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 **March 31, 2017**

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 April 30, 2017:

Class	**Number of Shares Outstanding**
Common Stock, $0.0001 par value	42,207,376

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VITAL THERAPIES, INC.

Condensed Consolidated Balance Sheets

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

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 86,636	$ 59,991
Other current assets and prepaid expenses	1,666	1,472
Total current assets	88,302	61,463
Property and equipment, net	2,489	2,505
Other assets	156	58
Total assets	$ 90,947	$ 64,026
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,308	$ 780
Accrued expenses	5,085	4,656
Other current liabilities	57	44
Total current liabilities	6,450	5,480
Long-term liabilities	69	100
Commitments and contingencies (note 4)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at March 31, 2017 and December 31, 2016	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized at March 31, 2017 and December 31, 2016; 42,207,376 and 32,143,475 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	4	3
Additional paid-in capital	340,817	302,185
Accumulated other comprehensive income	84	83
Accumulated deficit	(256,477)	(243,825)
Total stockholders' equity	84,428	58,446
Total liabilities and stockholders' equity	$ 90,947	$ 64,026

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 March 31,	
	2017	**2016**
Operating expenses:		
Research and development	$ 9,628	$ 6,857
General and administrative	3,059	2,799
Total operating expenses	12,687	9,656
Loss from operations	(12,687)	(9,656)
Other income (expense):		
Interest income	97	60
Other income (expense), net	(12)	7
Total other income	85	67
Net loss	$ (12,602)	$ (9,589)
Net loss per share, basic and diluted	$ (0.39)	$ (0.31)
Weighted-average common shares outstanding, basic and diluted	32,645,103	30,563,088

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 March 31,	
	2017	**2016**
Net loss	$ (12,602)	$ (9,589)
Other comprehensive income:		
Unrealized gains on available-for-sale cash equivalents	1	—
Total comprehensive loss	$ (12,601)	$ (9,589)

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)

	Three Months Ended March 31,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (12,602)	$ (9,589)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	335	494
Stock-based compensation	1,263	998
Other	(2)	—
Changes in operating assets and liabilities:		
Other current assets and prepaid expenses	(316)	18
Accounts payable	396	(361)
Accrued expenses	33	(1,476)
Other liabilities	(17)	(40)
Net cash used in operating activities	(10,910)	(9,956)
Cash flows from investing activities:		
Purchases of property and equipment	(274)	(125)
Proceeds from sale of equipment	3	2
Change in restricted cash	—	213
Net cash (used in) provided by investing activities	(271)	90
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	37,825	4,325
Proceeds from exercise of stock options	1	32
Deferred financing costs	—	(30)
Net cash provided by financing activities	37,826	4,327
Effect of exchange rate changes on cash and cash equivalents	—	(1)
Net change in cash and cash equivalents	26,645	(5,540)
Cash and cash equivalents, beginning of period	59,991	83,416
Cash and cash equivalents, end of period	$ 86,636	$ 77,876
Supplemental disclosure of noncash investing and financing activities:		
Stock offering costs included in liabilities	$ 481	$ 65
Purchases of property and equipment included in liabilities	$ 87	$ —
Change in stock option early exercise repurchase liability	$ —	$ 23

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

1. Description of Business and Basis of Financial Statements

We are a biotherapeutic company focused on developing a cell-based therapy targeting the treatment of liver failure. Our product candidate, the ELAD® System, or ELAD, is an extracorporeal human allogeneic cellular liver therapy designed to allow the patient's own liver to regenerate to a healthy state, or to stabilize the patient until transplant. Since inception, we have devoted essentially all of our efforts to product development, clinical testing and pilot manufacturing and have not recognized revenues from our planned principal operations. In August 2015, we reported that our VTI-208 phase 3 clinical trial of ELAD in alcohol-induced liver decompensation, or AILD, failed to reach its primary or secondary endpoints, although medically pertinent pre-specified subsets based on age and disease severity did show trends toward efficacy. Considering the results of the VTI-208 clinical trial and in an effort to focus our personnel and financial resources, we also discontinued our VTI-210 and VTI-212 clinical trials. We are currently enrolling subjects in our new phase 3 clinical trial of ELAD, known as VTL-308, in severe alcoholic hepatitis, which is a subset of AILD, based on our analysis of the results of the VTI-208 clinical trial. Our business, operating results, financial condition and growth prospects are subject to significant risks and uncertainties including the failure of our clinical trial to meet its endpoint, failure to obtain regulatory approval to commercialize ELAD and failure to secure adequate funding to complete the clinical testing, development and commercialization of ELAD.

Unaudited Interim Financial Information

The results for the three months ended March 31, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017 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, 2016, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 7, 2017.

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, 2016 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.

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

2. Summary of Significant Accounting Policies

Use of Estimates

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

Cash and Cash Equivalents

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

Fair Value of Financial Instruments

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

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

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

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

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

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

Property and Equipment

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

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. We have not recognized any impairment losses through March 31, 2017.

