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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended **September 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. ☒ 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 ☒ 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	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒
		Emerging growth company	☒

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. ☒

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

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

Class	**Number of Shares Outstanding**
Common Stock, $0.0001 par value	42,369,694

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VITAL THERAPIES, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)
(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 17,798	$ 56,901
Prepaid expenses and other current assets	1,263	1,220
Total current assets	19,061	58,121
Property and equipment, net	890	2,155
Other assets	37	108
Total assets	$ 19,988	$ 60,384
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,131	$ 1,049
Accrued expenses	4,552	9,141
Other current liabilities	8	91
Total current liabilities	5,691	10,281
Long-term liabilities	45	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 September 30, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized at September 30, 2018 and December 31, 2017; 42,369,694 and 42,368,864 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	4	4
Additional paid-in capital	349,132	345,915
Accumulated other comprehensive income	80	78
Accumulated deficit	(334,964)	(295,953)
Total stockholders' equity	14,252	50,044
Total liabilities and stockholders' equity	$ 19,988	$ 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 September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	$ 5,989	$ 9,689	$ 24,805	$ 29,151
General and administrative	2,461	2,950	11,054	8,724
Severance Costs	2,395	—	2,395	—
Impairment loss	1,219	—	1,219	—
Total operating expenses	12,064	12,639	39,473	37,875
Loss from operations	(12,064)	(12,639)	(39,473)	(37,875)
Other income (expense):				
Interest income	114	187	445	453
Other income (expense), net	9	(29)	17	(68)
Total other income	123	158	462	385
Net loss	$ (11,941)	$ (12,481)	$ (39,011)	$ (37,490)
Net loss per share, basic and diluted	$ (0.28)	$ (0.30)	$ (0.92)	$ (0.96)
Weighted-average common shares outstanding, basic and diluted	42,369,437	42,207,376	42,369,093	39,054,978

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$ (11,941)	$ (12,481)	$ (39,011)	$ (37,490)
Other comprehensive income (loss):				
Unrealized gain (loss) on cash equivalents	—	(3)	2	4
Foreign currency translation	—	1	—	1
Total comprehensive loss	$ (11,941)	$ (12,483)	$ (39,009)	$ (37,485)

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)

	Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (39,011)	$ (37,490)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	628	780
Impairment loss	1,219	—
Stock-based compensation	3,097	3,643
Common stock issued for services	115	—
Other	218	3
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(191)	(125)
Accounts payable	94	211
Accrued expenses	(4,583)	2,512
Other liabilities	(98)	(11)
Net cash used in operating activities	(38,512)	(30,477)
Cash flows from investing activities:		
Purchases of property and equipment	(597)	(574)
Proceeds from sale of equipment	2	7
Net cash used in investing activities	(595)	(567)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	—	37,529
Deferred financing costs	—	(86)
Proceeds from exercise of stock options	4	1
Net cash provided by financing activities	4	37,444
Net change in cash and cash equivalents	(39,103)	6,400
Cash and cash equivalents, beginning of period	56,901	59,991
Cash and cash equivalents, end of period	$ 17,798	$ 66,391
Supplemental disclosure of noncash investing and financing activities:		
Stock issuance costs included in liabilities	$ —	$ 10
Purchases of property and equipment included in liabilities	$ —	$ 21

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

1. Description of Business and Basis of Financial Statements

Description of Business

We are a biotherapeutic company that has been developing a cell-based therapy targeting the treatment of acute forms of liver failure. Our initial product candidate, the ELAD® System, or ELAD, is a human-cell-based, bio-artificial liver, which was 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 September 2018, we reported top-line data from our phase 3 clinical trial of ELAD, VTL-308, in 151 subjects with severe alcoholic hepatitis. Although there was a numerical improvement in survival in the ELAD-treated group between three months and one year following randomization, the study failed to meet the primary endpoint of a significant improvement in overall survival through at least ninety-one days. The secondary endpoint of the proportion of survivors at study day ninety-one also showed no statistically significant difference between the groups.

Considering these results, we do not believe the ELAD System can be approved in the United States or the European Union without additional clinical trials, if ever, and that such clinical trials would require substantial capital and time to complete. Consequently, we have ceased any further development of the ELAD System for the United States and Europe, substantially reduced our workforce, discontinued most of our supply and service agreements, and have shifted our strategic focus to identifying and exploring strategic alternatives including a merger, an acquisition or sale of assets or even a dissolution and liquidation of the company.

Our business, operating results, financial condition and prospects are subject to significant risks and uncertainties. As we currently have no commercial products or products in later stage development, it may be difficult to secure additional funding in light of these risks and circumstances. There can be no assurance any transaction will result from our evaluation of strategic alternatives.

Liquidity

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $335.0 million through September 30, 2018. In conjunction with our review of strategic alternatives and our decision to cease the further development of ELAD, we significantly reduced our projected monthly cash usage. Based on these actions, we believe that our existing cash and cash equivalents of $17.8 million would be sufficient to meet our known liabilities and commitments as of September 30, 2018; however, we expect our resource requirements to change materially to the extent we identify and enter into any strategic transactions. 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, future research and development efforts if any, the strategic options that we pursue, and any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned.

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. However, we expect the amounts available under the shelf registration statement to be significantly limited in the future if our public float remains below $75.0 million as measured on December 31, 2018, although we could use a registration statement on Form S-1 or private placements. Funding, however, is likely to be more difficult to secure due to our past clinical trials not meeting their primary or secondary endpoints.

There is no assurance that we will be able to obtain additional funding if needed on acceptable terms or at all. These factors described above and our history of ongoing losses, raise substantial doubt over whether we will continue as a going concern for one year from the date of the issuance of our condensed consolidated financial statements for the nine months ended September 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 nine months ended September 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 uncertainties related to whether we continue as a going concern.

Unaudited Interim Financial Information

The results for the nine months ended September 30, 2018 are not 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 have measured the fair value of certain of our property and equipment using level 3 unobservable inputs. We had no Level 3 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

We evaluate long-lived assets, such as property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Such events or changes in circumstances include, but are not limited to, a significant decrease in the fair value of the underlying asset or asset group, a significant decrease in the benefits realized from the acquired assets, difficulty and delays in integrating the business, or a significant change in the operations of the acquired assets or use of an asset or asset group. A long-lived asset is considered impaired if its carrying amount exceeds the estimated future undiscounted cash flows the asset or asset group is expected to generate. If a long-lived asset is considered to be impaired, the impairment to be recognized is the amount by which the carrying amount of the asset exceeds the fair value of the asset or asset group. Determining the fair value of an asset or asset group is highly judgmental in nature and involves the use of significant estimates and assumptions for market participants. We base our fair value estimates on assumptions we believe to be reasonable but that are unpredictable and inherently uncertain. Actual future results may differ from those estimates.

We recognized an impairment charge of 1.2 million on our property and equipment in the condensed consolidated statements of operations for the three and nine months ended September 30, 2018. We did not recognize any impairment loss for the three and nine months ended September 30, 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. As our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary, reported 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.

Research and Development

Research and development costs have consisted 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. If performance-based milestones are later determined not to be probable of achievement, then all previously recorded stock-based compensation expense associated with such options is reversed in the period that we make this determination.

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 September 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 September 30,	
	2018	**2017**
Options to purchase common stock	7,454,266	6,071,707
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 currently expect to adopt ASU 2018-07 in the first quarter of 2019. We do not expect the adoption of this standard to have a material impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, "*Fair Value Measurement - Disclosure Framework,*" or ASU 2018-13. ASU 2018-13, modifies the disclosure requirements for fair value measurements. The amendments relate to disclosures regarding unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty and are to be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, and early adoption is permitted.

3. Other Financial Information

Property and Equipment

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

	September 30, 2018	December 31, 2017
Manufacturing, clinical and laboratory equipment	$ 6,805	$ 7,500
Leasehold improvements	4,764	4,727
Office furniture and equipment	268	234
Construction in progress	—	17
	11,837	12,478
Less: accumulated depreciation and amortization	(10,947)	(10,323)
Total	$ 890	$ 2,155

Depreciation and amortization expense was $204,000 and $216,000 for the three months ended September 30, 2018 and 2017, respectively, and $628,000 and $780,000 for the nine months ended September 30, 2018 and 2017, respectively.

