our control, including:

- the size and nature of the subject population;
- timeliness of contracting with clinical trial sites, and obtaining approval of the trial by the applicable institutional review boards, or IRBs, or ethics committees;
- lack of a sufficient number of subjects who meet the enrollment criteria for our clinical trials;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- scheduling conflicts with participating clinicians; and
- proximity and availability of clinical trial sites and resources for prospective subjects.

In light of results and disclosures of our prior clinical trials by us or others, it is possible that subjects will be less willing to participate in future trials of the ELAD System. Even when we identify an appropriate subject population for a clinical trial, there can be no assurance that the subjects will elect to enroll in the study or complete the study. These difficulties could negatively impact any potential future clinical trials.

If we have difficulty enrolling a sufficient number of subjects to conduct our clinical trials as planned or if enrolled subjects fail to complete the study or comply with our protocols, particularly with regard to follow-up appointments, the completion of our clinical trials will be delayed, and our business would be harmed.

We may face delays in completing our clinical trials, and we may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with applicable regulatory requirements, the results are negative or inconclusive, or the clinical trials are not well-designed or executed as expected.

Our clinical trials must be conducted in accordance with regulations governing clinical studies, and are subject to oversight by the FDA, foreign governmental agencies, ethics committees and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials may require large numbers of test subjects. Changes in regulatory requirements may occur at any time, and we may need to amend clinical trial protocols to reflect such changes. In addition, we may voluntarily amend our protocols, as we did for our VTI-210 clinical trial. Amendments may require us to resubmit our clinical trial protocols to ethics committees or IRBs for reexamination, which may

impact the costs, timing or successful completion of the underlying trial.

Our clinical trials may require amendment or be delayed, not approved, unsuccessful or terminated as a result of many factors, including:

- delays or failures in designing an appropriate clinical trial protocol with sufficient statistical power and in reaching agreement on trial design with investigators and regulatory authorities;
- delays or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays or failure by CROs, investigators and clinical trial sites in ensuring the proper and timely conduct of our clinical trials;
- delays or failure by us in manufacturing sufficient quantities of the ELAD cartridges pursuant to required quality standards for use in our clinical trials and by third-party manufacturers in supplying necessary and suitable components for the ELAD System;
- delays or failure in transporting the ELAD System and cartridges to clinical trial sites with sufficient rapidity to enable treatment to begin early enough to have an opportunity for clinical benefit;
- delays or failure in completing data analysis and achieving primary and secondary endpoints;
- delays in subject enrollment or site initiation, including in light of, among other things, our prior clinical results;
- regulators or clinical site ethics committees or IRBs may not approve, delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about subject safety;
- we may suspend or terminate our clinical trials if we believe the ELAD System is exposing the participating subjects to unacceptable health risks or for other reasons;
- subjects may not complete our clinical trials due to safety issues, adverse events, inconvenience or other reasons;
- subjects in our clinical trials may die or suffer other adverse events for reasons that may be either related or unrelated to the ELAD System, particularly given the critically ill nature of these subjects;
- we may have difficulty in maintaining contact with subjects after treatment, preventing us from collecting the data required by our study protocol; and
- final analysis of the data from our clinical trials may conclude that the ELAD System lacks sufficient clinical efficacy or presents unacceptable safety risks.

If our clinical trials fail to provide evidence of safety and efficacy sufficient to satisfy the requirements of the regulatory authorities such as with VTI-208, the ELAD System will not be approved unless we are able to perform additional clinical trials showing such safety and efficacy. Delays in the completion of, or termination of, any clinical trial of the ELAD System may harm the future commercial prospects of the ELAD System, and our ability to generate revenues may be delayed or eliminated. In addition, any delay in completing our clinical trials increases our costs, slows down our development and approval process and delays or jeopardizes our ability to commercialize the ELAD System. These occurrences would harm our business, financial condition and prospects significantly.

Risks Related to Regulatory Matters

The FDA regulatory approval process is complex, time-consuming and inherently unpredictable. In addition, our negative VTI-208 data may adversely affect the attitude of regulatory authorities toward the development of the ELAD System.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of the ELAD System is subject to extensive regulation by the FDA. In the U.S., the ELAD System is regulated by the FDA as a combination biologic and medical device. Before the ELAD System can be marketed in the U.S., we must submit and the FDA must approve a BLA. In addition, the device components of the ELAD System must be found acceptable as part of the BLA. The ELAD System is a novel therapy involving a combination biologic and medical device and the regulatory review process is complex, time-consuming and unpredictable. As a result, our development costs, timelines and approvals are not readily predictable.

The time required to obtain approval by the FDA to market a new therapy is unpredictable but typically takes many years and depends upon many factors, including the substantial discretion of the regulatory authorities.
The ELAD System could fail to receive regulatory approval for many reasons, including the following:

- the FDA may disagree with the design or implementation of our clinical trials or study endpoints. For example, it has expressed concern about the open-label design and multiplicity of confounding variables, including the need for delineating the standard of care that both the treated and control groups will receive during our studies;
- we may be unable to demonstrate to the satisfaction of the FDA that the ELAD System is safe and effective for its proposed indications or that the ELAD System provides significant clinically relevant benefits or that the benefits outweigh the safety risks;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA for approval or may not support approval of a label that could command a price sufficient for us to be profitable;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA may not accept clinical data from trials which are conducted outside their jurisdiction;
- the opportunity for bias in the clinical trials as a result of the open-label design may not be adequately handled and may cause our trial to fail;
- the ELAD System may be subject to an FDA advisory committee review, which is triggered by an FDA request and is solely within the FDA's discretion, which may result in unexpected delays or additional hurdles to approval;
- the FDA may determine that the manufacturing processes at our facilities or facilities of third party manufacturers with which we contract for clinical and commercial supplies are inadequate;
- even if VTL-308 is successful in demonstrating a statistically significant improvement over standard of care, in light of the fact that certain confounding factors may be viewed by the FDA as limiting the persuasiveness of the study results, a single successful phase 3 clinical trial may not be sufficient to provide the substantial evidence of effectiveness necessary to support regulatory approval, and therefore we may need more than one phase 3 clinical trial to secure regulatory approval;
- the FDA has commented that even if one of our phase 3 clinical trials is a statistical and clinical success, a second confirmatory trial that substantiates positive results may be necessary to support a BLA;
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval; and
- the negative results from VTI-208 could result in more stringent requirements being imposed by regulatory bodies and advisory groups.

The FDA expressed concern with our past phase 3 clinical trial, VTI-208, that if there are significant differences in how the ELAD and control subjects are treated during the study and after discharge from the hospital, the study may not be able to provide convincing evidence of safety and efficacy. Differences in length of hospital stay, rates of hospital re-admission, alcohol recidivism rates, nutritional support, and concomitant medications could significantly confound the VTL-308 study results.
In addition, even if we were to obtain approval, the FDA may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve the ELAD System with a label that does not include the labeling claims necessary or desirable for successful commercialization of the ELAD System. Any of the above could materially harm the ELAD System's commercial prospects.

We do not have, and may never obtain, the regulatory approvals we need to market our product.

In responding to a BLA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose a post-approval study and other commitments or reporting requirements or other restrictions on product commercialization, or may deny the application. The FDA has established performance goals for review of BLAs; however, the FDA is not required to complete its review within these time periods. The timing of final FDA review and action varies greatly, but can take years in some cases and may involve the input of an FDA advisory committee of outside experts. Sales of the product in the United States may commence only when the BLA is approved.

To date, we have not applied for or received the regulatory approvals required for the commercial sale of any product in the United States or Europe. None of our product candidates have been determined to be safe and effective, and we have not submitted a BLA to the FDA or Europe for any of our product candidates.

It is possible that the ELAD System will never be approved for marketing. Failure to obtain regulatory approvals, or delays in obtaining regulatory approvals, may adversely affect the successful commercialization of the ELAD System, may impose additional costs on us, may diminish any competitive advantages that we may attain, and adversely affect our receipt of revenues.

The FDA may or may not grant an accelerated or “Priority Review” to our BLA, if requested by us, and even if the FDA designates Priority Review for the ELAD System, that designation would not assure FDA approval and may not even lead to a faster regulatory review or approval process.