Clinical Trial Accruals

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

Research and Development

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

Stock-Based Compensation

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

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

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

Effective in the first quarter of 2017, we began recognizing forfeitures as they occur (see "Recently Issued and/or Adopted Accounting Standards" below). In 2016 and earlier periods, stock-based compensation expense was recognized only for those awards that were ultimately expected to vest. Through 2016, we estimated forfeitures based on an analysis of our historical employee turnover. We revised the forfeiture estimate, if necessary, in subsequent periods if actual forfeitures differed from those estimates. Changes in estimated forfeitures, which were not material, impacted compensation cost in the period in which the change in estimate occurred.

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 historic 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 either the simplified method, which is an average of the contractual term of the option and its ordinary vesting period, or 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 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 Loss

Comprehensive 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 March 31, 2017 and December 31, 2016, 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 March 31,	
	2017	2016
Options to purchase common stock	4,863,702	3,733,711
Warrants to purchase common stock	240,620	250,539

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 March 2016, the FASB issued ASU No. 2016-09, "*Compensation-Stock Compensation: Improvements to Employee Share-Based Payment Accounting,*" or ASU 2016-09. ASU 2016-09 changes how companies account for certain aspects of share-based payments to employees. The amendments in this update cover such areas as the recognition of excess tax benefits and deficiencies, the classification of those excess tax benefits on the statement of cash flows, an accounting policy election for forfeitures, the amount an employer can withhold to cover employee income taxes and still qualify for equity classification and the classification of those taxes paid on the statement of cash flows. Effective in the first quarter of 2017, we adopted the provisions of ASU 2016-09 to recognize forfeitures as they occur. Upon the adoption of this standard, we recorded a cumulative-effect adjustment of $50,000 to increase additional paid-in capital and accumulated deficit reversing our estimate of forfeitures as of December 31, 2016.

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 will require 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. The amendments in this ASU are effective for interim periods beginning after December 15, 2017, with early adoption permitted. We will adopt this standard in 2018 and do not currently expect ASU 2016-18 to have a significant impact on our consolidated financial statements at the time of adoption.

3. Other Financial Information

Property and Equipment

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

	March 31, 2017	December 31, 2016
Manufacturing, clinical and laboratory equipment	$ 7,416	$ 7,325
Leasehold improvements	4,682	4,450
Office furniture and equipment	235	220
Construction in progress	92	111
	12,425	12,106
Less: accumulated depreciation and amortization	(9,936)	(9,601)
Total	$ 2,489	$ 2,505

Depreciation and amortization expense was $335,000 and $494,000 for the three months ended March 31, 2017 and 2016, respectively.

Accrued Expenses

Accrued expenses consist of (in thousands):

	March 31, 2017	December 31, 2016
Accrued clinical and related costs	$ 3,213	$ 2,316
Accrued compensation and related taxes	1,330	2,154
Accrued other	542	186

Total	$ 5,085	$ 4,656

4. Commitments and Contingencies

Operating Leases

We lease office, manufacturing and research and development facilities and equipment under various non-cancellable operating lease agreements with expiration dates into 2019. In August 2016, we entered into amendments to extend certain leases for office and research and development space to January 2019. Our facility leases generally provide for periodic rent increases and many contain escalation clauses. The amended leases do not include renewal options. Our leases require us to pay property taxes and routine maintenance.

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 $255,000 and $217,000 for the three months ended March 31, 2017 and 2016, respectively. Current and long-term deferred rent totaled $57,000 and $69,000 at March 31, 2017, and $44,000 and $99,000 at December 31, 2016, respectively.

Legal Proceedings

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

5. Fair Value

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

	Fair Value Measurement at March 31, 2017			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 85,137	$ 85,137	$ —	$ —

	Fair Value Measurement at December 31, 2016			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 57,715	$ 57,715	$ —	$ —

There were no liabilities measured at fair value on a recurring basis as of March 31, 2017 or as of December 31, 2016. The carrying amounts of other current assets and prepaid expenses, accounts payable, accrued expenses, and other current liabilities approximate their fair values due to their short-term nature.

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

6. Common Stock and Stock Warrants

Shelf Registration Statement

We currently have an effective shelf registration statement on Form S-3 on file. The 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 $75.0 million of our common stock that may be issued and sold under an "at-the-market" sales agreement, or ATM, with Cantor Fitzgerald & Co.

In October 2015, we completed a follow-on public offering raising gross proceeds of $34.5 million under the shelf registration statement. During the year ended December 31, 2016, we raised gross proceeds of $12.2 million pursuant to the ATM selling 1.5 million shares of our common stock at a weighted average price of $7.90 per share. The net proceeds to us from the ATM were $11.7 million after deducting underwriter commissions of $366,000 and estimated offering expenses of $173,000. We did not sell any shares under the ATM during the three months ended March 31, 2017. In March 2017, we completed an additional follow-on public offering under the shelf registration statement raising gross proceeds of $40.3 million. Under this follow-on public offering, we sold 10.1 million shares of our common stock, which includes an additional 1.3 million shares of our common stock sold upon full exercise of the underwriters' option to purchase additional shares of common stock, at a price of $4.00 per share. The net proceeds to us from the March 2017 follow-on offering were $37.3 million, after deducting underwriting discounts and commissions of $2.4 million and estimated offering expenses of approximately $500,000.

At March 31, 2017, $113.1 million remains available for issuance and sale under the shelf registration statement, $62.8 million of which may be offered, issued and sold under the ATM.