In September 2018, we ceased substantially all of our development efforts related to ELAD. This resulted in a substantial change in the expected use of our long-lived assets and a significant decrease in the benefits expected to be realized from these assets. Accordingly, we recognized an impairment charge of 1.2 million on our property and equipment in the condensed consolidated statements of operations for the three and nine months ended September 30, 2018 reflecting the difference in the carrying value of such property and equipment and its estimated fair value. The impairment charge is reflected as a reduction in the cost of the related assets.

Accrued Expenses

Accrued expenses consist of (in thousands):

	September 30, 2018	December 31, 2017
Accrued clinical and related costs	$ 3,289	$ 5,377
Accrued compensation and related taxes	1,081	3,591
Accrued other	182	173
Total	$ 4,552	$ 9,141

As a result of the completion of our VTL-308 clinical trial, we gained access to subject-specific information for estimating our clinical accruals as of September 30, 2018. This enabled us to further analyze the clinical trial accrual against the actual services performed and to adjust our clinical trial accrual based on such information. As a result of this analysis, we reduced our clinical trial accrual as of September 30, 2018 and reduced research and development expense for the three and nine months ended September 30, 2018 by $356,000.

4. Commitments and Contingencies

Operating Leases

We lease office, manufacturing and research and development facilities and equipment under various non-cancellable operating lease agreements. Leases for our office and research and development facilities expire in January 31, 2019 and the lease on our manufacturing facility expires in June 2022. Our manufacturing facility lease provides for periodic rent increases and an option to extend the term for five years.

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 $270,000 and $253,000 for the three months ended September 30, 2018 and 2017, respectively, and $844,000 and $736,000 for the nine months ended September 30, 2018 and 2017, respectively. Current and long-term deferred rent totaled $8,000 and $45,000 at September 30, 2018, and $91,000 and $59,000 at December 31, 2017, respectively. We have not estimated the contract termination costs associated with any of our leases as we have not yet reached the cease-use date.

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 measured at fair value on a recurring basis (in thousands):

	Fair Value Measurement at September 30, 2018			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 14,940	$ 14,940	$ —	$ —

	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 September 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. We estimated the fair value of certain property and equipment based on third-party market value appraisals, and classified the fair value of such property and equipment as a Level 3 measurement due to the significance of the unobservable inputs. 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. We expect the amounts available under the shelf registration statement to be significantly limited in the future if our our public float remains below $75.0 million as measured on December 31, 2018.

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 nine months ended September 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. 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 were adjusted to fair value based on the closing price at the end of each reporting period with the expense being recorded ratably over the 180-day period. We recognized expense in connection with these consulting shares of $115,000 during the nine months ended September 30, 2018 in general and administrative expenses.

Stock Warrants

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

Stock Reserved for Future Issuance

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

	Number of Shares
Common stock reserved for issuance for outstanding options	7,454,266
Common stock options available for future grant:	
2014 Equity Incentive Plan	1,548,678
2017 Inducement Equity Incentive Plan	254,708
Common stock reserved for issuance for outstanding warrants	240,620
Total common shares reserved for future issuance	9,498,272

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.

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, or the Board, may determine.

Pursuant to such provisions, the number of shares available for issuance under the 2014 Plan was increased by 1,200,000 shares effective April 16, 2018. Shares available for grant under the 2014 Plan totaled 1,548,678 shares as of September 30, 2018.

In September 2017, our board of directors approved the 2017 Inducement Equity Incentive Plan, or the Inducement Plan, and amended and restated the Inducement 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 nine months ended September 30, 2018, we granted options to purchase 1,699,636 shares of our common stock under the Inducement Plan and 104,344 shares were forfeited or cancelled, leaving 254,708 shares available for grant under the Inducement 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 were set to become fully vested and exercisable only on achievement of the performance conditions while the participant was 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, the Board approved grants for performance-based stock options to certain employees and consultants under the 2014 Plan. Performance-based stock options that were not forfeited would have fully vested on the third anniversary of the grant date if (i) our VTL-308 clinical trial had achieved statistical significance in its primary efficacy endpoint and (ii) the participant was a continuing service provider through the third anniversary of the grant date (as such terms are defined in the 2014 Plan). Prior to the announcement of the VTL-308 clinical trial results, we deemed the performance conditions as being probable and recorded stock-based compensation expense over the requisite service period for all performance-based stock options held by employees of $119,000 and $357,000 for the three and nine months ended September 30, 2018, respectively. In September 2018, we announced that the VTL-308 clinical trial failed to achieve its primary efficacy endpoint. Accordingly, the performance conditions of the performance-based stock options were not met. In connection with this determination, we recorded a reversal of stock-based compensation expense of $1.7 million, including $873,000 to research and development expense and $862,000 to general and administrative expense in the condensed consolidated statements of operations for the three and nine months ended September 30, 2018.

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	2,815,900	$ 6.05		
Exercised	(830)	$ 5.35		
Forfeited or expired	(1,444,286)	$ 5.33		
Outstanding as of September 30, 2018	7,454,266	$ 6.77	6.5	$ —
Options vested and expected to vest as of September 30, 2018	6,744,346	$ 6.87	6.2	$ —
Options exercisable as of September 30, 2018	4,473,207	$ 7.34	4.7	$ —

Stock-Based Compensation Expense

The weighted-average grant date fair value of stock options granted during the nine months ended September 30, 2018 and 2017 was $4.18 and $2.29, 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:

	Nine Months Ended September 30,	
	2018	2017
Employees:		
Risk-free interest rate	2.0% - 2.5%	1.5% - 1.9%
Expected dividend yield	0%	0%
Expected volatility	79.7% - 82.0%	82.6% - 85.4%
Expected term of options (years)	5.9 - 6.2	5.9 - 6.1
Fair value of common stock	$0.45 - $8.00	$2.75 - $5.05
Non-employees:		
Risk-free interest rate	1.0% - 3.0%	1.0% - 1.9%
Expected dividend yield	0%	0%
Expected volatility	70.7% - 82.3%	71.6% - 83.9%
Expected term of options (years)	0.1 - 9.3	0.8 - 4.5
Fair value of common stock	$0.28 - $6.85	$2.90 - $5.05

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Employees:				
Research and development	$ (474)	$ 414	$ 299	$ 1,244
General and administrative	233	777	2,592	2,343
Total	$ (241)	$ 1,191	$ 2,891	$ 3,587
Non-employees:				
Research and development	$ (11)	$ 33	$ 80	$ 56
General and administrative	(11)	—	126	—
Total	$ (22)	$ 33	$ 206	$ 56

As of September 30, 2018, there was $9.2 million and $11,000 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 2.8 years and 2.6 years, respectively.

8. Severance Costs

In September 2018, we announced a staff reduction plan in order to reduce operating expenses and to conserve cash resources. The plan reduced our workforce by approximately 85%. As a result, we estimate we will incur approximately $2.4 million in costs for the affected employees, including severance payments, limited reimbursement of medical insurance premiums and outplacement services. The staff reduction plan was completed by the end of September 2018.

During the three months ended September 30, 2018, we paid $1.7 million in severance benefits to separating employees related to the staff reduction plan. At September 30, 2018, unpaid severance costs of $704,000 are included in current liabilities in the condensed consolidated balance sheet and are expected to be paid by the end of the first quarter of 2019.

9. Subsequent Event

On October 10, 2018, Jean-Jacques Bienaimé, Douglas E. Godshall, Errol R. Halperin, J. Michael Millis, M.D. and Muneer A. Satter tendered their resignations from the Board, and as a member of each committee on which such director served in order to reduce expenses. The Board has accepted each such resignation. The decision of each of Messrs. Bienaimé, Godshall, Halperin, Satter and Dr. Millis did not result from any disagreement with the company on any matter related to our operations, policies or practices. Following the resignation of Messrs. Bienaimé, Godshall, Halperin, Satter and Dr. Millis, the size of the Board was reduced its size to four members in accordance with the provisions of our Certificate of Incorporation and bylaws.