On the date the FDA receives the original BLA submission, a 60 calendar day filing review period starts. Assuming the FDA accepts the submission for filing, a ten-month standard BLA review clock begins, which means the FDA has an aggregate twelve months from its receipt of the original submission to take regulatory action. We may be eligible for Priority Review for our BLA submission if the FDA determines that the ELAD System, if approved, would provide a significant improvement in safety or effectiveness. A six-month Priority Review clock would begin at the conclusion of the 60 calendar day filing review period that starts on the date of FDA receipt of the original BLA submission. Therefore, if Priority Review is granted, the FDA has a total of eight months to take action on an application as opposed to the standard timeline of twelve months. We may request Priority Review if and when we submit a BLA. The FDA has broad discretion whether or not to grant Priority Review even if we believe our product is eligible. Moreover, even if a product is designated for Priority Review, such a designation does not assure a faster regulatory review process or confer any advantage with respect to FDA approval. Moreover, a designation of Priority Review or even a standard review from the FDA does not guarantee approval within the eight-month or twelve-month review period, respectively, or at any time thereafter. Accordingly, we cannot assure you that our BLA will be approved in a timely manner, or at all.

The regulatory approval processes of foreign regulatory authorities are complex, time-consuming and inherently unpredictable.

Outside the U.S., our ability to market the ELAD System is contingent upon receiving marketing authorizations from appropriate regulatory authorities. If our clinical programs are successful, we currently anticipate submitting applications for marketing authorization in Europe. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country, and we may be unable to meet such requirements. If the regulatory authority is satisfied that adequate evidence of safety, efficacy, and quality has been presented, a marketing authorization should be granted. The foreign regulatory approval process involves all of the risks associated with FDA approval.

Even if the ELAD System receives regulatory approval, we will be subject to ongoing regulatory requirements and may face regulatory or enforcement action.

If any ELAD System product receives regulatory approval, we will be subject to significant ongoing regulation by the FDA and other regulatory authorities, including regulation of our manufacturing operations and any third-party manufacturing operations to ensure our compliance with applicable current Good Manufacturing Practices, or cGMP,

and/or Quality System Regulation, or QSR, post-approval clinical data, adverse event reporting and complaint handling, and advertising and promotional activities. Failure to comply with regulatory requirements may subject us to sanctions. These may include warning letters, adverse publicity, civil and criminal penalties, injunctions, product seizures or detention, and refusal to approve pending product marketing applications.

Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in fraud, misconduct or other illegal activity or that they do not comply with regulatory standards and requirements. Misconduct or non-compliance by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate (1) FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (2) quality standards, including Good Laboratory Practices, or GLP, Good Clinical Practice, or GCP, and cGMP, (3) federal and state healthcare fraud and abuse laws and regulations, (4) laws that require the reporting of true and accurate financial information and data, (5) securities laws and regulations, (6) the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, or (7) General Data Protection Regulation. If we obtain FDA approval of our product candidate and begin commercializing that product in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and business arrangements in the healthcare industry are also subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of subject recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties. We may fail to identify and deter misconduct or non-compliance by employees and third parties, or the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of changes to or even the halt of any ongoing clinical trials or manufacturing or civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to the Medical Device Components of the ELAD System

If we or our third-party manufacturers fail to comply with QSR in the U.S. or Medical Device Directives and Standards in Europe, our business would suffer.

We are required to demonstrate and maintain compliance with applicable regulations for the manufacturing of combination biologic products, including specified parts of the QSR and European Medical Device Directives, or MDD. Our third-party medical device manufacturers are required to demonstrate and maintain compliance with the QSR and MDD. The QSR and MDD are complex regulatory schemes that cover the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of the ELAD System. Regulatory agencies enforce the QSR and MDD through periodic inspections. Prior to approval of the ELAD System, our manufacturing facility will be subject to a preapproval inspection to determine compliance with the applicable regulations, including cGMPs, parts of the QSR, the European drug cGMP regulations, and the MDD. In addition, our third-party medical device component manufacturers will be subject to a preapproval inspection to determine compliance with QSR and MDD requirements. Our failure, or the failure of our third-party manufacturers, to pass a preapproval inspection, or to take satisfactory and prompt corrective action in response to an adverse inspection, could prevent or significantly delay approval of the ELAD System.

The ELAD System bedside unit is based on a cardio-pulmonary bypass system that was replaced with an updated system, and regulatory authorities may not view the systems as interchangeable, which could cause regulatory approvals to be significantly delayed.

The ELAD System bedside unit was originally based exclusively on the LivaNova (formerly Sorin) Stöckert Perfusion System S3 Double Head Pump Module, a medical device indicated for use during cardio-pulmonary bypass surgery. All or part of our early clinical trials were carried out using an ELAD System bedside unit based on LivaNova's S3 system. However, LivaNova stopped selling the S3 system and replaced it with an updated S5 system. We carried out testing of an ELAD System bedside unit based on the S5 and we believe that the S3 and S5 systems are equivalent and interchangeable from a clinical and regulatory perspective. We have submitted information to both the U.S. and the European regulatory authorities to support equivalence. Both the S3 and S5 systems were used in our VTI-208 and VTI-210 clinical trials and both were used in our VTL-308 clinical trial. There can be no assurance that regulatory authorities will continue to view the S3 and S5 systems interchangeably, or that LivaNova will cooperate with us or provide us with the documentation necessary for inclusion in a BLA submission, if any, which would be required to obtain regulatory approval of our ELAD System. If regulatory authorities do not view the S3 and S5 systems as equivalent, or LivaNova fails to provide the information necessary for inclusion in our regulatory filings, approval of our ELAD System may be significantly delayed or prevented. In addition, effective January 1, 2018, LivaNova no longer supports its S3 systems. Accordingly, if our trial is successful, we would expect to commercialize ELAD with only the LivaNova S5 system.

One of the ELAD System component suppliers was subject to an FDA consent decree, which could have forced us to find another supplier for this component.

One of the components of the ELAD System bedside unit is manufactured by Terumo Cardiovascular Systems, or Terumo. In March 2011, Terumo entered into a consent decree with the FDA which limited its ability to ship products from certain of its manufacturing facilities including the one that manufactures the component we use. We received notice from Terumo in June 2016 that all restrictions listed in the 2011 consent decree were lifted. If we had been unable to source the component we use from Terumo, we would have had to source the component from an alternative supplier. If Terumo or another component supplier has similar issues in the future, there is no guarantee that a qualified alternative supplier can be found that will agree to terms reasonably acceptable to us on a timely basis or at all.

Changes in any of the device components could affect our ability to complete clinical trials and to obtain and maintain approval and commercialization efforts.

The device components of the ELAD System will be reviewed as part of any BLA for the ELAD System. If the manufacturers of those components make modifications, discontinue supplying or are unable to supply sufficient quantities of such components during any clinical testing or after any approval, or if we elect to change a component, we will need to perform validation testing and obtain FDA and other regulatory approval prior to using the modified or replacement component. For example, one of our suppliers of a key component in our manufacturing process was having an issue meeting all of their customer orders for the component. If we are unable to obtain sufficient quantities of the component on a timely basis, there could be a delay in enrollment in any future clinical trials or, following approval if any, in the marketing of ELAD until additional supplies become available, or we would be required to validate an alternative component to use, which could delay any clinical trials or the marketing of ELAD, and increase our costs. If the FDA or any other regulatory body fails to approve use of those modified or replacement devices or if we are unable to validate a replacement component, we would not be able to complete any ongoing clinical trials or, in the future, we might not be able to market or could have to suspend marketing of the ELAD System in certain jurisdictions.

We may be unable to demonstrate that devices cleared for different uses may be safe and effective for use in the ELAD System.

Most device components of the ELAD System have been previously cleared for use by the FDA or other regulatory authorities. However, in many instances, we will be using the components outside the scope of their cleared indications. Other device components have no regulatory approvals. We may need to conduct additional testing to bridge the differences between the cleared indications for use and the proposed use in the ELAD System in order to

obtain approval, or we could be required to obtain separate clearance for one or more of the components used in the ELAD System. The failure to provide adequate bridging information or to obtain separate clearance of these device components for use in the ELAD System, if required, could delay or prevent approval of the ELAD System.

Risks Related to the Cellular Component of the ELAD System and Related Components

If we fail to comply with cGMPs, our business will suffer.

We are required to demonstrate and maintain compliance with cGMPs. The cGMPs describe the methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a biologic to assure the biologic meets the requirements for safety, and has the quality, purity, and potency characteristics that it purports or is represented to possess. Regulatory agencies enforce these requirements through periodic inspections. Prior to approval of the ELAD System, our manufacturing facilities will be subject to a preapproval inspection to determine compliance with U.S. and European cGMPs and applicable QSR and MDD requirements. Our failure to pass such an inspection, or take satisfactory and prompt corrective action in response to an adverse inspection, could prevent or significantly delay approval of the ELAD System.

We rely on third party suppliers, and in many instances, a single third party supplier, for critical components of the ELAD System, and these suppliers could cease to manufacture the components, go out of business or otherwise not perform as anticipated.