Private Placement of Common Stock

In August 2016, we entered into a securities purchase agreement, or the Securities Purchase Agreement, with a newly-appointed board member pursuant to which we agreed to issue and sell an aggregate of $700,000 of our common stock in a private placement of shares that have not been registered under the Securities Act of 1933, or the Securities Act, by reason of a specific exemption from the registration provisions of the Securities Act. On August 12, 2016, we sold 118,243 shares of common stock under the Securities Purchase Agreement at a price of $5.92 per share.

Stock Reserved for Future Issuance

Shares reserved for future issuance at March 31, 2017 are as follows:

	Number of Shares
Common stock options outstanding	4,863,702
Common stock options available for future grant	146,268
Common stock warrants	240,620
Total common shares reserved for future issuance	5,250,590

Stock Warrants

We issued warrants to purchase redeemable convertible preferred stock in connection with financing activities and for consulting services. In connection with the junior preferred stock financing in February 2012, all warrants to purchase Series B, Series C and Series D preferred stock converted to common stock warrants. As of March 31, 2017 and December 31, 2016, only the Series D warrants were outstanding and exercisable for 240,620 shares of common stock at an exercise price of $92.99 and expire in September 2019.

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.

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

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

Shares available for grant under the 2014 Plan totaled 146,268 shares as of March 31, 2017.

Option grants made under the 2014 Plan and the 2012 Plan generally vest over one or four years except for performance-based stock options. Our performance-based stock options will fully vest and become exercisable only on achievement of the performance conditions while the participant is a continuing service provider. Options generally expire ten years from the grant date or earlier in accordance with the terms of the plans and the related stock option agreement.

The 2012 Plan provided for the grant of stock options, restricted stock, restricted stock units, stock purchase rights, and performance awards to employees, directors, and consultants. Option grants under our 2012 Plan are exercisable immediately, subject to a repurchase right that lapses as the option vests. As of March 31, 2017, all options exercised under the 2012 Plan were vested. To date, we have not repurchased any shares related to early exercises.

The following table summarizes stock option activity:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2017	4,841,274	$ 7.78		
Granted	35,408	$ 5.05		
Exercised	(1,401)	$ 0.43		
Forfeited or expired	(11,579)	$ 11.27		
Outstanding as of March 31, 2017	4,863,702	$ 7.76	7.10	$ 1,414,901
Options vested and expected to vest as of March 31, 2017	4,761,730	$ 7.77	7.07	$ 1,414,901
Options exercisable as of March 31, 2017	3,039,736	$ 7.92	6.07	$ 1,414,901

Stock-Based Compensation Expense

The weighted-average grant date fair value of stock options granted during the three months ended March 31, 2017 and 2016 was $3.48 and $6.04, 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:

	Three Months Ended March 31,	
	2017	2016
Employees:		
Risk-free interest rate	1.5%	1.7%
Expected dividend yield	0%	0%
Expected volatility	85.4%	77.1%
Expected term of options (years)	5.9	6.0
Fair value of common stock	$5.05	$8.97
Non-employees:		
Risk-free interest rate	1.0% - 1.9%	0.6% - 1.4%
Expected dividend yield	0%	0%
Expected volatility	75.6% - 83.3%	76.9% - 84.9%
Expected term of options (years)	1.3 - 4.5	0.8 - 5.5
Fair value of common stock	$4.00	$9.07

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

	Three Months Ended March 31,	
	2017	2016
Employees:		
Research and development	$ 460	$ 392
General and administrative	787	531
Total	$ 1,247	$ 923
Non-employees:		
Research and development	$ 16	$ 63
General and administrative	—	12
Total	$ 16	$ 75

As of March 31, 2017, there was $7.2 million and $184,000 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 1.95 years and 2.09 years, respectively.

8. Subsequent Event

In May 2017, we entered into a new lease, or the Lease, extending the term of our existing manufacturing and research and development facility lease from June 2017 to June 2022. The Lease includes a renewal option and requires the payment of our proportionate share of the facility's operating expenses.

Future minimum annual obligations under all non-cancellable operating lease commitments including the Lease on a pro forma basis at March 31, 2017 would have been (in thousands):

	Operating Lease Obligations
Nine months ending December 31, 2017	$ 689
2018	1,029
2019	467
2020	387
2021	435
Thereafter	221
Total	$ 3,228

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, 2016. 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, many of which are beyond our control, are subject to certain risks and uncertainties, 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" or similar expressions.

Forward-looking statements discuss matters that are not historical facts. Our forward-looking statements involve assumptions that, if they never materialize or prove correct, could cause our results to differ materially from those expressed or implied by such forward-looking statements. In this Quarterly Report, for example, we make forward-looking statements, among others, regarding: the strategy, timing and conduct of our clinical trials, regulatory requirements and markets for the ELAD® System; financial estimates and projections; and the sufficiency of our capital resources to fund our operations.