On October 11, 2018, we entered into an investment banking agreement, or the Engagement Agreement, with Ladenburg Thalmann & Co. Inc., or Ladenburg, pursuant to which Ladenburg will act as our strategic financial advisor to assist in the review of our business and assets and exploration of strategic opportunities for enhancing stockholder value, including the potential sale or merger of the company. Under the Engagement Agreement, as compensation for the services provided by Landenburg, the Company shall pay, or cause to be paid, to Ladenburg, the following nonrefundable fees: (i) if the Company consummates a Transaction, it shall pay to Ladenburg a transaction fee of $1,000,000 (the "Transaction Fee") at the closing of the Transaction, (ii) a retainer fee of $75,000, which is creditable against the Transaction Fee, and (iii) an opinion fee of $250,000. While we have commenced evaluating our available options, no conclusion as to any specific option or transaction has been reached, nor has any specific timetable been fixed for this effort, and there can be no assurance that any strategic or financial option or transaction will be presented, implemented or consummated.

On October 25, 2018, we received a letter from the staff of Nasdaq providing notification that, for the previous 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement, or the Bid Price Requirement, for continued listing on the Nasdaq Global Select Market. The notification had no immediate effect on the listing of our common stock. In accordance with Nasdaq listing rules, we are afforded 180 calendar days, or until April 23, 2019, to regain compliance with the Bid Price Requirement. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds to sustain our operations and our ability to successfully enter into strategic transactions, and could result in the loss of investor interest.

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,” “anticipate,” “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 potential strategic options; 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 our ability to identify and consummate a strategic or financial transactions which enhance or maximize stockholder value, to retain certain personnel important to our ongoing operations and 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 biotherapeutic company that has been developing a cell-based therapy targeting the treatment of acute forms of liver failure. Our initial product candidate, the ELAD® System, or ELAD, is a human-cell-based, bio-artificial liver, which was 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 September 2018, we reported top-line data from a phase 3 clinical trial of ELAD, VTL-308, in 151 subjects with severe alcoholic hepatitis. Although there was a numerical improvement in survival in the ELAD-treated group between three months and one year following randomization, the study failed to meet the primary endpoint of a significant improvement in overall survival through at least ninety-one days. The secondary endpoint of the proportion of survivors at study day ninety-one also showed no statistically significant difference between the groups.

Considering these results, we do not believe the ELAD System can be approved in the United States or the European Union without additional clinical trials, if ever, and that such clinical trials would require substantial capital and time to complete. Consequently, we have ceased any further development of the ELAD System for the United States and Europe, substantially reduced our workforce, discontinued most of our supply and service agreements, and have shifted our strategic focus to identifying and exploring strategic alternatives including a merger, an acquisition or sale of assets or even a dissolution and liquidation of the company.

Our business, operating results, financial condition and prospects are subject to significant risks and uncertainties. As we currently have no commercial products or products in later stage development, it may be difficult to secure additional funding in light of these risks and circumstances. There can be no assurance any transaction will result from our evaluation of strategic alternatives.

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $335.0 million through September 30, 2018. In conjunction with our review of strategic alternatives and our decision to cease the further development of ELAD, we significantly reduced our projected monthly cash usage. Based on these actions, we believe that our existing cash and cash equivalents of $17.8 million will be sufficient to meet our known liabilities and commitments as of September 30, 2018; however, we expect our resource requirements to change materially to the extent we identify and enter into any strategic transactions. 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, future research and development efforts if any, the strategic options that we pursue, and any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned.

Results of Operations

Research and Development Expenses

Research and development expenses have principally related to the development of the ELAD System and are expensed as incurred. Our research and development expenses consisted 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 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 can result in a significant change in the costs and timing associated with clinical development. For example, if we were to conduct an additional clinical trial, we would be required to expend significant additional financial resources and time on the completion of the clinical development of the ELAD System. However, based on our current plan, and in light of our VTL-308 clinical trial results, we expect significantly reduced research and development costs over at least the next several quarters.

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. Based on our current plans and the recent reduction in our workforce, we expect significantly reduced general and administrative costs at least over the next several quarters.

Severance Costs

As a result of the failure of the Company's clinical trial, the Company completed a staff reduction plan in order to reduce operating expenses and to conserve cash. The plan reduced our workforce by approximately 85%. The staff reduction was completed in September 2018.

Impairment Loss

We evaluate long-lived assets, such as property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. If a long-lived asset is considered to be impaired, the impairment to be recognized is the amount by which the carrying amount of the asset exceeds the fair value of the asset or asset group. The resulting impairment charge is included as a loss from operations in the condensed consolidated statements of operations. We do not expect any significant future impairment losses.

Other Income

Interest Income

Our cash and cash equivalents are and 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 while the funds await use in operations.

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

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

	Three Months Ended September 30,		Change	
	2018	2017	$	%
(dollars in thousands)	(unaudited)			
Operating expenses:				
Research and development	$ 5,989	$ 9,689	$ (3,700)	(38)%
General and administrative	2,461	2,950	(489)	(17)%
Severance Costs	2,395	—	2,395	100 %
Impairment loss	1,219	—	1,219	100 %
Total operating expenses	$ 12,064	$ 12,639	$ (575)	(5)%

Research and development expense decreased by $3.7 million during the three months ended September 30, 2018 as compared to the three months ended September 30, 2017. The decrease includes a reduction in clinical trial costs of $1.9 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 in the third quarter of 2017, while no subjects were enrolled in the second quarter of 2018 due to the completion of enrollment. Research and development expense also reflects a $1.2 million reduction in estimated incentive compensation costs and a $930,000 net reversal of stock-based compensation costs in the 2018 quarter, both reflecting that our VTL-308 clinical trial did not successfully reach its primary or secondary endpoints.

Total general and administrative expenses during the three months ended September 30, 2018 decreased by $489,000 as compared to the three months ended September 30, 2017. The decrease reflects a $624,000 reduction in estimated incentive compensation and a $557,000 net reversal of stock-based compensation costs in the 2018 quarter, both reflecting that our VTL-308 clinical trial did not successfully reach either its primary or secondary endpoints. These decreases were partially offset by an increase of $275,000 in legal costs, primarily associated with financing activities no longer being pursued as a result of the outcome of our clinical trial.

In September 2018, we ceased substantially all of our development efforts related to the ELAD System. This resulted in a substantial change in the expected use of our long-lived assets and a significant decrease in the benefits expected to be realized from these assets. Accordingly, we recognized an impairment charge of $1.2 million on our property and equipment reflecting the difference in the carrying value of such property and equipment and its estimated fair value, and severance costs of $2.4 million in the condensed consolidated statement of operations for the three months ended September 30, 2018.

Comparison of the Nine Months Ended September 30, 2018 and 2017

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

	Nine Months Ended September 30,		Change	
	2018	2017	$	%
(dollars in thousands)	(unaudited)			
Operating expenses:				
Research and development	$ 24,805	$ 29,151	$ (4,346)	(15)%
General and administrative	11,054	8,724	2,330	27 %
Severance Costs	2,395	—	2,395	100 %
Impairment loss	1,219	—	1,219	100 %
Total operating expenses	$ 39,473	$ 37,875	$ 1,598	4 %

Research and development expense decreased by $4.3 million during the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017. The decrease reflects a reduction in clinical trial costs of $4.1 million due to the completion of enrollment in VTL-308 in the first quarter of 2018. There were 74 subjects enrolled in the VTL-308 clinical trial in the nine months ended September 30, 2017, while there were 19 subjects enrolled in the nine months ended September 30, 2018 due to the completion of enrollment. Research and development expense also reflects a $982,000 reduction in estimated incentive compensation costs and a $920,000 net reversal of stock-based compensation in the 2018 period, both reflecting that our VTL-308 clinical trial did not successfully reach its primary or secondary endpoints. Costs for conferences and sponsorships were also lower by $527,000 in 2018 period as activity declined with the completion of enrollment. In the nine-month period ended September 2018, we also had higher consulting and compensation costs of $1.4 million and $767,000, respectively, primarily to support the preparation of an anticipated biologics license application, or BLA, submission. Following the completion of enrollment in the first quarter of 2018, manufacturing, quality and regulatory functions began focusing their efforts and resources on preparing for a BLA submission as opposed to clinical development. Upon the release of results from the VTL-308 clinical trial in September 2018, we ceased substantially all development efforts related to the ELAD System.