While the growth of our VTL C3A cells is under our control, the manufacture of all of the other parts and components of the ELAD System are undertaken by third party suppliers. We currently rely on a single source of supply for many critical components, including components of the ELAD System bedside unit, the ultrafiltrate generator cartridges, the media we use to grow and ship our VTL C3A cells, the cartridges in which our VTL C3A cells are grown, the final cell filter cartridges and the bioreactors that have been developed to grow and store the ELAD cartridges. We are investigating additional sources of supply for some of these components to support any future clinical development and, ultimately, commercialization of the ELAD System. If we fail to develop additional sources of supply, and a single source of supply of a critical component of the ELAD System were to become unavailable, our ability to continue the development or to initiate commercialization of the ELAD System would be severely compromised. In addition, we rely on third party suppliers for the safety of products of human and animal origin that are incorporated in the ELAD System production process, and these suppliers could cease to manufacture the components, inadequately test these components, go out of business or otherwise not perform as anticipated. We do not have long-term agreements with our suppliers, and we purchase components on a purchase order basis. For components that are not readily available from other sources, we are subject to the risks that our suppliers will raise their prices or impose other terms or conditions that are less favorable or unacceptable to us.

For instance, bovine serum, which is a component of the cell growth media, is used in the manufacture of the ELAD System cartridges. It is obtained from an outside supplier. We are wholly reliant on the guarantee of our supplier that the calf serum used in our manufacturing procedures is free of transmitted animal viruses and other pathogens. Should the source of supply become infected, or the supplier become unable to continue to supply calf serum of the quality necessary to support human use, or the regulations change such that the calf serum cannot be used for human use, we would have to find alternative sources of supply and manufacturing methods, for which there is no guarantee of success.

Human albumin and Trypsin-EDTA are also used in the manufacture of the ELAD System cartridges and are each provided by a single supplier. In addition, while these products are tested to be free of contamination by the supplier, we cannot guarantee that will continue to be the case.

If our facility becomes inoperable, we will be unable to continue manufacturing our product candidate and as a result, our business will be harmed until we are able to secure a new facility.

We manufacture and assemble the ELAD System at our facility in San Diego, California. No other manufacturing or assembly facilities are currently available to us, and any additional manufacturing or assembly facilities that we use will need to be qualified and approved by regulatory authorities prior to our use. Our facility and the equipment would be costly to replace and could require substantial lead-time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our research, development and manufacturing for some period of time. The inability to perform our research, development and manufacturing activities, combined with our limited inventory of reserve raw materials and manufactured supplies, may result in the delay of any clinical trials or, if approved for sale, the loss of customers, or harm our reputation, and we may be unable to reestablish relationships

with those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses or may not continue to be available to us on acceptable terms, or at all.

We may be unable to manage our anticipated manufacturing growth to support our clinical development activities and long-term commercial demand for the ELAD System.

If and when the ELAD System is approved for sale, we will need to expand our manufacturing space in San Diego and build new manufacturing facilities to meet anticipated demand for the ELAD System in the U.S. and abroad. These activities will involve significant expense, including the construction and validation of new clean rooms and bioreactors, the movement and installation of key manufacturing equipment and the modification of manufacturing processes. In addition, we must also notify, and in some cases obtain approval from, the FDA and other regulatory authorities of any changes or modifications to our manufacturing facilities and processes, and there is no assurance that they will authorize us to proceed. If we are not able to expand our manufacturing capacity to meet future demand, our business would be harmed.

Further, commercialization would place additional strain on our organization, employees and third-party suppliers, resulting in an increased need for us to carefully monitor quality. Any failure by us to manage any future growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

We rely on third parties for certain aspects of the manufacture of our clinical product supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of the ELAD System, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or if they encounter other manufacturing issues.

Although we currently have an operational San Diego manufacturing facility, we intend to continue to use third parties for certain parts of our production process during the commercialization period. Our anticipated manufacturing procedures expose us to a number of risks, including the following:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any manufacturers. This approval would require new testing and good manufacturing practices compliance inspections by the FDA. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products.
- Our third-party manufacturers might be unable to timely manufacture the components and custom materials and supplies used in the ELAD System and delivery of ELAD therapy, or to produce the quantity and quality required to meet our commercial needs.
- Contract manufacturers may not be able to execute or comply with our manufacturing procedures and other logistical support requirements appropriately.
- Our contract manufacturers may not perform as agreed, may not devote sufficient resources to us, or may not remain in the contract manufacturing business and alternative manufacturers that can meet our requirements may be difficult to identify and qualify on a timely basis, if at all.
- Manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state agencies to ensure strict compliance with current good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, and they are also be subject to the same ongoing periodic unannounced inspection. Any license to manufacture product candidates will be subject to continued regulatory review. Failure to meet such standards could result in the need to take corrective actions and even withdrawal of product from the market.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process, or in the manufacture of the custom materials used in the manufacture thereof.
- Our third-party manufacturers could breach or terminate their agreement with us.
- Our contract manufacturers may have unacceptable or inconsistent product quality, success rates and yields.
- We do not yet have sufficient information to reliably estimate the cost of commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of the ELAD System.
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Our manufacturers may experience manufacturing difficulties due to resource constraints and labor disputes, as well as natural or man-made disasters.

Each of these risks could delay or prevent the completion of future clinical trials or the approval of our product by the FDA, result in higher costs, or adversely impact commercialization of the ELAD System. If our contract manufacturers are unable to successfully produce any of the ELAD System's components or any related supplies for our clinical trials or commercialization, our clinical trials or our commercial efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We forecast the requirements for components and materials used in the ELAD System, and if our forecasts are incorrect, we may experience delays in shipments or increased inventory costs.

We keep limited materials, components and finished product on hand. To manage our manufacturing operations with our suppliers, we forecast anticipated product orders and material requirements to predict our future inventory needs and enter into purchase orders on the basis of these requirements. Our limited historical experience may not provide us with enough data to accurately predict future demand. If our business expands, our demand for components and materials would increase and our suppliers may be unable to meet our demand. Many of our components are medical devices, which have fixed future expiration dates. If we overestimate our component and material requirements, we will have excess inventory, which may have to be disposed of if it exceeds approved expiration dates, which would increase our expenses. If we underestimate our component and material requirements, we may have inadequate inventory, which could interrupt, delay or prevent delivery of the ELAD System to our customers. Any of these occurrences would negatively affect our financial performance and the level of satisfaction our customers have with our business.

We may not be able to grow our VTL C3A cells reliably and cost-effectively.

Operations with human cells, even a stable, cell line such as the VTL C3A cells used in the ELAD System, can be subject to conditions and influences that we may not be able to control. Although our VTL C3A cells are stored at three separate locations in the U.S. and the U.K., it is possible that all three locations could be destroyed and we could lose all or a portion of our cell banks. It is also possible that the cells will simply cease to function. While we take precautions to prevent this from happening, the ELAD System employs new technologies and we could encounter unforeseen complications. To date, we have only produced the small number of the ELAD cartridges required to support our clinical trials. As we increase production to support commercial demand, we could experience significant scale-up issues, which may cause quality and cost problems. If we cannot produce the required number of the ELAD cartridges in a cost-effective manner, our business could be materially harmed.

Cellular therapy is complex, and we do not have a complete understanding of the mechanism of action of the ELAD System.

Cellular therapy is a complex treatment with multiple variables that are not fully understood. Our VTL C3A cells used in the ELAD cartridges produce hundreds of metabolites. Likewise, the plasma ultrafiltrate formed from blood, which has been treated by our VTL C3A cells in our ELAD cartridges, is a similarly complex material. The composition and stability of the treated blood can be affected by the conditions of its generation in the ELAD System bedside unit, which could affect treatment outcomes. For instance, while subjects treated with the ELAD System typically only require a single set of cartridges, some subjects require more than one set during their treatment period, which may have implications for not only efficacy, but also cost of goods. While we believe that we have identified the key parameters of the ELAD System VTL C3A cartridges and set them in an appropriate range, it is possible that there are other variables that are important to safety and efficacy that have not been anticipated. We believe that we have set these parameters at realistic levels that can be controlled by the specifications set for a supplier and confirmed by us in our quality control procedures, but it is possible that unanticipated complications will emerge.

Likewise, our research into the potential mechanism of action for the ELAD System is ongoing, and although we are developing theories behind how the ELAD System may exert a clinical effect, the proposed mechanism of action remains unproven and may never be proven. The ELAD System's mechanism of action appears complex, may involve numerous pathways and we may not succeed in ever elucidating the exact role of any given pathway. Moreover, our research on mechanism of action is primarily based on laboratory studies, and needs correlation with in vivo studies and patient outcomes. Additional research, some of which is underway, is needed.