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

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

Overview

We are a biotherapeutic company focused on developing a human hepatic cell-based treatment targeting acute forms of liver failure. Our product candidate, the ELAD® System, or ELAD, is an extracorporeal human allogeneic cellular liver therapy designed to allow the patient's own liver to potentially regenerate to a healthy state or to stabilize the patient until transplant. The ELAD System is the only liver support system containing immortal human liver-derived cells, in our case VTL C3A cells, to enter phase 3 clinical trials. We designed the ELAD System to supplement key aspects of normal liver function to improve patient survival. We estimate that at least 40,000 patients annually in the United States, or U.S., experience the acute forms of liver failure that may be addressed by the ELAD System, such as severe alcoholic hepatitis, or sAH, surgery-induced liver failure and fulminant hepatic failure for a portion of which the ELAD System may be a life-saving therapy. Except for liver transplant, which is severely limited by the availability of organs and not available to many patients, the current standard of care for these acute forms of liver failure is primarily focused on the management of complications, which does not restore lost liver function and is associated with a high rate of mortality. The ELAD System has received orphan designation in the U.S. and Europe for the treatment of patients with acute liver failure. This designation provides tax credits for qualified clinical testing, seven years of market exclusivity in the U.S. and ten years of market exclusivity in Europe for the first orphan drug approved for a given indication. However, orphan designation does not alter the standard regulatory requirements or the process for obtaining marketing approval.

The ELAD System is currently being tested in a phase 3 randomized, open-label, multicenter, controlled, pivotal study, designed to evaluate ELAD in subjects with sAH, referred to as VTL-308. VTL-308 is based on pre-specified and post-hoc analyses of our VTI-208 phase 3 clinical trial in alcohol-induced liver decompensation, or AILD, of which sAH is a subset. VTI-208 was completed in 2015. Although VTI-208 failed to reach either its primary or secondary endpoints, our pre-specified and post-hoc analyses identified criteria for a group of subjects in which favorable survival trends were observed. The inclusion and exclusion criteria for the VTL-308 trial are based on these findings. We expect to enroll at least 150 subjects in VTL-308 at over 50 sites in the U.S. and Europe. As of May 8, 2017, we have enrolled 67 subjects in VTL-308 and have 46 clinical sites open for enrollment. We expect to report top-line data for VTL-308 around mid-2018. While the VTL-308 phase 3 clinical trial has been designed to show statistical significance based on a subset of pre-specified and post-hoc analyses of the VTI-208 trial, there can be no assurance that the data from the trial or that a single trial will be sufficient to support a marketing application in any country.

We have incurred net losses since inception of $256.5 million through March 31, 2017. We anticipate that we will continue to incur losses for at least the next several years. Due to the uncertainties involved with biological product development and the clinical trial process, we cannot accurately predict the timing or amount of future expenses, when product approval for the ELAD System might occur, if ever, or when profitability may be achieved or sustained.

Results of Operations

Research and Development Expenses

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

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

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

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

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

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, information technology, marketing and legal functions. Other general and administrative expenses include but are not limited to related facility costs, stock-based compensation, professional fees for legal, consulting, accounting and tax services and insurance costs.

Other Income

Interest Income

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

Comparison of the Three Months Ended March 31, 2017 and 2016

The following table summarizes our operating expenses for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,		Change	
	2017	2016	$	%
(dollars in thousands)	(unaudited)			
Operating expenses:				
Research and development	$ 9,628	$ 6,857	$ 2,771	40%
General and administrative	3,059	2,799	260	9%
Total operating expenses	$ 12,687	$ 9,656	$ 3,031	31%

The $2.8 million increase in research and development expense during the three months ended March 31, 2017 as compared to the three months ended March 31, 2016 principally reflects a $2.2 million increase in costs related to the VTL-308 clinical trial, primarily for higher subject, site, manufacturing and consulting costs. As enrollment started in the second quarter of 2016, no subjects were enrolled in the VTI-308 clinical trial in the first quarter of 2016, while 24 subjects were enrolled during the three months ended March 31, 2017. Costs also increased by $347,000 for activities to support a potential BLA submission in the future.

The $260,000 increase in general and administrative expense during the three months ended March 31, 2017 as compared to the three months ended March 31, 2016 was largely the result of a $245,000 increase in stock-based compensation expense related to an increase in the number of stock options outstanding.

We do not expect our research and development costs will increase significantly for the remainder of 2017 relative to the first quarter subject to the timing of subject enrollment in the VTL-308 clinical trial. We also expect general and administrative costs to remain relatively constant for the remainder of 2017 as compared to the first quarter.

Liquidity and Capital Resources

Overview

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $256.5 million through March 31, 2017. We believe we will need additional capital to fund our operations, which we may seek to obtain through a combination of equity or debt financings, or government or other third-party financing, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. In this regard, we currently have an effective shelf registration statement on Form S-3 on file with the SEC. The shelf registration statement permitted: (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 $75.0 million of our common stock under an "at-the-market" sales agreement, or ATM, with Cantor Fitzgerald & Co.

Through March 31, 2017, we have raised gross proceeds of $74.8 million pursuant to follow-on offerings in 2015 and 2017 and gross proceeds of $12.2 million pursuant to the ATM in 2016 under the shelf registration statement. We did not sell any shares under the ATM during the three months ended March 31, 2017. At March 31, 2017, $113.1 million remains available under the shelf registration statement, $62.8 million of which may be offered, issued and sold under the ATM.