Total general and administrative expenses during the nine months ended September 30, 2018 increased by $2.3 million as compared to the nine months ended September 30, 2017. The increase reflects an increase in compensation costs of $1.6 million for the payment of a signing bonus and an increase in stock-based compensation related to the hiring of our new chief executive officer. In addition, we incurred higher costs of $1.0 million for marketing consultants and services and for investor relations, which included $115,000 in stock issued for services, and $767,000 for patent and other legal costs, including costs associated with financing activities, in the nine months ended September 30, 2018 as compared to the corresponding period in 2017. These increases were partially offset by a $862,000 reduction in stock-based compensation for the reversal of previously recognized expense related to performance-based stock options and a $557,000 reduction in estimated incentive compensation costs, both reflecting that our VTL-308 clinical trial did not successfully reach its primary or secondary endpoints.

In September 2018, we ceased substantially all of our development efforts related to the ELAD System. This resulted in a substantial change in the expected use of our long-lived assets and a significant decrease in the benefits expected to be realized from these assets. Accordingly, we recognized an impairment charge of $1.2 million on our property and equipment reflecting the difference in the carrying value of such property and equipment and its estimated fair value, and severance costs of $2.4 million in the condensed consolidated statement of operations for the nine months ended September 30, 2018.

Liquidity and Capital Resources

Overview

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $335.0 million through September 30, 2018. In conjunction with our review of strategic alternatives and our decision to cease the further development of the ELAD, we significantly reduced our projected monthly cash usage. Based on these actions, we believe that our existing cash and cash equivalents of $17.8 million would be sufficient to meet our known liabilities and commitments as of September 30, 2018; however, we expect our resource requirements to change materially to the extent we identify and enter into any strategic transactions. 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, future research and development efforts if any, the

strategic options that we pursue, and any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned.

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. However, we expect the amounts available under the shelf registration statement to be significantly limited in the future if our public float remains below $75.0 million as measured on December 31, 2018, although we would still expect to be able to raise funds through a registration statement on Form S-1 or through private placements. Funding is expected to be more difficult to secure due to our past clinical trials not meeting their primary or secondary endpoints.

There is no assurance that we will be able to obtain additional funding if needed on acceptable terms or at all. The factors described above and our history of ongoing losses, raise substantial doubt over whether we will continue as a going concern for one year from the date of the issuance of our condensed consolidated financial statements for the nine months ended September 30, 2018.

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 September 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 nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	**2017**
(in thousands)	**(unaudited)**	
Cash (used in) provided by:		
Operating activities	$ (38,512)	$ (30,477)
Investing activities	(595)	(567)
Financing activities	4	37,444

Net cash used in operating activities

During the nine months ended September 30, 2018, operating activities used $38.5 million of cash. The use of cash primarily related to our net loss of $39.0 million adjusted for non-cash charges of $3.1 million related to stock-based compensation, $1.2 million in impairment losses, and $628,000 related to depreciation and amortization, and a $4.8 million net decrease in our operating assets and liabilities. Changes in our operating assets and liabilities during the nine months ended September 30, 2018 consisted primarily of a decrease of $4.5 million in accrued expenses and accounts payable. The decrease in accrued expenses and accounts payable was primarily attributable to the payment of 2017 bonuses in the first quarter of 2018, and a decrease in the amounts due for and related to our VTL-308 clinical trial.

During the nine months ended September 30, 2017, operating activities used $30.5 million of cash. The use of cash primarily related to our net loss of $37.5 million adjusted for non-cash charges of $3.6 million related to stock-based compensation and of $780,000 related to depreciation and amortization, and a $2.6 million change in our operating assets and liabilities. Changes in our operating assets and liabilities during the nine months ended September 30, 2017 consisted primarily of an increase of $2.7 million in accrued expenses and accounts payable, partially offset by an increase of $125,000 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.

Investing Activities

During the nine months ended September 30, 2018, net investing activities used $595,000 of cash due primarily to capital expenditures for facilities improvements and purchases of equipment for manufacturing and research and development. During the nine months ended September 30, 2017, net investing activities used $567,000 of cash, primarily due to capital expenditures of $574,000 for facilities improvements and purchases of equipment for manufacturing and research and development.

Financing Activities

During the nine months ended September 30, 2018, financing activities provided $4,000 of cash related to proceeds from the exercise of stock options. During the nine months ended September 30, 2017, financing activities provided $37.4 million of cash primarily 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 timing and structure of any strategic options and transactions, if any;
- the cost, timing and outcome of any future litigation costs;
- personnel-related expenses, including salaries, benefits, stock-based compensation expense and other compensation expenses related to retention and termination of personnel;
- the scope, progress, results and costs of research and development and any future clinical trials;
- the cost and timing of future regulatory submissions;
- the cost and timing of developing and validating manufacturing processes for any potential product candidates;
- the cost and timing of any commercialization activities, including reimbursement, marketing, sales and distribution costs;
- 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 (if any);
- 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 from the sales of, or royalties on any future product candidates, if any.

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, corporate reverse merger transactions, asset sales 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 it 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, we would expect to relinquish substantial rights to our technologies or our future products, or grant licenses on terms that are not favorable to us. If we were to complete a merger, we may relinquish all control over the organization and could experience detrimental tax effects. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets. Any of these factors could harm our operating results.

Off-Balance Sheet Arrangements

Through September 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 nine months ended September 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 nine 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.

Recently Issued Accounting Standards

See note 2 "Summary of Significant Accounting Policies" to the condensed consolidated financial statements contained in this form 10-Q for additional information related to recently issued accounting standards.

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 our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures during the nine months ended September 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 nine months ended September 30, 2018, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2018 that have materially affected, or are 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 Evaluation of Strategic Alternatives

Our activities to evaluate and pursue strategic alternatives may not be successful.

In September 2018, we voluntarily discontinued our development of our product candidate, the ELAD® System, or ELAD, in view of the results of our VTL-308 Phase 3 clinical trial in the U.S. and Europe. We have engaged Ladenburg Thalmann & Co. Inc., as a financial advisor to assist us in pursuing strategic alternatives. We are evaluating strategic alternatives in order to enhance stockholder value, including the possibility of a merger or sale of our company, and we have suspended many of our research and development activities to reduce operating expenses while we evaluate these opportunities. We expect to devote significant time and resources to identifying and evaluating strategic transactions; however, there can be no assurance that such activities will result in any agreements or transactions that will enhance stockholder value. In addition, potential strategic transactions that require stockholder approval may not be approved by our stockholders. Further, any strategic transaction that is completed ultimately may not deliver the anticipated benefits or enhance stockholder value.

We also may acquire additional businesses, products or product candidates. Integrating any newly acquired business, product or product candidate could be expensive and time-consuming. We may not be able to integrate any acquired business, product or product candidate successfully. Our future financial performance will depend, in part, on our ability to manage any future growth effectively and our ability to integrate any acquired businesses.

Any strategic transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- the inability to retain key employees of our company or any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any strategic transactions of the nature described above. Any transactions that we do complete may be subject to the foregoing or other risks and could have a material adverse effect on our business, financial condition and prospects.

If we do not successfully consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the process to identify a strategic transaction will result in a successfully consummated transaction. If no transaction is completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations; (ii) obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our company; (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business; and (iv) non-cancelable facility lease obligations. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company.

Our business to date has been almost entirely dependent on the success of ELAD and we have recently decided to discontinue further development of ELAD in the U.S. and Europe, and devote significant time and resources to identifying and evaluating strategic alternatives, which may not be successful.