Risks Related to the ELAD System's Future Commercialization

Our financial results may fluctuate unpredictably, making it difficult to forecast our future performance.

Our limited operating history makes it difficult for us to predict our future commercialization efforts. A number of factors, over which we have limited or no control, may contribute to fluctuations in our financial results, such as:

- delays in the receipt of necessary supplies needed for the manufacturing process;
- our ability to recruit, train and retain sales, marketing, training and support personnel;
- our inability to educate physicians about the ELAD System and drive the adoption of the ELAD System therapy for any approved indications;
- performance of our targeted sales force in the U.S. and Europe and future partners in other markets;
- results of clinical trials evaluating the ELAD System therapy;
- positive or negative media coverage of the ELAD System or products of our competitors or our industry;
- our ability to obtain further regulatory clearances or approvals, including for other indications;
- delays in, or failure of, product and component deliveries by our subcontractors and suppliers;
- changes in the length of the sales process;
- changes in healthcare coverage and reimbursement policies;
- customer response to the introduction of new product offerings; and
- fluctuations in foreign currencies.

In addition, because we have only manufactured the ELAD System for clinical use and have never manufactured at commercial scale, we cannot accurately predict the costs of transitioning to commercial scale manufacturing or what our costs would be to manufacture the ELAD System commercially. While we believe we would be able to realize attractive gross margins on sales of the ELAD System, if approved, we may not achieve gross margins that we or our investors deem adequate due to higher costs or lower pricing than we currently expect based on the limited information available to us.

If the market size for the ELAD System is smaller than we anticipate, it could significantly and negatively impact our business, financial condition and results of operations.

It is very difficult to estimate the future commercial potential of the ELAD System due to factors such as changing standards of care, third-party payor reimbursement standards, ability of patients to meet co-payment amounts (if any), patient and physician preferences, the availability of competitive alternatives that may emerge, and indications for use (that may be based on, among other things, certain MELD scores, age ranges, or other factors). Further, the design of our VTL-308 clinical trial incorporates limits on age, MELD score, creatinine, bilirubin and INR, thereby narrowing any potential future indication for use. If the ELAD System is approved for commercialization, these limitations may restrict the potential market size and opportunity for the ELAD System. For example, we limited enrollment in the VTL-308 clinical trial to subjects within restrictions on subjects' age, MELD score and the three components of the MELD score. If we extrapolate the number of subjects in VTI-208 with those characteristics to the overall estimated sAH population, then the population treatable by the ELAD System would be limited further, unless we are able to develop strategies to get patients into treatment before their MELD scores and some of the components of MELD rise above certain thresholds. Through our analysis of the proportion of sAH subjects from VTI-208 that had the characteristics targeted in VTL-308, we did observe that roughly 60% of VTI-208 subjects were under the age of 50, which is the age limit in VTL-308, and that 90% of subjects were under the age of 60. If the potential eligible patient population is lower than anticipated, our business, financial condition and results of operations could be significantly and negatively impacted.

The human clinical trial results may not be representative of the results that are obtained after the ELAD System product launch.

Human clinical trials are very complicated undertakings and working with subjects in liver failure is particularly difficult because of the serious nature of the disease and the co-morbidities experienced by the subjects. Not enough is known about the function of the liver to understand the progression of liver disease and any single subject can react differently to the ELAD System therapy. This means that clinical trials done at different times in different groups of subjects may obtain different results. Safety risks not identified in our clinical trials may first appear after we obtain approval and commercialize the ELAD System. Any new post-marketing adverse events may significantly impact our ability to market the ELAD System and may require that we recall and discontinue commercialization of the product. Any of these events would harm our business.

The ELAD System is a very complicated therapy and will need to be delivered by well-trained staff. There is no guarantee that we will be able to implement such training and find sufficient numbers of people to enable us to grow at an acceptable rate.

In the initial commercialization period, it will be essential for us to have our own trained staff present during the delivery of the ELAD System therapy. This may entail the construction and operation of training centers and will require the hiring of personnel of appropriate ability to be adequately trained. The differences in language and culture may make this a difficult undertaking. If we cannot recruit, train and retain significant numbers of physicians and nurses, our ability to grow will be restrained, and we may find that the ELAD System therapy is being delivered by people with a substandard level of training, and with potentially material adverse results. If the ELAD System therapy is delivered improperly, or the bedside device or the ELAD cartridges are not properly maintained, the ELAD System may not provide the intended benefit or could harm patients. This may in turn result in perceptions, even if unfounded, that the ELAD System is ineffective or that our bedside device or the ELAD cartridges are defective, which could materially harm our reputation and ability to market the ELAD System effectively.

We could lose our key employees. If we are unable to retain our management, scientific staff and scientific advisors, our business will be seriously jeopardized.

Competition among biotechnology companies for qualified employees is intense, and the ability to retain our key employees is critical to our ability to effectively manage our resources. We are highly dependent on the efforts of our key employees, including senior management and senior scientific, clinical, regulatory, operational and other personnel. The development of new therapeutic products requires expertise from a number of different disciplines, some of which are not widely available.

Our key employees have a significant amount of know-how and experience in our company, and the loss of one or more of them could have a material and adverse effect on our operations. While we have taken steps to incentivize and to retain our employees, including the granting of stock options, paying competitive salaries and implementing appropriate bonus programs, these factors may not be enough to retain the key employees that we need.

The loss of the services of existing personnel, the failure to recruit additional, suitable key scientific, managerial, clinical, regulatory, operational and other personnel in a timely manner, and the loss of our employees to our competitors would harm our research and development programs and our business. We may experience difficulty in hiring and retaining highly-skilled employees with appropriate qualifications. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

Furthermore, while we have entered into employment letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. It can be challenging to retain qualified personnel. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede our ability to identify and execute on our strategy.

Competitive products could be developed which would make the ELAD System obsolete.

The biotherapeutic and medical device industries are highly competitive, and we face potential competition from pharmaceutical, specialty pharmaceutical, medical device and biotechnology companies worldwide. Given the significant unmet medical need for novel therapies to treat liver failure, many companies, universities and research organizations are actively engaged in the discovery, research and development of potential therapies in this field. This includes entities engaged in research on cell-based approaches to liver failure.

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There are reports of human cell-based systems under development in China, including a company conducting a clinical trial using a human cell-based, extracorporeal system. Additionally, a number of companies have performed research work on various human hepatocyte cell lines, and several academic researchers and companies are actively pursuing animal research in this area. Companies have also attempted to develop extracorporeal therapy based upon primary porcine hepatocytes and may be in early stage clinical studies with pig-cell based systems designed for the treatment of liver failure. Other than noted above, we are not aware of other entities being close to undergoing human clinical trials with a human cell-based product for the treatment of liver failure; however, it is possible that these trials are occurring without our knowledge, and that such a product may get to market much faster than we expect.

Liver dialysis systems are commercially available in the U.S. and Europe, and further development of albumin and other dialysis systems is ongoing. Most of these systems rely on not only traditional dialysis circuits to remove water-soluble toxins, but also albumin dialysis circuits to remove albumin-bound molecules. To our knowledge none of these non-cellular systems has shown an improvement in long-term survival among patients with liver failure. It has also been reported that a clinical trial in decompensated liver disease for a novel liver dialysis (non-bioartificial) system incorporating albumin dialysis along with a selective adsorption technology has been initiated.

CytoSorbents Corporation, a critical care immunotherapy company using its CytoSorb® blood purification technology to treat inflammation in critically-ill and cardiac surgery patients, announced in May 2018 that it has received European Union regulatory approval to expand the use of CytoSorb to reduce elevated bilirubin and myoglobin from blood.

In addition, there are several drugs available to treat symptoms associated with liver failure, including steroids, pentoxifylline and N-acetylcysteine. These three drugs, alone or in combination, are used frequently in patients with liver failure resulting from acute hepatocellular insult. Gilead Sciences has initiated a phase 2 trial to evaluate the safety of a non-cellular, drug therapy known as GS-4997 in combination with a steroid named prednisolone, compared with prednisolone alone, in subjects with severe alcoholic hepatitis.

The coverage and reimbursement status of new therapies is uncertain, and failure to obtain adequate coverage and reimbursement for the ELAD System therapy could limit our ability to generate revenue and become profitable.