As of March 31, 2017, we had cash and cash equivalents of approximately $86.6 million. 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 March 31, 2017, such funds were held in cash and money market funds.

Cash Flows

The following table shows a summary of our cash flows for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
	2017	2016
(in thousands)	(unaudited)	
Cash (used in) provided by:		
Operating activities	$ (10,910)	$ (9,956)
Investing activities	(271)	90
Financing activities	37,826	4,327

Net cash used in operating activities

During the three months ended March 31, 2017, operating activities used $10.9 million of cash. The use of cash primarily related to our net loss of $12.6 million adjusted for non-cash charges of $1.3 million related to stock-based compensation and $335,000 related to depreciation and amortization, partially offset by a $96,000 change in our operating assets and liabilities. Changes in our operating assets and liabilities during the three months ended March 31, 2017 consisted primarily of an increase of $429,000 in accrued expenses and accounts payable partially offset by an increase of $316,000 in other current assets and prepaid expenses. The increase in accrued expenses and accounts payable was primarily attributable to the increase in the amounts due for our VTL-308 clinical trial partially offset by the payout of 2016 bonuses and the reduction in amounts due to clinical sites for our prior clinical trials. The increase in the current assets and prepaid expenses is related to an increase in our prepaid costs associated with our VTL-308 clinical trial.

During the three months ended March 31, 2016, operating activities used $10.0 million of cash. The use of cash primarily related to our net loss of $9.6 million adjusted for non-cash charges of $1.0 million related to stock-based compensation and $494,000 related to depreciation and amortization, partially offset by a $1.9 million change in our operating assets and liabilities. Changes in our operating assets and liabilities during the three months ended March 31, 2016 consisted primarily of a decrease of $1.5 million in accrued expenses and a decrease of $361,000 in accounts payable. The decrease in accrued expenses was primarily attributable to the payout of 2015 bonuses and to payments to clinical sites for our prior clinical trials.

Investing Activities

During the three months ended March 31, 2017, net investing activities used $271,000 of cash, primarily due to capital expenditures of $274,000 for facilities improvements and purchases of equipment for manufacturing and research and development.

During the three months ended March 31, 2016, net investing activities provided $90,000 of cash, including $213,000 from a decrease in restricted cash requirements relating to our clinical trials, partially offset by capital expenditures of $125,000 for facilities improvements and purchases of equipment for manufacturing and research and development.

Financing Activities

During the three months ended March 31, 2017, financing activities provided $37.8 million of cash related to net cash proceeds after underwriters' commissions and cash payments for offering costs from the follow-on offering completed in March 2017.

During the three months ended March 31, 2016, financing activities provided $4.3 million of cash, which included net proceeds of $4.3 million after underwriters' commissions and offering costs from the ATM.

Based on the structure and timing of the VTL-308 clinical trial, assuming limited BLA-related activities and that we do not begin building any significant commercial infrastructure, we believe that our existing cash and cash equivalents of $86.6 million as of March 31, 2017 will be sufficient to fund our operations through the first quarter of 2019, past the expected announcement of topline data for the VTL-308 clinical trial, which we currently anticipate in mid-2018. The timing and amount of our actual expenditures will be based on many factors, including, but not limited to, the timing of and enrollment in our clinical trials, the timing of any possible filing of a BLA, decisions with respect to building commercial operations, and any unforeseen cash needs. To the extent we require additional funds in the future, we may raise funds pursuant to our shelf registration statement (including through the ATM), or we may seek to obtain additional funding through a combination of other equity or debt financings, government or other third-party financing, marketing and distribution arrangements or other collaborations, strategic alliances and licensing arrangements.

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

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

- the timing, receipt and amount of sales of, or royalties, if any, on the ELAD System and any future product candidates.

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

Off-Balance Sheet Arrangements

Through March 31, 2017, 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, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

Critical Accounting Policies and Estimates

The preparation of 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 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 three months of 2017, 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 7, 2017 for a more complete discussion of our critical accounting policies and estimates.

Recently Issued Accounting Standards

In February 2016, the Financial Accounting Standards Board, or FASB, issued 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 March 2016, the FASB issued ASU No. 2016-09, "*Compensation-Stock Compensation: Improvements to Employee Share-Based Payment Accounting,*" or ASU 2016-09. ASU 2016-09 changes how companies account for certain aspects of share-based payments to employees. The amendments in this update cover such areas as the recognition of excess tax benefits and deficiencies, the classification of those excess tax benefits on the statement of cash flows, an accounting policy election for forfeitures, the amount an employer can withhold to cover employee income taxes and still qualify for equity classification and the classification of those taxes paid on the statement of cash flows. Effective in the first quarter of 2017, we adopted the provisions of ASU 2016-09 to recognize forfeitures as they occur.

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 will require

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. The amendments in this ASU are effective for interim periods beginning after December 15, 2017, with early adoption permitted. We will adopt this standard in 2018 and do not currently expect ASU 2016-18 to have a significant impact on our consolidated financial statements at the time of adoption.

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 7, 2017.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Management, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures during the three months ended March 31, 2017. 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 three months ended March 31, 2017, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2017, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the three months ended March 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II - OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors.