To date, we have invested substantially all of our efforts and financial resources into the research and development of the ELAD System, or ELAD, which was our only product candidate to enter clinical trials. In September 2018, we voluntarily discontinued our development of ELAD in the U.S. and Europe in view of the results of our VTL-308 Phase 3 clinical trial.

We are evaluating strategic alternatives with a goal to enhance stockholder value , including the possibility of a merger or sale of our company, and have suspended most of our research and development activities, other than our early stage normothermic liver perfusion program, to reduce operating expenses while we evaluate these opportunities.

There can be no assurance that our process to identify and evaluate potential strategic alternatives will result in any definitive offer to consummate a strategic transaction, or if made, what the terms thereof will be or that any transaction will be approved or consummated. If any definitive offer to consummate a strategic transaction is received, there can be no assurance that a definitive agreement will be executed or that, if a definitive agreement is executed, the transaction will be consummated. In addition, there can be no assurance that any transaction, involving our company and/or assets, that is consummated would enhance stockholder value. There also can be no assurance that we will conduct additional research or development activities in the future.

We are substantially dependent on our remaining employees to facilitate the consummation of a strategic transaction. We could lose such key employees, in particular, as a result of the VTL-308 data and the reduction in our workforce that we announced in September 2018.

In September 2018, we instituted across the board expense reductions to conserve capital, including a workforce reduction of approximately 85%. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel, particularly Russell J. Cox, our Chief Executive Officer, Duane D. Nash M.D., our President, Robert A. Ashley, our Executive Vice President and Chief Scientific Officer, Michael V. Swanson, our Executive Vice President and Chief Financial Officer, and John M. Dunn, our General Counsel and Secretary. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to evaluate and pursue strategic alternatives, as well as fulfill our reporting obligations as a public company.

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 and to consummate a strategic transaction. Although we have suspended most of our research and development activities, if we resume the development of ELAD outside the U.S. or of new therapeutic products, such development requires expertise from a number of different disciplines, some of which are not widely available. The failure of the VTL-308 clinical trial will likely make it more challenging to retain qualified personnel and difficult to recruit personnel in the future, if necessary. 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 a strategic path forward.

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 or ability to consummate a strategic transaction. 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, particularly in light of the recent failure of our VTL-308 clinical trial.

The loss of the services of existing personnel or the failure to recruit additional, suitable key scientific, managerial, clinical, regulatory, operational and other personnel in a timely manner could harm our business. We may experience difficulty in hiring and retaining highly-skilled employees with appropriate qualifications as needed, particularly in light of the recent failure of our VTL-308 clinical trial. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects and our ability to consummate a strategic transaction 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.

Risks Related to Our Business

We were dependent on the success of the ELAD System, and we do not expect be able to complete the development of, successfully obtain regulatory or marketing approval for, or successfully commercialize, the ELAD System in the United States, or U.S., or Europe.

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 September 2018, we announced that our VTL-308 clinical trial failed to meet both its primary and secondary endpoints. In light of these results, we do not believe that the ELAD System can be approved in the U.S. or Europe, if ever, without additional clinical trials that would require substantial capital and time to complete. Consequently, we have ceased any further development of the ELAD System and are exploring strategic options. We do not have any other product candidates in our near-term product pipeline, other than our normothermic liver perfusion program which is early in development.

Our VTL-308 clinical trial was performed in certain subjects with severe alcoholic hepatitis, or sAH. Any additional indications we elect to pursue in future trials 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 and VTL-308 clinical trials failed to meet both their primary and secondary endpoints. There is no guarantee that any potential future clinical trials will be completed in a timely fashion or will succeed. However, there can be no assurance that any potential future clinical trials will be timely, successful, or that regulators will approve the ELAD System in a timely manner, or at all. Finally, even if clinical testing of the ELAD System is resumed in the future and the ELAD System is subsequently proven to be safe and effective and ultimately receives regulatory approval, there is no guarantee that its commercialization will be successful.

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, and engaging in research and development. Our VTL-308, 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 or profitably commercialize any approved products.

We have not obtained regulatory approval for any of our product candidates in the U.S. or any other country, and we do not believe that the ELAD System can obtain regulatory approval in the U.S. or Europe, if ever, without additional clinical trials that would require substantial capital and time to complete.

We require regulatory approval for each indication we seek 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 Europe. In light of the clinical results from our VTL-308 clinical trial, we do not believe that the ELAD System can be approved in the U.S. or Europe, if ever, without additional clinical trials that would require substantial capital and time to complete.

Although we have suspended our research and development activities related to the ELAD System, if we resume development, and if we were able to secure marketing approval, our commercial success would be determined by our ability to obtain acceptable pricing and reimbursement for the ELAD System.

Although we have suspended our research and development activities related to the ELAD System, if we resume the development of 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 do not expect to pursue regulatory approval of the ELAD System at this time, we believe it may be difficult to sustain a commercial price outside of the U.S. at or above the commercial price within 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 were able to secure marketing approval for the ELAD System. In markets where payment would be made by private individuals and their families, such private payors may not be prepared to pay an acceptable price.

Although we have suspended our research and development activities related to the ELAD System, if we resume development, and 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 or any other product candidates and may not reach profitability.

Although we have suspended our research and development activities, if we resume the development of the ELAD System or of any of our other product candidates, we may not be able to effectively commercialize any potential product candidates. Our technology is new and complex, and potential customers will have limited knowledge of, or experience with, our current products. In addition, we have no related sales and marketing experience either domestically or abroad. We have not commercialized any products anywhere. Our commercial success would depend on our ability to market and receive adequate reimbursement. This success will also depend on our ability to obtain and maintain adequate pricing.

Further, 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 of any of our product candidates, if we were to obtain marketing approval, we would need to establish a sales and marketing organization, and we are unable to currently predict how we would market any product candidates.

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 $39.0 million for the nine months ended September 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 September 30, 2018, we had an accumulated deficit of $335.0 million. Even though we discontinued most of our research efforts in September 2018, we expect to continue to spend a considerable amount of our resources on strategic opportunities. We also 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 our decisions on strategic alternatives which may include a merger and other strategic partnerships, an acquisition and the sale of assets. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We anticipate incurring additional losses and negative cash flow from operations for the foreseeable future. We are not currently generating revenues, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale, we may never generate significant revenue from selling products or achieve profitability and we may never resume the development of the ELAD System or complete the development of any other product candidates. We do not have a product candidate that has been approved for marketing in the United States or elsewhere, and we may never receive any such approval. Our two most recent clinical trials, VTI-208 and VTL-308, failed to reach both their primary and secondary endpoints. Our only product in development is our normothermic liver perfusion program, which is too early in development to assess its product value or potential product sales. If we do develop or acquire other product candidates, we would expect our research and development expenses to increase significantly. If we do acquire a new product candidate and successfully develop and obtain regulatory approval for it, we also expect to incur significant sales and marketing expenses.

We are evaluating strategic alternatives with a goal to enhance stockholder value, including the possibility of a merger or sale of the company, and have suspended most of our research and development activities to reduce operating expenses while we evaluate these opportunities. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we evaluate these strategic alternatives.

As a result of these factors, we expect to continue to incur significant operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have a material adverse effect on our stockholders' deficit, financial position, cash flows and working capital. We are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to produce revenue and achieve profitability is dependent on our ability to complete the development of product candidates, obtain necessary regulatory approvals, and to successfully manufacture and market products. We cannot assure you that we will ever be profitable even if we successfully enter into strategic transactions or

commercialize products. Failure to become and remain profitable or the perception that we may never become profitable would adversely affect the market price of our common stock and our ability to raise capital and continue operations.

Although we have suspended most of our research and development activities, if we resume the clinical development of any product candidates, we would need to obtain additional financing to fund our operations and, if we were then unable to obtain such financing, we may be unable to complete the development and commercialization of any potential product candidates.

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $335.0 million through September 30, 2018. Based on our current employees, our known commitments, and our ongoing administrative costs to explore and pursue strategic options, we believe that our existing cash and cash equivalents of $17.8 million as of September 30, 2018 should be sufficient to meet our known liabilities and commitments as of September 30, 2018; however, we expect our resource requirements to change materially to the extent we identify and enter into any strategic transactions. To advance the development of product candidates, we expect we will need to obtain additional financing. Moreover, our expenses such as rent and other contractual commitments are substantial and may need to increase in the future.