There is significant uncertainty surrounding the third-party coverage and reimbursement of novel and newly-approved therapies, particularly for indications for which there is no current effective treatment or the current standard of care is relatively inexpensive. Due to the novel nature of the ELAD System and the potential for it to offer therapeutic benefit after a single administration of continuous therapy lasting up to five days, we face additional uncertainty related to coverage and reimbursement. We will depend in large part on the availability of coverage and the establishment of adequate reimbursement levels for the ELAD System from third-party payors, including government payors, such as the Medicare and Medicaid programs, and managed care organizations. Although we believe that the single largest category of ELAD-appropriate patients are covered by private insurance, followed by Medicaid and then Medicare, this analysis is based on small numbers, may not be accurate and may change in the future.

Third-party payors are increasingly focused on containing healthcare costs by limiting both coverage and the level of reimbursement for new therapies and, as a result, they may not cover or provide adequate payment for the ELAD System. Obtaining adequate coverage and reimbursement approval for a product from a third-party payor is a time-consuming, costly and sometimes unpredictable process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of the ELAD System. However, we cannot guarantee that we will be able to provide data sufficient to gain acceptance with respect to adequate coverage and reimbursement. Payors may conclude that the ELAD System is less safe, less effective or less cost-effective than existing or later introduced therapies, and third-party payors may not approve the ELAD System for coverage and reimbursement or may cease providing or provide inadequate coverage and reimbursement. Coverage and reimbursement determinations are made on a payor-by-payor basis, and it may take several years to obtain appropriate reimbursement codes, if ever. Obtaining acceptable coverage and reimbursement from one payor does not guarantee that we will obtain similar acceptable coverage or reimbursement from another payor. As there is a large number of third-party payors, obtaining coverage and reimbursement in the U.S. and internationally will consume significant time and resources. A third-party payor's decision to provide coverage does not imply that an adequate reimbursement rate will be approved. There can be no assurance that our clinical data will allow for satisfactory pricing of the ELAD System, and the failure to obtain

coverage and adequate reimbursement for the ELAD System would materially and adversely affect our business. Moreover, healthcare cost containment initiatives that limit or deny reimbursement for the ELAD System would also materially and adversely affect our business.

Our relationships with investigators, healthcare professionals, institutional providers, consultants, third-party payors and customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations.

Healthcare providers, physicians and others play a primary role in the recommendation and prescribing of any product candidates for which we may obtain marketing approval. In the U.S., our current business operations and future arrangements with investigators, healthcare professionals, institutional providers, consultants, third-party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products that obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations, include, but are not limited to, the following:

- the federal healthcare program anti-kickback statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, service or item for which payment is made, in whole or in part, under a federal healthcare program;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the omnibus rule, such as health plans, clearinghouses and healthcare providers, and their associates;
- HIPAA, imposes criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program regardless of the payor (e.g., public or private) and knowingly or willfully falsifying, concealing, or covering up by any trick, scheme or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- the federal transparency law, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), and its implementing regulations, require manufacturers of drugs, devices, biologicals and medical supplies to report to the U.S. Department of Health and Human Services information related to payments and other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state laws and regulations, including but not limited to: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state laws and regulations that require manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value

provided to healthcare professionals and entities; and

- European Union, or EU, data protection regulations, which may require member states of the EU to impose minimum restrictions on the collection and use of personal data that, in many respects, are more stringent, and impose more significant burdens on subject businesses, than current privacy standards in the U.S.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these or any other health regulatory laws or any other governmental regulations that may apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, enhanced government reporting and oversight under a corporate integrity agreement or other similar arrangement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operation of our business. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable healthcare laws, they also may be subject to similar penalties.

Healthcare policy changes, including recent laws to reform the U.S. healthcare system, may have a material adverse effect on us.

In the U.S. and in other countries, there have been, and we expect there will continue to be, a number of legislative and regulatory proposals to change the healthcare system in ways that could significantly and adversely affect the business of developing and marketing new therapies by reducing the costs paid for medical products and services. For instance, the U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the passing of the ACA. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from third-party payors. For instance, under the ACA, there is a 2.3% U.S. federal excise tax on the sale of certain medical devices. While we do not believe the tax will be applicable to us, the U.S. may seek to enforce the tax on us. In addition, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell the ELAD System profitably, if it is ultimately approved. The continuing efforts of the U.S. and other governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect the prices we are able to charge for the ELAD System, if approved, and our ability to generate revenues and achieve and maintain profitability.

Risks Related to Doing Business Internationally

We plan to do business internationally, which may prove to be difficult and fraught with economic, regulatory and political issues.

We may commercialize the ELAD System in countries where the business, economic and political climates are very different from those of the U.S. We may not be aware of some of these issues, and it may be difficult for a U.S. company to overcome these issues and ultimately become profitable. For instance, we completed our Chinese pivotal clinical trial in 2007 and submitted our data to the China FDA, or CFDA, showing a statistically significant improvement in transplant-free survival among the ELAD System-treated subjects compared with control subjects. However, this application has been neither approved nor rejected and the timing and nature of any potential decision is highly uncertain. Moreover, currency controls are in effect in many foreign countries and could become much tighter in the future, which will hinder our ability to repatriate any profits or capital. These foreign countries may also favor businesses that are owned by nationals of those countries as opposed to foreign-owned businesses operating locally. As a small company, we may not have the resources to engage in the negotiation and time-consuming work needed to overcome some of these potential issues.

In the event that we receive marketing approval in foreign countries outside of the U.S. and Europe, we currently anticipate, in most cases, creating wholly-owned subsidiaries in those countries. These subsidiaries will need to build an effective sales, marketing, distribution, training and support staff and system, find an effective marketing partner or

both. Any internal sales, marketing, training and support capabilities of the subsidiaries will need to be developed by these subsidiaries and will need to be built from scratch. The culture and accepted practices related to selling medical products in many foreign countries are unique, and it is possible that we will not be able to successfully penetrate these markets. A similar consideration applies to selling in the U.S., since each medical system is very different and requires a different strategic approach. We cannot guarantee that our approach to the U.S., European, Chinese or any other international market will be effective.

The medical systems in many foreign countries are very different from that of the U.S. and could cause significant problems for the ELAD System.

The medical systems in many countries around the world pose challenges to the commercialization of the ELAD System. For instance, most medical care in China is delivered on a private pay basis, and it may be difficult to receive payment for the ELAD System therapy delivered or the price of our product, which we expect to be relatively high, may prove to be beyond the capability of the targeted Chinese patient to pay. Further, as we have encountered in our clinical trials, the standard and the operation of the delivery of care in China are different, causing problems with the operation of the ELAD System therapy. These issues include the withholding of necessary medicines, the inadequate staffing of Chinese hospitals, the shortage of blood products, the differing practice of delivery of extracorporeal therapies, and the attitude of physicians and nurses. These issues and others are likely to occur in other countries around the world and there is no assurance that we will overcome these challenges or succeed in commercializing the ELAD System in foreign countries.

We face increased risks of doing business due to the extent of our operations internationally.

We currently anticipate our foreign commercialization efforts will be through wholly-owned, foreign domiciled subsidiaries. Our efforts to expand internationally pose risks that could adversely affect our business. These risks include, among others, the effects of:

- fluctuations in foreign currency exchange rates and controls;
- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements in non-U.S. countries;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- negative consequences from changes in tax laws;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- potential liability under the Foreign Corrupt Practices Act or comparable foreign laws;
- business interruptions resulting from geo-political actions or natural disasters including earthquakes, typhoons, floods and fires;
- competitive disadvantages to established foreign businesses with significant current market share and business and customer relationships;
- nationalization;
- tax and regulatory policies of local governments and the possibility of trade embargoes;
- political instability, war, terrorism, or other hostilities; and
- laws and policies of the U.S. and foreign governments affecting foreign trade and investment.

Any of these risks could cause significant interruptions in our operations, which would adversely affect our ability to commercialize the ELAD System internationally and our financial condition, results of operations and business.

Revenues, profits and cash flows derived in foreign countries by foreign subsidiaries may be denominated in foreign currency. The value of this currency may be controlled or adjusted periodically by foreign governments, and may be subject to changes in the political and economic conditions.

Foreign economic, political and social conditions and government policies could materially and adversely affect our business.

A significant portion of our operations may be conducted in foreign countries and it is anticipated that a significant percentage of our revenues may be derived from these countries. Accordingly, our results of operations, financial condition and prospects would be subject, to a significant degree, to economic, political, legal and social developments around the world. The economies of many of these countries differ from the economy of the U.S. in many respects, including:

- level of government involvement;
- economic structure;
- allocation of resources;
- level of development;
- inflation rates;
- growth rate; and
- control of foreign exchange.

The legal systems in many foreign countries have inherent uncertainties that could limit the legal protections available to us.