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

Risks Related to Our Business

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

In August 2015, we announced that the ELAD System, our sole product candidate, failed to meet its primary and secondary endpoints in our VTI-208 phase 3 clinical trial. Following this announcement, we discontinued our VTI-210 and VTI-212 clinical trials and began a series of pre-specified and post-hoc analyses of the VTI-208 data to determine if there was a basis for continuing the development of the ELAD System. Based on these analyses, we prepared a preliminary protocol for a new clinical trial, VTL-308, incorporating changes based on clinically relevant trends we observed in subset data from the VTI-208 clinical trial, including limits on subjects' age, Model for End-stage Liver Disease, or MELD, score and the three components of MELD score associated with kidney dysfunction (creatinine), blood clotting dysfunction defined as international normalization ratio, or INR, and liver function (bilirubin). In November 2015, we received written responses from the U.S. Food and Drug Administration, or the FDA, to our Type C meeting request on the VTL-308 phase 3 clinical trial. At the FDA's suggestion, we have incorporated an event-driven feature into the trial design consistent with the primary endpoint of overall survival. Under the modified design, enrollment will continue until at least 150 subjects have been enrolled and 55 events have occurred, consistent with the event rate seen in the target subpopulation from VTI-208.

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

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

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

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

We are a clinical-stage company and we have no approved products or revenues from the sale of products. Our operations to date have been limited to organizing, staffing and financing our company, applying for patent rights, manufacturing on a clinical scale, undertaking clinical trials of our product candidate, and engaging in research and development. Our most recent clinical trials failed to reach both their primary and secondary endpoints or were terminated. We have not yet demonstrated an ability to obtain regulatory approval, manufacture products on a commercial scale, or conduct the sales and marketing activities necessary for successful product commercialization. As a result, there is limited information about us for investors to use when assessing our future viability and our potential to successfully develop product candidates, conduct clinical trials, manufacture our products on a commercial scale, obtain regulatory approval and profitably commercialize any approved products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are a clinical-stage company, and clinical development of a novel therapy is a highly speculative undertaking. We have incurred significant losses in each fiscal year since our inception, including net losses of $12.6 million for the three months ended March 31, 2017 and $41.0 million, $52.0 million and $47.7 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of March 31, 2017, we had an accumulated deficit of $256.5 million. We expect to spend a considerable amount of our resources on the completion of our clinical programs and the work necessary to submit and gain approval of our ELAD System, on the production of the ELAD cartridges and bedside units, on investment in production facilities, and on the commercial launch and sales and marketing of the ELAD System. We also expect to expend considerable resources on research and development to develop new and improved products and to understand the mechanism of action of the ELAD System. To date, we have not generated significant revenues, and we anticipate incurring additional losses and negative cash flow from operations for at least the next several years. Even if we do achieve profitability in the future, there is no guarantee that we will be able to sustain this profitability in subsequent periods, and we may need to raise additional capital.

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

As of December 31, 2016, we had net operating loss, or NOL, carryforwards of approximately $168.5 million and $159.6 million, 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 to offset future taxable income. We believe our existing NOLs are subject to limitations arising from previous ownership changes, and if we undergo any further ownership changes, our ability to utilize NOLs could be further limited. Future changes in our stock ownership, some of which are outside of our control, could also result in additional ownership changes under Section 382. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. In addition, in 2013, California adopted a single factor, sales, for apportioning income and losses to the state. Although completely offset by our valuation allowance, we had recognized NOL carryforwards from 2013 through 2015 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, even if we attain profitability.

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

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

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

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

Risks Related to the ELAD System's Clinical Development

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

Our VTI-208 phase 3 randomized, controlled, open-label trial evaluating the ELAD System in subjects with AILD 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 new clinical trial in sAH, VTL-308, incorporates limits on subjects' age, MELD score and its three components. While the endpoints and populations for VTL-308 are derived from results of our prior studies, including the results of VTI-208, and based on medical literature, in none of those prior studies have we demonstrated a statistically significant effect on the population based on the endpoints prospectively described in the study plan. Our prior clinical trials of the ELAD System in AILD, of which sAH is a subset, did not demonstrate statistically significant improvement over standard of care in the primary endpoint of survival through at least study day ninety-one. Similarly, our prior clinical trials of the ELAD System in fulminant hepatic failure, or FHF, did not demonstrate statistically significant improvement in the primary endpoint of 28-day survival. The lack of statistical significance could be attributed to various factors, including the lack of power to demonstrate significance, the design of the studies or the lack of an ELAD System treatment benefit.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In light of disclosures of our VTI-208 data by us and others, it is possible that subjects will be less willing to participate in future trials of the ELAD System. Additionally, we may experience difficulties enrolling new subjects based on the new exclusion and inclusion criteria for VTL-308. Even when we identify an appropriate subject population for a clinical trial, there can be no assurance that the subjects will elect to enroll in the study or complete the study. These difficulties could impact our anticipated budget and timeline for VTL-308.