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate any potential future research and development programs or potential future commercialization efforts. Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this forecast on a number of assumptions that may prove to be wrong, and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate.

Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and structure of any strategic options that are being considered by us;
- 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 (if any);
- the timing and progress in the development of our normothermic liver perfusion program;
- the scope, progress, results and costs of research and development and future clinical trials, if any, related to the ELAD System or other product candidates;
- the cost and timing of any regulatory submissions;
- the cost and timing of scaling up and validating the manufacturing process for the ELAD System or any other potential 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);
- the costs involved with being a public company;
- the cost, timing and outcome of any future litigation costs;
- 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 we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances, marketing or distribution arrangements or a combination thereof. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. General market conditions or the market price of our common stock may not support capital raising transactions such as an additional public or private offering of our common stock or other securities. In addition, our ability to raise additional capital may be dependent upon our stock being quoted on The Nasdaq Global Select Market, or Nasdaq, or upon obtaining stockholder approval. On October 25, 2018, we received a letter from the staff of Nasdaq providing notification that, for the previous 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement, or

the Bid Price Requirement, for continued listing on Nasdaq. The notification had no immediate effect on the listing of our common stock. In accordance with Nasdaq listing rules, we were afforded 180 calendar days, or until April 23, 2019, to regain compliance with the Bid Price Requirement. There can be no assurance that we will be able to satisfy the criteria for continued listing on Nasdaq or that we will be able to obtain stockholder approval, if it is necessary, to take the steps needed to remedy the Bid Price Requirement. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds to sustain our operations and could result in the loss of institutional investor interest, limit our strategic alternatives, and result in fewer development opportunities. If adequate funds are not available, we may be required to close our operations.

We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Our inability to obtain additional funding when we need it could seriously harm our business.

If we resume the clinical development of any product candidates, additional capital that we may need to operate or expand our business may not be available.

We may require additional capital to operate or expand our business. The failure of the VTL-308 clinical trial to meet its primary or secondary endpoints may make it very difficult for us to seek and obtain financing from the capital markets on favorable terms, or at all. If we raise additional funds through the issuance of equity or convertible securities, the percentage ownership of holders of our common stock could be substantially diluted and these newly issued securities may have rights, preferences or privileges senior to those of holders of our common stock. Furthermore, volatility in the credit or equity markets may have an adverse effect on our ability to obtain debt or equity financing or the cost of such financing. If we do not have funds available to enhance any potential product candidates, maintain the competitiveness of our technology and pursue business opportunities, this could have an adverse effect on our business, operating results and financial condition.

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. The strategic options that we are pursuing will likely create an ownership change under Section 382 of the Internal Revenue Code, which could limit all or substantially all of our NOLs and tax credit carryforwards. Furthermore, our ability to utilize NOLs and tax credit carryforwards of companies that we may acquire in the future may be subject to limitations.

Furthermore, 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, what impact they may have on the way in which we conduct our business, or how they may impact 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 and likelihood of consummating a strategic transaction.

Our internal computer systems, cloud-based systems and those systems previously used, or that may in the future be 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 any of our development programs.

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 systems previously used, or that may in the future be used, by us, 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 any clinical development or manufacturing activities. For example, the loss of clinical trial data could result in delays in future 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 any future clinical development or other development of product candidates 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 and ability to consummate strategic transactions.

Our industry is characterized by frequent claims and litigation, including claims regarding patent or other intellectual property rights, as well as product liability. Additionally, in the past, companies that experience volatility in the market price of their stock have been subject to securities class action litigation. For example, 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. We are at a heightened risk of, and could be subject to, additional litigation following our announcement in September 2018 that the ELAD System failed to meet its primary and secondary endpoints in our VTL-308 phase 3 clinical trial. 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 and ability to consummate strategic transactions.

Risks Related to the ELAD System's or other Product Candidates' Potential Future Clinical Development

If we resume the clinical development of any product candidates, 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 severe alcoholic hepatitis, or 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 subsequent clinical trial of the ELAD system in sAH, VTL-308, incorporated limits on subjects' age, model for end-stage liver disease score, or MELD score, and its three components. While the endpoints and populations for VTL-308 were derived from results of our prior studies, including the results of VTI-208, and based on medical literature, in none of those prior studies had 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. In September 2018, we announced that the VTL-308 clinical trial failed to meet both its primary and secondary endpoints. The lack of statistical significance from these previous trials could be attributed to various factors, including the lack of power to demonstrate significance, the design of the studies and the lack of an ELAD System treatment benefit.

If we resume the clinical development of the ELAD System or any of our product candidates, 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 potential future clinical trials will necessarily succeed. For example, our primary endpoint in VTL-308 was based on the results of a subset of subjects in our VTI-208 clinical trial. Additionally, our primary endpoint in VTI-208 was based on the results of a subset of subjects in our VTI-206 clinical trial. Although these subsets showed a trend toward increased survival up to at least study day ninety-one, the subsequent trials still failed to meet their primary and secondary endpoints. 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 any potential future clinical trials of any product candidates will provide statistically significant data sufficient to support regulatory approval.

Random variation or changes in standard of care could cause any potential future 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 any of our potential future clinical trials will meet that standard. In addition, we have designed all of our past clinical trials to be judged by a survival primary endpoint, which may have been 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. Such difficulties may continue in any potential future clinical trials.

Any of these factors, which are beyond our control, could materially and adversely affect the results of any potential future trials and prevent us from gaining regulatory approval of any product candidates. In addition, even if the results of any potential future 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.

If we resume clinical development, the ELAD System treatment could result in significant clinical risks to the patient, including death.

The ELAD System therapy was targeted toward very sick patients who were 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 received the ELAD System therapy were at risk of dying due to other serious health problems even if the ELAD System was demonstrated to be 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 prior 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 our study in China. 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 and there have been no such reported cases of cancer in VTL-308. These or other adverse events, even those that are currently unforeseen, could significantly affect any potential future development and commercialization efforts, cause the regulatory authorities to place any potential future clinical trials on hold or to refuse to grant or maintain any potential future marketing approval or result in withdrawal of the ELAD System from the market in the event that development of the ELAD System is resumed and ultimately receives marketing approval.

Due to ethical considerations, we have conducted open-label clinical trials of the ELAD System, where control subjects do not receive a sham treatment, and this could introduce unacceptable bias into any future trial results.

We did not conduct our VTI-208, VTI-210, VTI-212 or VTL-308 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 design 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 had developed a protocol that attempted 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-treated 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 might have significantly confounded the trial data. However, there is no guarantee that bias will not enter into any potential future clinical trial, affect the results of such trials or cause regulatory agencies to refuse marketing approval of the ELAD System or any other product candidates.

If we resume the clinical development of any product candidates, and if we encounter difficulties enrolling subjects, any potential future clinical trials could be delayed or otherwise adversely affected.

Clinical trials for the ELAD System required us to identify and enroll a large number of subjects that met all of the entry criteria set forth in our protocols, including having the disease under investigation. If we resume the development of any product candidates and conduct any future clinical trials, 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 potential future 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 any potential future trials. Even if we were to 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 any potential future clinical trials or if enrolled subjects fail to complete the study or comply with our protocols, particularly with regard to follow-up appointments, the completion of any potential future clinical trials would be delayed, and our business would be harmed.

If we resume the clinical development of any product candidates, we may face delays in completing any potential future clinical trials, and we may be required to suspend, repeat or terminate any potential future 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.

Any potential future 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 any potential future clinical trial protocols to ethics committees or IRBs for reexamination, which may impact the costs, timing or successful completion of the underlying trial.