We are subject to the laws and regulations of foreign governments, including those applicable to foreign investment and, in particular, laws applicable to wholly foreign-owned enterprises. Any litigation in these countries may be protracted and may result in substantial costs and diversion of resources and management attention. For example, in 2007, one of our clinical sites in China was sued in connection with the death of a subject of our clinical trial. An expert panel concluded that neither the ELAD System nor the clinical site was at fault and dismissed the lawsuit. Nevertheless, we were later informed that the subject's family had been awarded approximately $100,000 in a subsequent civil proceeding brought against the clinical site. We ultimately decided to reimburse the clinical site for $100,000, which was partially insured. In addition, these countries may enact new laws or amend current laws that may be detrimental to us, which may have a material adverse effect on our business operations.

We have limited business insurance coverage internationally.

The insurance industry in many parts of the world is still in an early stage of development. Insurance companies in many countries offer only limited business insurance options. As a result, we may not be able to maintain any liability, hazard or other insurance covering our services, business, operations, errors, acts or omissions, personnel or properties in all of the countries where we ultimately commercialize the ELAD System. To the extent that we are unable to recover from others for any uninsured losses, such losses could result in a loss of capital and significant harm to our business. If any action, suit, or proceeding is brought against us and we are unable to pay a judgment rendered against us or defend ourselves against such action, suit, or proceeding, our business, financial condition and operations could be negatively affected.

We must comply with the U.S. Foreign Corrupt Practices Act and similar foreign anti-corruption laws.

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Other countries, such as the U.K. and China, have similar laws with which we must comply. Although we attempt to rigidly adhere to the requirements of the U.S. Foreign Corrupt Practices Act and all similar laws to which we are subject, there remains the risk that an employee or agent of ours could be accused of violating one or more of these laws, particularly in geographic regions where significant overlap exists between local government and healthcare industries. Such an accusation, even if unwarranted, could prove disruptive to our developmental and commercialization efforts.

We could be subject to additional income and other tax liabilities.

We are subject to income and other taxes in the U.S. and may be subject to income and other taxes in various other foreign jurisdictions. Significant planning is required in evaluating a worldwide provision for income and other taxes. During the ordinary course of business, there may be transactions for which the ultimate tax determination is uncertain. We may be subject to audit in various jurisdictions and such jurisdictions may assess additional income or other tax against us. Although we may believe our tax positions are reasonable, the final determination of tax audits and any related litigation could be materially different from our historical income tax provisions and accruals. The results of an audit or litigation could have a material and adverse effect on our operating results or cash flows in the period or periods for which that determination is made.

The United Kingdom's impending departure from the European Union could adversely affect our business.

The United Kingdom held a referendum in June 2016 in which a majority of voters voted to exit the European Union, or Brexit. Negotiations are underway to determine the future terms of the United Kingdom's relationship with the European Union, including, among other things, the terms of trade between the United Kingdom and the European Union as well as other world trading partners. The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to European Union markets either during a transitional period or more permanently. Brexit could adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets, including volatility in the value of the sterling and euro. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replace or replicate, including laws that could impact our clinical trials and our ability to obtain approval of our products or sell our products in the United Kingdom. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, results of operations, financial condition and cash flows.

Risks Related to Intellectual Property

Our patent rights may prove to be an inadequate barrier to competition.

We hold a patent in the U.S. which claims a method of using C3A cells to treat a patient's blood, which we believe covers the ELAD System therapy. In addition, we hold another U.S. patent with claims covering an extracorporeal device configuration, which we believe includes our ELAD System, independent of the cell-type used. Foreign counterparts of these patents have been issued or allowed in Australia, Brazil, Canada, Europe, Indonesia, Israel, Japan, Mexico, New Zealand, Singapore, South Africa, South Korea, the Philippines and Taiwan and remain under review in certain jurisdictions, including but not limited to Europe, Hong Kong and India. In addition to these two U.S. patents, we hold two additional patents in the U.S. However, the lifespan of any one patent is limited and each of these patents will ultimately expire, and we cannot be sure that pending applications will be granted, or that we will discover new inventions which we can successfully patent. Moreover, any of our granted patents may be held invalid by a court of competent jurisdiction, and any of these patents may also be construed narrowly by a court of competent jurisdiction in such a way that it is held to not directly cover the entire ELAD System or treatment. Furthermore, even if our patents are held to be valid and of broadly enforceable scope, third parties may find legitimate ways to compete with the ELAD System by inventing around our patents to avoid claims of patent infringement. Finally, the process of obtaining new patents is lengthy and expensive, as is the process for enforcing patent rights against an alleged infringer. Any such litigation could take years, cost large sums of money and pose a significant distraction to management. Indeed, certain jurisdictions outside of the U.S. and Europe where we hope to commercialize the ELAD System have a history of inconsistent, relatively lax or ineffective enforcement of patent rights. In such jurisdictions, even a valid patent may have limited value. Our failure to effectively enforce our patents would likely have a harmful impact on our ability to commercialize the ELAD System in these jurisdictions.

We do not hold any patents covering our VTL C3A cells or the production processes we use to grow the VTL C3A cells in the ELAD cartridges.

C3A cells are publicly available and the proprietary methods and production process that we use to grow our VTL C3A cells in the ELAD cartridges are our trade secrets, but they are not currently covered by a patent and no patents are pending. Although we have sought patent protection for certain aspects of our technology, such as our method of using human liver-derived C3A cells to treat a patient's blood, and we have obtained orphan designation in the U.S. and Europe for the use of C3A cells to treat acute liver failure, we have not sought patent protection for the proprietary methods we use to grow VTL C3A cells in our facility. Although we believe that some of these methods may be patentable, we prefer to avoid the disclosure requirements inherent in the patenting process, as such disclosure could provide competitors with insights that allow them to invent around any granted patents. We believe that this concern is particularly appropriate since C3A cells are publicly available, and have been available for research purposes for more than twenty years. Despite this availability, we are not aware of any third parties who have either demonstrated an ability to grow C3A cells in the quantities we do, or succeeded in treating a human subject with such cells. In addition, patent protection expires 20 years after the application's priority date which does not apply to trade secret protection. In light of the foregoing, we do not currently contemplate seeking patent protection for our production methods and instead intend to keep our production methods protected as trade secrets, which does not require us to publicly disclose these methods and which is not subject to a formal expiration date. However, trade secrets are vulnerable to inadvertent disclosure and misappropriation. In addition, independent discovery and publication of these methods by third parties, which is feasible given the public availability of C3A cells, would also destroy their trade secret protection. If any of these were to occur, our business may be harmed.

We protect much of our intellectual property as trade secrets. Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

Trade secrets offer a relatively limited form of protection as they do not create any barrier for third-parties who independently develop this information and who may even patent the information. In the course of our research and development activities and our business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements may be used, for example, when we talk to vendors of laboratory or clinical development services or potential strategic partners. In addition, each of our employees is required to sign a confidentiality agreement upon joining us. We take steps to protect our proprietary information, and our confidentiality agreements are carefully drafted to protect our proprietary interests. Nevertheless, there can be no assurance that an employee or an outside party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how, which would harm our business.

If our ELAD cartridges or our VTL C3A cells are stolen, misappropriated or reverse engineered, others could produce competing products.

Third parties, including those involved in shipping our ELAD System cartridges or in any manufacturing abroad that we may undertake, often have custody or control of our ELAD cartridges. If our ELAD cartridges, or VTL C3A cells from our proprietary VTL C3A cell bank that are stored to grow in these cartridges, were stolen, misappropriated or reverse engineered, they could be used by other parties who may be able to reproduce these cartridges for their own commercial gain. If this were to occur, it would be difficult for us to challenge this type of use, especially in countries with limited intellectual property protection or in countries in which we do not have patents covering the misappropriated ELAD cartridges. In such instance, our business would be harmed.

Ownership of our intellectual property may be claimed by others.

The ELAD System has been under development for over 20 years and certain of our predecessor companies have filed for reorganization and bankruptcy. We were founded in 2003 by acquisition of the assets of a prior company after a bankruptcy. While we believe we have performed extensive diligence on the ownership of the intellectual property rights and have developed our own innovative technology which is independent of prior intellectual property rights, there could be claims by parties associated with the prior entities that could lead to costly and time consuming legal actions. In addition, we have engaged in collaborations with third parties where intellectual property has been developed. In one instance, we were engaged in a dispute over the ownership of intellectual property when a collaborator of ours pursued patent rights over technology which we believe we may have held rights to under the collaboration agreement. Although a patent which claims a different configuration than our ELAD System was ultimately issued in the U.S. to our former collaborator, we do not hold any rights to this patent. We are unaware of any active development with respect to the claimed system. Other such disputes could arise in the future or emerge from past activities which could lead others to claim our intellectual property.