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

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

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

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

- delays or failures in designing an appropriate clinical trial protocol with sufficient statistical power and in reaching agreement on trial design with investigators and regulatory authorities;
- delays or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays or failure by CROs, investigators and clinical trial sites in ensuring the proper and timely conduct of our clinical trials;
- delays or failure by us in manufacturing sufficient quantities of the ELAD cartridges pursuant to required quality standards for use in our clinical trials and by third-party manufacturers in supplying necessary and suitable components for the ELAD System;
- delays or failure in transporting the ELAD System and cartridges to clinical trial sites with sufficient rapidity to enable treatment to begin early enough to have an opportunity for clinical benefit;
- delays or failure in completing data analysis and achieving primary and secondary endpoints;
- delays in subject enrollment or site initiation, including in light of, among other things, our negative results from VTI-208;
- regulators or clinical site ethics committees or IRBs may not approve, delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe the ELAD System is exposing the participating subjects to unacceptable health risks or for other reasons;
- subjects may not complete our clinical trials due to safety issues, adverse events, inconvenience or other reasons;
- subjects in our clinical trials may die or suffer other adverse events for reasons that may be either related or unrelated to the ELAD System, particularly given the critically ill nature of these subjects;
- we may have difficulty in maintaining contact with subjects after treatment, preventing us from collecting the data required by our study protocol; and
- final analysis of the data from our clinical trials may conclude that the ELAD System lacks sufficient clinical efficacy or presents unacceptable safety risks.

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

Risks Related to Regulatory Matters

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

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

The time required to obtain approval by the FDA to market a new therapy is unpredictable but typically takes many years and depends upon many factors, including the substantial discretion of the regulatory authorities.

The ELAD System could fail to receive regulatory approval for many reasons, including the following:

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

The FDA expressed concern with our past phase 3 clinical trial, VTI-208, that if there are significant differences in how the ELAD and control subjects are treated during the study and after discharge from the hospital, the study may not be able to provide convincing evidence of safety and efficacy. Differences in length of hospital stay, rates of hospital re-admission, alcohol recidivism rates, nutritional support, and concomitant medications could significantly confound the VTL-308 study results.

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

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

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

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

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

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

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

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

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

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

If any ELAD System product receives regulatory approval, we will be subject to significant ongoing regulation by the FDA and other regulatory authorities, including regulation of our manufacturing operations and any third-party manufacturing operations for compliance with applicable current Good Manufacturing Practices, or cGMP, and/or Quality System Regulation, or QSR, post-approval clinical data, adverse event reporting and complaint handling, and advertising and promotional activities. Failure to comply with regulatory requirements may subject us to sanctions. These may include warning letters, adverse publicity, civil and criminal penalties, injunctions, product seizures or detention, and refusal to approve pending product marketing applications.

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in fraudulent conduct 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 or (6) the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA. Sales, marketing 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. 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 our clinical trials or clinical manufacturing or civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to the Medical Device Components of the ELAD System

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

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

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

The ELAD System bedside unit was originally based exclusively on the 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 Sorin's S3 system. However, Sorin stopped selling the S3 system and replaced it with an updated S5 system. We have carried out testing of an ELAD System bedside unit based on the S5 and we believe that the S3 and S5 systems are equivalent and interchangeable from a clinical and regulatory perspective. We have submitted information to both the U.S. and the European regulatory authorities to support equivalence. Both the S3 and S5 systems were used in our VTI-208 and VTI-210 clinical trials and both are being used in our VTL-308 clinical trial. There can be no assurance that regulatory authorities will continue to view the S3 and S5 systems interchangeably, or that Sorin 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 Sorin fails to provide the information necessary for inclusion in our regulatory filings, approval of our ELAD System may be significantly delayed or prevented. In addition, we have been notified that Sorin will only support its S3 systems through 2017. Accordingly, if our trial is successful, we would expect to commercialize ELAD with only the Sorin 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 System, or Terumo. In March 2011, Terumo entered into a consent decree with the FDA which limited its ability to ship products from certain of its manufacturing facilities including the one that manufactures the component we use. We received notice from Terumo in June 2016 that all restrictions listed in the 2011 consent decree were lifted. If we were unable to source the component we use from Terumo, we would have to source the component from an alternative supplier. If Terumo or another component supplier has similar issues in the future, there is no guarantee that a qualified alternative supplier can be found that will agree to terms reasonably acceptable to us on a timely basis or at all.

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

The device components of the ELAD System will be reviewed as part of any BLA for the ELAD System. If the manufacturers of those components make modifications, discontinue supplying or are unable to supply sufficient quantities of such components during our 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 had an issue sourcing a raw material that is used in the manufacturing of tubing, which is a component of the ELAD System. If we had not been able to obtain sufficient quantities of this tubing on a timely basis, we would have had to delay enrollment in our clinical trials until additional supplies became available, or we would have been required to validate an alternative tubing to use, which could have delayed our clinical trials and increased our costs. If the FDA or any other regulatory body fails to approve use of those modified or replacement devices, takes significant enforcement action against the manufacturer or if we are unable to validate a replacement component, we would not be able to complete our clinical trials or, in the future, we might not be able to market or could have to suspend marketing of the ELAD System in certain jurisdictions.