Any potential future 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 any potential future clinical trials;
- delays or failure by us in manufacturing sufficient quantities of product pursuant to required quality standards and by third-party manufacturers in supplying the product or necessary and suitable components;

- delays or failure in transporting products 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 or may delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about subject safety;
- we may suspend or terminate any potential future clinical trials if we believe our product is exposing the participating subjects to unacceptable health risks or for other reasons;
- subjects may not complete any potential future clinical trials due to safety issues, adverse events, inconvenience or other reasons;
- subjects in any potential future clinical trials may die or suffer other adverse events for reasons that may be either related or unrelated to our product;
- 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 any potential future clinical trials may conclude that such product candidate lacks sufficient clinical efficacy or presents unacceptable safety risks, such as occurred with the VTL-308 clinical trial.

Due to the failure of VTI-208 and VTL-308 to provide evidence of safety and efficacy sufficient to satisfy the requirements of the regulatory authorities, we do not expect the ELAD System to be approved unless we are able to perform additional clinical trials showing such safety and efficacy.

Risks Related to Regulatory Matters

If we resume the clinical development of any product candidates, the FDA regulatory approval process is complex, time-consuming and inherently unpredictable. In addition, the failure of our VTL-308 and VTI-208 clinical trials may adversely affect the attitude of regulatory authorities toward any potential future development of the ELAD System.

Potential future clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution is subject to extensive regulation by the FDA. In the U.S., the ELAD System has been regulated by the FDA as a combination biologic and medical device. Before a biologic product can be marketed in the U.S., we must submit, and the FDA must approve, a Biologics License Application, or BLA. In addition, for a combination biologic and medical device, the device components must be found acceptable as part of the BLA. The regulatory review process for a novel therapy is complex, time-consuming and unpredictable. As a result, 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 regulatory authorities.

Even if a product shows evidence of safety and efficacy in clinical trials, it could fail to receive regulatory approval for many reasons, including the following:

- the FDA may disagree with the design or implementation of the clinical trials or the study endpoints. For example, in our ELAD clinical trials, the FDA had 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 received during our studies;
- we may be unable to demonstrate to the satisfaction of the FDA that our product is safe and effective for its proposed indications or that the product provides significant clinically relevant benefits or that the benefits outweigh the safety risks;
- the results of a clinical trial 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 any 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 any potential future clinical trials as a result of the open-label design may not be adequately handled and may cause any potential future trial to fail;
- the product 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 a future clinical trial 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 additional phase 3 clinical trial to secure regulatory approval;
- the approval policies or regulations of the FDA may significantly change in a manner rendering any future clinical data insufficient for approval; and
- the failure of prior clinical trials could result in more stringent requirements being imposed by regulatory bodies and advisory groups.

The FDA expressed concern with our past phase 3 clinical trials that there are significant differences in how treated 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. For example, differences in length of hospital stay, rates of hospital re-admission, alcohol recidivism rates, nutritional support, and concomitant medications could significantly confound the reported study results.

In addition, even if we were to obtain approval following any potential future clinical trials, the FDA may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a label that does not include the labeling claims necessary or desirable for successful commercialization. Any of the above could materially harm a product's commercial prospects.

If we begin or resume the clinical development of any biologic product candidates, 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 light of the clinical results from our VTL-308 clinical trial, we do not believe that the ELAD System can be approved for marketing for sAH in the U.S. or Europe, if ever, without additional clinical trials that would require substantial capital and time to complete. Therefore, the ELAD System may never be approved for marketing.

If we resume the development of any product candidates, the FDA may or may not grant an accelerated or "Priority Review" to any potential future BLA, if requested by us, and even if the FDA designates Priority Review for any product candidate, 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 an 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 a BLA submission if the FDA determines that the product candidate, 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 we were to submit a BLA; however, the FDA has broad discretion whether or not to grant Priority Review even if we believe a 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 any future BLA will be approved in a timely manner, or at all.

If we resume the development of any product candidates, the regulatory approval processes of foreign regulatory authorities are complex, time-consuming and inherently unpredictable.

Outside the U.S., our ability to market a product is contingent upon receiving marketing authorizations from appropriate regulatory authorities. If any potential future clinical programs were to be successful, we would anticipate submitting applications for marketing authorization in Europe and other foreign countries based on need. 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.

If any product candidate receives regulatory approval, we will be subject to ongoing regulatory requirements and may face regulatory or enforcement action.

If any 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, requirements for 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 were to obtain FDA approval of any future product candidate and begin commercializing that product in the United States, our potential exposure under such laws would increase significantly, and our costs associated with compliance with such laws would also be 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 potential future 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 or Any of Our Products

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, with respect to any biological product candidates. 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 and for the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of the regulated products. Regulatory agencies enforce the QSR and MDD through periodic inspections. Prior to any potential approval of any such product in the U.S. and Europe, our manufacturing facility would 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 any product.

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 should we resume development of ELAD for new indications.

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, VTI-210 and VTL-308 clinical trials. 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, future development and approval of the ELAD System, if any, may be significantly delayed or prevented. In addition, effective January 1, 2018, LivaNova no longer supports its S3 systems. Accordingly, if a future trial is undertaken and 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 used in our prior clinical trials. 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. This and similar situations with other suppliers could significantly delay the development of future products.

In the development of combination biologic and device products, changes in any of the device components could affect our ability to complete any future clinical trials or to obtain and maintain approval and commercialization efforts.

The device components of the ELAD System must be reviewed as part of any BLA for ELAD. If the manufacturers of those components make modifications, discontinue supplying or are unable to supply sufficient quantities of such components during any potential 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 were unable to obtain sufficient quantities of the component on a timely basis, there could have been a delay in enrollment in our clinical trial or, following an approval, in the marketing of ELAD until additional supplies became available, or we would be required to validate an alternative component to use, which could delay any clinical trials or the marketing of a product, 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 were unable to validate a replacement component, we would not be able to initiate or complete clinical trials or, in the future, we might not be able to market or could have to suspend marketing in certain jurisdictions.

If we determine to resume the clinical development of ELAD, 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 would be using the components outside the scope of their cleared indications. Other device components have no regulatory approvals. If we resume development of the ELAD System, we may need to conduct additional testing to bridge the differences between the cleared indications for use and its use in the ELAD System in order to obtain any 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 an approval of the ELAD System should further development of the ELAD System be pursued.

Risks Related to the Cellular Products 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 any potential approval of any such product, our manufacturing facilities would be subject to a preapproval inspection to determine compliance with U.S. and European cGMPs and applicable QSR and MDD requirements or other foreign regulatory agencies. 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 such a product.

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

While the growth of VTL C3A cells for ELAD 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 have previously relied 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 have investigated additional sources of supply for some of these components to support any potential 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 develop or to initiate commercialization of the ELAD System would be severely compromised should we determine to pursue the further development of ELAD for new indications or geographical regions. In addition, we have relied 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 will have to purchase components on a purchase order basis. For components that are not readily available from other sources, we would be 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 if we resume development of the ELAD System.

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 ELAD System cartridges and are each provided by a single supplier. In addition, while these products were tested to be free of contamination by the supplier, we cannot guarantee that will always continue to be the case.

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

We have manufactured our biologic product and assembled the device component 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 might use would 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 manufacturing activities, combined with our limited inventory of reserve raw materials and manufactured supplies, could result in the delay of any potential future clinical trials.

We often rely on third parties for certain aspects of the manufacture of our clinical products and supplies. 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 a San Diego manufacturing facility, we expect to use third parties for certain parts of our production process for any products under development. This would 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 any potential future products.
- Any third-party manufacturers might be unable to timely manufacture the components and custom materials and supplies we require, or to produce the quantity and quality required to meet our needs.

- Contract manufacturers may not be able to execute or comply with our manufacturing procedures and other logistical support requirements appropriately.
- Any 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 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.
- Any third-party manufacturers could breach or terminate their agreement with us.
- Any contract manufacturers may have unacceptable or inconsistent product quality, success rates and yields.
- The actual cost to manufacture and process any future product candidates could materially and adversely affect their commercial viability.
- Any 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 any potential future clinical trials or the approval of any future product by the FDA, result in higher costs, or adversely impact commercialization. If our contract manufacturers are unable to successfully produce any components or any related supplies for potential future clinical trials or commercialization, potential future clinical trials or potential future 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 our products and, if our forecasts are incorrect, we may experience delays in shipments or increased inventory costs.