We may be involved in future costly intellectual property litigation, which could impact our future business and financial performance.

Our industry has been characterized by frequent intellectual property litigation. Our competitors or other patent holders may assert that our ELAD System and the methods we employ are covered by their patents. For instance, we are aware of other patents issued in the liver support field which we believe do not cover our ELAD System or its use. If our ELAD System or methods are found to infringe any valid patents, we could be prevented from marketing our ELAD System. In addition, we do not know whether our competitors or potential competitors have applied for, or will apply for or obtain, patents that will prevent, limit or interfere with our ability to make, use, sell, import or export our ELAD System.

Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, can be expensive and time-consuming and could divert management’s attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, and prohibit us from using technologies essential to our ELAD System, any of which would have a material adverse effect on our business, results of operations and financial condition. We do not know whether necessary licenses would be available to us on satisfactory terms, or whether we could redesign our ELAD System or processes to avoid infringement.

Competing products may also appear in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, we could be prevented from marketing our ELAD System in one or more countries. In addition, we may hereafter become involved in litigation to protect our trademark rights associated with our company name or the names used with our ELAD System. Names used with our ELAD System and procedures may be claimed to infringe names held by others or to be ineligible for proprietary protection. If we have to change the name of our company or our ELAD System, we may experience a loss in goodwill associated with our brand name, customer confusion and a loss of sales.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets owned by third parties.

Many of our employees were previously employed at universities or other life science companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other confidential or proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key personnel could hamper our ability to develop and commercialize the ELAD System, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Capital Requirements and Finances

We do not currently have sufficient resources to fund our future planned operations and will need to raise additional capital in order to advance the development of the ELAD system.

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $323.0 million through June 30, 2018. We are development stage company and do not have any products on the market. Assuming limited BLA-related activities and that we do not begin building any significant commercial infrastructure, we believe that our existing cash and cash equivalents of $31.1 million as of June 30, 2018 will be sufficient to fund our operations through the first quarter of 2019, past the expected announcement of topline data for the VTL-308 clinical trial which we currently anticipate to be in the second half of September 2018. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. As a result of the above, there exists substantial doubt about our ability to continue as a going concern for a year from the date of the issuance of our condensed consolidated financial statements for the three months ended June 30, 2018.

We will need additional liquidity to fund our operations subsequent to the first quarter of 2019 and we may need additional funds earlier to meet operational needs and capital requirements for product development, BLA-related activities and building for commercialization. Our capital requirements and our ability to fund such requirements are expected to be different based on the outcome of our VTL-308 clinical trial. With successful clinical data, we expect to substantially increase our BLA and commercialization activities and, therefore, our costs. Should the VTL-308 clinical trial require additional clinical development or should the trial be unsuccessful, we would expect to substantially restructure our operations to conserve funds and possibly sell assets or even liquidate the company, depending on the data.

As a result of our liquidity needs, vendors and other key contract counterparties may be reluctant to enter into contracts with us if they believe we may not be able to satisfy our obligations. In addition, there is no assurance that we will be able to obtain additional funding on acceptable terms or at all. If we are not able to secure adequate additional funding, we will be required to make reductions in certain spending to extend current funds, we may have to liquidate some or all of our assets, or we may have to delay, reduce the scope of, or eliminate some or all of our development programs. We may also have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technology that we would otherwise seek to commercialize. Our inability to enter into such contracts or raise additional funding would adversely affect our business, liquidity, financial condition, results of operations and cash flows.

To conserve capital, we may undertake workforce and cost reduction activities in the future. These activities may cause us to be unable to fully support and manage our operations.

In September 2015, we instituted across the board expense reductions to conserve capital, and we may, in the future, need to undertake additional workforce reductions or restructuring activities largely subject to the outcome of our VTL-308 clinical trial. However, we also need to effectively manage our operations and facilities. Following any workforce reduction, it is possible that our infrastructure may be inadequate to support our future efforts and business strategy or to maintain operational, financial and management controls and reporting systems and procedures. If we cannot successfully manage our operations, we may be unsuccessful in executing our business strategy.

Our future capital needs are uncertain, and we will need to raise additional funds in the future.

We may need to raise substantial additional capital to:

- complete clinical trials and related regulatory applications;
- fund our operations;
- commence and expand the commercialization of our products; and
- further our research and development.

Our future funding requirements will depend on many factors, including:

- the cost of our research and development activities;
- the cost and timing of any further clinical development activities;
- the cost of filing and prosecuting patent applications;
- the cost of defending litigation or any claims that we infringe third-party patents or violate other intellectual property rights;
- the cost and timing of regulatory clearances or approvals, if any;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost and timing of establishing additional technical support capabilities;
- market acceptance of our products;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no significant commitments or agreements relating to any of these types of transactions.

We may not be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, which we have no prior experience in, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs.

If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our operating results.

Raising additional funds through debt or equity financing is likely to be challenging, could be highly dilutive and may cause the market price of our common stock to decline.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of those securities could result in substantial dilution for our current stockholders and the terms may include liquidation or other preferences that adversely affect the rights of our current stockholders. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings. The failure of the VTI-208 clinical trial to meet its primary or secondary endpoints, in addition to general market conditions, may make it very difficult for us to seek and obtain further financing from the capital markets on favorable terms, or at all. If we cannot raise additional capital, we may be required to delay, reduce or eliminate certain aspects of our operations, raising substantial doubt about our ability to continue as a going concern.

In order to raise required funds we may choose to enter into one or more collaborations. Such collaborations could require us to give up substantial rights to the ELAD System in the U.S. and/or outside the U.S.

We may choose to enter into one or more collaborations in order to continue the development of the ELAD System. These collaborations could require us to relinquish substantial rights, potentially including the grant of an exclusive license to make, use and sell the ELAD System, to another company.

Any acquisitions that we make could disrupt our business and harm our financial condition.

We expect to evaluate potential strategic acquisitions of complementary businesses, products or technologies. We may also consider joint ventures, licensing and other collaborative projects. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance or integrate acquisitions of any businesses, products or technologies. Furthermore, the integration of any acquisition and management of any collaborative project may divert our management's time and resources from our core business and disrupt our operations. We do not have any experience with acquiring companies or products. Any cash acquisition we pursue would diminish the funds otherwise available to us for other uses, and any stock acquisition would dilute our stockholders' ownership. While we from time to time evaluate potential collaborative projects and acquisitions of businesses, products and technologies, and anticipate continuing to make these evaluations, we have no present understandings, commitments or agreements with respect to any significant acquisitions or collaborative projects.

Risks Related to Being a Public Company

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain executive management and qualified board members.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the Nasdaq Stock Market LLC and other applicable securities rules and regulations. Compliance with these rules and regulations increases our legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and increases demand on our systems and resources, and even more so after we are no longer an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight are required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. To assist us in complying with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from development activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

For as long as we remain an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and shareholder approval of any golden parachute payments not previously approved. We will take advantage of these reporting exemptions until we are no longer an "emerging growth company." We may remain an "emerging growth company" until as late as December 31, 2019 (the fiscal year-end following the fifth anniversary of the completion of our initial public offering), although we may cease to be an "emerging growth company" earlier under certain circumstances, including if our gross revenue exceeds $1.07 billion in any fiscal year.

As a public company it is more expensive for us to maintain and obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors may also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Under Section 107(b) of the JOBS Act, "emerging growth companies" can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail our company of this exemption from new or revised accounting standards and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting. If we do not maintain a proper and effective system of internal control over financial reporting, or if these internal controls are determined not to be designed or operating effectively, it may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the 2018 fiscal year. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting.

We have and will continue to evaluate and test our system of internal control over financial reporting. If, during the evaluation and testing process, we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective, which could result in a loss of investor confidence in the accuracy and completeness of our financial reports. This could cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC.

We are required to disclose changes made in our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an “emerging growth company” pursuant to the exemptions contained in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied that our internal controls over financial reporting are designed and operating effectively to prevent or detect a material misstatement to the financial statements.

If we do not remediate any material weaknesses in our internal control over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected.

In prior years, we had not maintained an effective control environment to ensure that the design and execution of our controls consistently resulted in effective review of our financial statements and supervision by appropriate individuals. As a result of these factors, certain misstatements in our annual financial statements for periods prior to becoming a public company were identified and brought to the attention of management by our independent registered public accounting firm for correction. We and our independent registered public accounting firm concluded that these control deficiencies constituted a material weakness in our internal control over financial reporting. A material weakness is a control deficiency, or a combination of control deficiencies, in internal control over financial reporting, indicates that there is a reasonable possibility that a material misstatement of our annual or interim condensed consolidated financial statements will not be prevented or detected on a timely basis.