We keep limited materials, components and, if applicable, 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 our future needs. 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 our products. Any of these occurrences would negatively affect our financial performance and the level of satisfaction any potential customers or partners have with our business.

We may not be able to grow cells used in our products reliably and cost-effectively.

Operations with human cells, even a stable, cell line such as the VTL C3A cells, which are 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 United Kingdom, or UK, 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, we could encounter unforeseen complications. To date, we have only produced the small number of the ELAD cartridges required to support our prior clinical trials. If we were to resume development of the ELAD System and needed to increase production to support demand, we could experience significant scale-up issues, which may cause quality and cost problems and our business could be materially harmed.

Cellular therapy is complex, and we may not ever have a complete understanding of the mechanism of action of any cellular therapy.

Cellular therapy is a complex treatment with multiple variables that are not fully understood. For example, our VTL C3A cells, which were 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 also be affected by the conditions of its generation in the ELAD System bedside unit, which could affect treatment outcomes. For instance, while most subjects treated with the ELAD System typically only required a single set of cartridges, some subjects required more than one set during their treatment period, which may have implications for efficacy and costs. While we believed that we had identified the key parameters of the ELAD System VTL C3A cartridges and set them in an appropriate range, it was possible that there were other variables that were important to safety and efficacy that were not anticipated.

Likewise, our past research into the potential mechanism of action for the ELAD System 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 was primarily based on laboratory studies, and needed correlation with *in vivo* studies and patient outcomes.

Risks Related to Doing Business Internationally

If we were to do business internationally, it may prove to be difficult and fraught with economic, regulatory and political issues.

If we were to commercialize the ELAD System or any other product 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 Food and Drug Administration, 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 could create wholly-owned subsidiaries or work with a partner in those countries or in a region. 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 if foreign commercialization is pursued.

If we were to resume development and ultimately pursue foreign commercialization of ELAD, the medical systems in many countries around the world would 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 prior 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 could overcome these challenges or succeed in commercializing the ELAD System or any other product in any foreign country.

If we were to pursue foreign commercialization we would face increased risks of doing business due to the extent of our operations internationally.

If we were to pursue foreign commercialization, these efforts may 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 potential future operations, which would adversely affect our ability to commercialize products 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 political and economic conditions.

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

If we were to pursue foreign commercialization, a significant portion of our potential future operations may be conducted in foreign countries and it is possible 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 in which we have operations. 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 UK 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 if such efforts are resumed.

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 any potential future 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 one additional patent 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 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 potentially commercialize the ELAD System in these jurisdictions.

We do not hold any patents covering our VTL C3A cells or the production processes we used 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. 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 have 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 previously involved in, or that may in the future be 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, if our efforts to develop ELAD are resumed. 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, if efforts to develop ELAD are resumed.

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, if any.

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 have limited resources to fund our operations and expect to need to raise additional capital in conjunction with and as a result of our review of strategic alternatives.

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $335.0 million through September 30, 2018. Based on our current employees, our known commitments, and our ongoing administrative costs to explore and pursue strategic options, we believe that our existing cash and cash equivalents of $17.8 million as of September 30, 2018 should be sufficient to meet our known liabilities and commitments as of September 30, 2018; however, we expect our resource requirements to change materially to the extent we identify and enter into any strategic transactions. 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, future research and development efforts if any, the strategic options that we pursue, and any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned.

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, or ATM, with Cantor Fitzgerald & Co. However, we expect the amounts available under the shelf registration statement to be significantly limited in the future if our public float remains below $75.0 million, as will be measured on December 31, 2018. Additionally, funding is expected to be more difficult to secure due to our VTL-308 clinical trial not meeting its primary or secondary endpoints.

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 when needed on acceptable terms or at all. If we are not able to secure adequate additional funding, we would be required to make further reductions in certain spending to extend current funds, we may have to liquidate some or all of our assets, delay, reduce the scope of, or eliminate some or all of any development programs or even close our operations.

We may also have to delay development of any potential products or license to third parties the rights to our products or technology that we would otherwise seek to develop. 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 additional 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, and again in September 2018, 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. As a result of the reduction in our workforce, we face an increased risk of employment litigation. We also need to effectively manage our operations and facilities. Following our recent workforce reduction in September 2018, 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, including potential strategic options.

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

We may need to raise substantial additional capital to:

- pursue strategic options for the company;
- complete any potential future clinical trials and related regulatory applications;
- fund our operations;
- commence and expand the commercialization of any products we may acquire; and
- further our research and development.

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

- the cost, timing and structure of any potential strategic options that we pursue;
- the cost of any future 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 any 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, delay, reduce the scope of or eliminate some or all of any potential future development programs or close our operations.

If we do not have, or are not able to obtain, sufficient funds, we may have to delay development of any potential products or license to third parties the rights to develop our products or technologies that we would otherwise seek to develop. 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 and VTL-308 clinical trials to meet their 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. There is no assurance that we will be able to obtain additional funding on acceptable terms or at all.

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 resume 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 may 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

Our common stock may be delisted from The Nasdaq Global Select Market if we are unable to maintain compliance with Nasdaq's continued listing standards.

Nasdaq Global Select Market imposes certain continued listing standards including minimum bid and public float requirements. On October 25, 2018, we received a letter from Nasdaq providing notification that, for the previous 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement, or the Bid Price Requirement, for continued listing on The Nasdaq Global Select Market. The notification had no immediate effect on the listing of our common stock. In accordance with Nasdaq listing rules, we were afforded 180 calendar days, or until April 23, 2019, to regain compliance with the Bid Price Requirement. If we are unable to regain compliance, Nasdaq may determine to delist our common stock. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds to sustain our operations and could result in the loss of institutional investor interest, limit our strategic alternatives, and result in fewer development opportunities.

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 stockholder 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 will 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).

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 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. 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 a research analyst 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 $0.23 to $35.20, through October 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. Then again in September 2018, our announcement that the VTL-308 clinical trial failed to meet its primary or secondary endpoints resulted in a significant decline in the market price of our common stock. Following the announcement on the morning of September 12, 2018 that our VTL-308 clinical trial failed to meet its primary or secondary endpoints, the price of our common stock dropped $5.85 per share, or 93%, from $6.30 per share as of the close of business on September 11, 2018 to $0.45 per share as of the close of business on September 12, 2018. The closing price of our common stock was $0.31 as of October 31, 2018. 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 past and recent 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 any potential future clinical trials or transactions.

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

- any potential strategic options that we pursue;
- clinical data and government approvals relating to products in development;
- 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, including intellectual property or securities 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 our products or products of our competitors;
- volume and timing of sales of products;
- 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 nine months ended September 30, 2018. At September 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. However, we expect the amounts available under the shelf registration statement to be significantly limited in the future if our public float remains below $75.0 million, as measured on December 31, 2018, and our ability to use the ATM may likewise be limited or completely unavailable based on the requirements of the ATM. Additionally, funding is expected to be more difficult to secure due to our VTL-308 clinical trial not meeting its primary or secondary endpoints.

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 September 30, 2018, options to purchase 4,473,207 shares of our common stock were exercisable.

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.

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 working capital requirements 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.

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; and
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;

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 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 September 30, 2018, we did not have any sales of unregistered securities.

Item 5. Other Information

None.

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: November 7, 2018 By: /s/ Michael V. Swanson

Michael V. Swanson
Chief Financial Officer
(Principal Financial and Accounting
Officer and Duly Authorized Officer)

Exhibit 31.1

CERTIFICATIONS

I, Russell J. Cox, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vital Therapies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of and for the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2018

By: /s/ Russell J. Cox

Russell J. Cox
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Michael V. Swanson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vital Therapies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of and for the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2018

By: /s/ Michael V. Swanson

Michael V. Swanson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Vital Therapies, Inc. (the "Company") for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Russell J. Cox, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2018

By: /s/ Russell J. Cox
Russell J. Cox
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Vital Therapies, Inc. (the "Company") for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Michael V. Swanson, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2018

By: /s/ Michael V. Swanson
Michael V. Swanson
Chief Financial Officer
(Principal Financial and Accounting Officer)