Efforts to remediate the control deficiencies that led to the material weakness discussed above were completed. However, the measures we have taken to date, or any measures we may take in the future, may not be sufficient to avoid potential future material weaknesses. In addition, an independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional significant deficiencies or material weaknesses may have been identified. If we are unable to successfully remediate any significant deficiency or material weakness in our internal control over financial reporting, or identify any additional significant deficiencies or material weaknesses that may exist, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result.

Risks Related to our Common Stock

If securities or industry analysts do not continue to publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. Although certain equity research analysts currently cover us, we do not have any control of the analysts or the content and opinions included in their reports or whether any such analysts will continue to, or whether new analysts will, cover us for any given period of time. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors.

The market price of our common stock has been and is likely to continue to be highly volatile. Since our initial public offering in April 2014 at a price of $12.00 per share, the sale price of stock as reported on the Nasdaq Global Market has ranged from $2.25 to $35.20, through July 31, 2018. Our announcement in 2015 that the VTI-208 clinical trial failed to meet its primary or secondary endpoints resulted in a significant decline in the market price of our common stock. In addition, as with any public company, some investors hold a short position in our common stock. Such investors have published and distributed information about our company including on current and past clinical trials. Activities by these investors may increase the volatility of the market price of our common stock, and may affect our ability to raise additional funds and to complete our clinical trials and operations.

Our stock price could be subject to wide fluctuations due to many factors, including:

- clinical data and government approvals relating to the ELAD System;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- disputes or other developments with respect to our intellectual property rights or the intellectual property rights of others;
- product liability claims or other litigation;
- sales of large blocks of our common stock, including sales by our executive officers and directors;
- changes in earnings estimates or recommendations by securities analysts;
- our ability to meet investors' expectations regarding our future operating performance;
- media exposure of the ELAD System or products of our competitors;
- volume and timing of sales of the ELAD System;
- the introduction of new products or product enhancements by us or our competitors;
- our ability to develop, obtain regulatory clearance or approval for and market new and enhanced products on a timely basis;
- quarterly variations in our or our competitors’ results of operations;
- developments in our industry; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

In addition, an active and liquid market may not develop or persist, and you may not be able to sell your shares quickly or at the recently reported price. These and other factors may make the price of our stock volatile and subject to unexpected fluctuations.

Sale of a substantial number of shares of our common stock by existing stockholders or by us may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock into the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

In May 2018, we filed a shelf registration statement on Form S-3, or the 2018 Shelf Registration Statement, which became effective in June 2018. The 2018 Shelf Registration Statement permits: (i) the offering, issuance and sale by us of up to a maximum aggregate offering price of $200.0 million of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination; (ii) sales of up to 2.5 million shares of common stock by certain selling stockholders; and (iii) the offering, issuance and sale by us of up to a maximum aggregate offering price of $60.0 million of our common stock that may be issued and sold under an “at-the-market” sales agreement, or ATM, with Cantor Fitzgerald & Co. We did not sell any shares under the 2018 Shelf Registration Statement during the six months ended June 30, 2018. At June 30, 2018, $200.0 million remains available for issuance and sale under the 2018 Shelf Registration Statement, $60.0 million of which may be offered, issued and sold under the ATM.

Under our prior registration statement filed on Form S-3 in May 2015, or the 2015 Shelf Registration Statement, we raised gross proceeds of $74.7 million from two follow-on public offerings and $12.8 million pursuant to the ATM through December 31, 2017. We did not sell any shares under the 2015 Shelf Registration Statement during the six months ended June 30, 2018.

In addition, we have filed registration statements on Form S-8 registering a total of 9,634,695 shares of common stock subject to options or reserved for future issuance under our 2012 Stock Option Plan, 2014 Equity Incentive Plan and 2017 Inducement Equity Incentive Plan. Shares registered under these registration statements are available for sale in the public market subject to vesting arrangements, the exercise of such options and, in the case of our affiliates, the restrictions of Rule 144. As of June 30, 2018, options to purchase 4,297,119 shares of our common stock were exercisable.

Certain of our existing stockholders are also entitled, under contracts providing for registration rights, to require us to register shares of our common stock owned by them for public sale in the U.S. Any additional sales of securities by these stockholders, or the expectation that such sales may occur, could have a material adverse effect on the trading price of our common stock and make it more difficult for investors to sell shares of our common stock.

To the extent we raise additional capital by selling and issuing common stock, convertible securities or other equity securities, it may result in material dilution to our existing stockholders and new investors could gain rights superior to our existing stockholders. Sales by us or by our current stockholders also could cause the price of our common stock to fall and make it more difficult for you to sell shares of our common stock.

Our directors, officers and their affiliates have significant voting power and may take actions that may not be in the best interests of our other stockholders.

Our officers, directors and their affiliates collectively control approximately 28.1% of our outstanding common stock, including one stockholder and his affiliates who control approximately 26.9% of our outstanding common stock, as of June 30, 2018. As a result, these stockholders, if they act together, will be able to exert substantial influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

We have broad discretion to use of proceeds from our public offerings for working capital and general corporate purposes and we may not use them effectively.

The net proceeds of our public offerings are being allocated to fund the continuing development of the ELAD System and the remainder for working capital and other general corporate purposes. Our management has broad discretion over the use and investment of the net proceeds of our public offerings within those categories, and accordingly, investors will need to rely upon the judgment of our management with respect to the use of proceeds.

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Anti-takeover provisions in our amended and restated certificate of incorporation, amended and restated bylaws, and Fourth Amended and Restated Investors' Rights Agreement, as well as Delaware law, could discourage a takeover. Our amended and restated certificate of incorporation, bylaws, Fourth Amended and Restated Investors' Rights Agreement, and Delaware law, contain provisions that might enable our management to resist a takeover, and might make it more difficult for an investor to acquire a substantial block of our common stock. These provisions:

- authorize our board of directors to issue, without further action by our stockholders, up to 20,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by a supermajority (75%) vote of our directors then in office;
- specify that our board of directors may amend or repeal our bylaws only pursuant to a supermajority (75%) vote of our directors then in office;
- specify that our stockholders may amend or repeal our bylaws only pursuant to a supermajority (75% and majority of the minority, if applicable) vote of the outstanding shares of our capital stock;
- require in general the approval of a supermajority (75% and majority of the minority, if applicable) vote of our outstanding shares of capital stock to amend or repeal certain provisions of our certificate of incorporation;
- require the approval of a supermajority (75% and majority of the minority, if applicable) vote of our outstanding shares of capital stock to approve the sale or liquidation of the company;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that directors may be removed only for cause by a supermajority (75%) vote of our outstanding shares of capital stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that in general the number of directors on our board may only be fixed from time to time by a supermajority (75%) vote of our directors then in office;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms; and
- provide that certain stockholders affiliated with Muneer A. Satter, referred to as the Satter Investors, have rights to nominate up to a specific percentage of our directors (currently 30%) based on the Satter Investors' ownership percentage in our Company.

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

Our certificate of incorporation also contains a provision that provides us with protections similar to Section 203 of the Delaware General Corporation Law and will prevent us from engaging in a business combination with a person who acquires at least 15% of our common stock for a period of three years from the date such person acquired such common stock, except for certain of our current stockholders, including Mr. Satter and entities affiliated with him, and, in certain instances, persons who purchase common stock from certain of our current stockholders, and unless board or stockholder approval is obtained prior to the acquisitions. These anti-takeover provisions and other provisions under Delaware law could discourage, delay or prevent a transaction involving a change in control of our company, even if doing so would benefit our stockholders. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect or remove directors of your choosing and to cause us to take other corporate actions you desire.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our stock may be less valuable because a positive return on your investment will only occur if our stock price appreciates.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

During the three months ended June 30, 2018, we did not have any sales of unregistered securities.

Item 5. Other Information

Compensatory Arrangements of Certain Officers.

In June 2018, our board of directors approved base salaries for fiscal year 2018 for certain of our named executive officers and Chief Financial Officer as follows: Duane D. Nash, M.D., J.D., $414,800; Robert A. Ashley, M.A., $396,344; and Michael V. Swanson, M.B.A., $396,923.

Item 6. Exhibits

Exhibit Number	Exhibit Title
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Database
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release

No. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VITAL THERAPIES, INC.

Date: August 7, 2018 By: /s/ Michael V. Swanson
Michael V. Swanson
Chief Financial Officer
(Principal Financial and Accounting
Officer and Duly Authorized Officer)