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

Most device components of the ELAD System have been previously cleared for use by the FDA or other regulatory authorities. However, in some instances, we will be using the components outside the scope of their cleared indications. Other device components have no regulatory approvals. We may need to conduct additional testing to bridge the differences between the cleared indications for use and the proposed use in the ELAD System in order to obtain approval, or we could be required to obtain separate clearance for one or more of the components used in the ELAD System. The failure to provide adequate bridging information or to obtain separate clearance of these device components for use in the ELAD System, if required, could delay or prevent approval of the ELAD System.

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

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

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

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

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

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

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

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

We manufacture and assemble the ELAD System at our facility in San Diego, California. No other manufacturing or assembly facilities are currently available to us, and any additional manufacturing or assembly facilities that we use will need to be qualified and approved by regulatory authorities prior to our use. Our facility and the equipment we use to manufacture the ELAD System would be costly to replace and could require substantial lead-time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our research, development and manufacturing for some period of time. The inability to perform our research, development and manufacturing activities, combined with our limited inventory of reserve raw materials and manufactured supplies, may result in the delay of clinical trials or, if approved for sale, the loss of customers, or harm our reputation, and we may be unable to reestablish relationships with those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the ELAD System's Future Commercialization

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

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

- delays in receipt of anticipated purchase orders;
- our ability to recruit, train and retain sales, marketing, training and support personnel;

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

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

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

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

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

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

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

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

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

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

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

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

Furthermore, while we have entered into employment letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. It can be challenging to retain qualified personnel, and, considering the failure of VTI-208, it may be more difficult to recruit personnel in the future. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede our ability to identify and execute on our strategy.

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

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

It has been reported that an academic team in China is planning to initiate a Phase 1 clinical study of a human cell-based bioartificial liver support system in subjects with acute liver failure. Additionally, a number of companies have performed research work on various human hepatocyte cell lines, and several academic researchers and companies are actively pursuing animal research in this area. Companies have also attempted to develop extracorporeal therapy based upon primary porcine hepatocytes and may be in early stage clinical studies with pig-cell based systems designed for the treatment of liver failure. Other than noted above, we are not aware of other entities being close to undergoing human clinical trials with a human cell-based product for the treatment of liver failure; however, it is possible that these trials are occurring without our knowledge, and that such a product may get to market much faster than we expect.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Doing Business Internationally

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

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

In the event that we receive marketing approval in foreign countries outside of the U.S. and Europe, we currently anticipate, in most cases, creating wholly-owned subsidiaries in those countries. These subsidiaries will need to build an effective sales, marketing, distribution, training and support staff and system, find an effective marketing partner or both. Any internal sales, marketing, training and support capabilities of the subsidiaries will need to be developed by these subsidiaries and will need to be built from scratch. The culture and accepted practices related to selling medical products in many foreign countries are unique, and it is possible that we will not be able to successfully penetrate these markets. A similar consideration applies to selling in the U.S., since each medical system is very different and requires a different strategic approach. We cannot guarantee that our approach to the U.S., European, Chinese or any other international market will be effective.

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

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

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

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

- fluctuations in foreign currency exchange rates and controls;
- 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 or other hostilities; and
- laws and policies of the U.S. and foreign governments affecting foreign trade and investment.

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

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

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

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

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

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

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

We have limited business insurance coverage internationally.

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

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

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

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

We are subject to income and other taxes in the U.S. and may be subject to income and other taxes in various other foreign jurisdictions. Significant planning is required in evaluating a worldwide provision for income and other taxes. During the ordinary course of business, there may be transactions for which the ultimate tax determination is uncertain. We may be subject to audit in various jurisdictions and such jurisdictions may assess additional income or other tax against us. Although we 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 beginning to determine the future terms of the United Kingdom's relationship with the European Union, including, among other things, the terms of trade between the United Kingdom and the European Union as well as other world trading partners. The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to European Union markets either during a transitional period or more permanently. Brexit could adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets, including volatility in the value of the sterling and euro. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replace or replicate, including laws that could impact our clinical trials and our ability to obtain approval of our products or sell our products in the United Kingdom. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, results of operations, financial condition and cash flows.

Risks Related to Intellectual Property

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

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

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

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

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

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

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

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

Ownership of our intellectual property may be claimed by others.

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

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

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

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

Competing products may also appear in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, we could be prevented from marketing our ELAD System in one or more countries.

In addition, we may hereafter become involved in litigation to protect our trademark rights associated with our company name or the names used with our ELAD System. Names used with our ELAD System and procedures may be claimed to infringe names held by others or to be ineligible for proprietary protection. If we have to change the name of our company or our ELAD System, we may experience a loss in goodwill associated with our brand name, customer confusion and a loss of sales.

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

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

Risks Related to Our Capital Requirements and Finances

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

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

Enrollment in our VTL-308 clinical trial could take longer than we expect resulting in the need for additional funds.

While we expect the VTL-308 clinical trial to enroll subjects at a rate similar to VTI-208, it is possible that the changes in enrollment criteria will result in slow enrollment and that we will need to raise more capital than anticipated to complete the trial or that we will exhaust our funds and the company will fail.

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

We may need to raise substantial additional capital to:

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

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

- market acceptance of our products;
- the cost of our research and development activities;
- the cost and timing of our clinical development activities, in particular the rate of initiation of our clinical sites, the rate of enrollment of our clinical trials and the need for any additional clinical trials;
- 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;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no significant commitments or agreements relating to any of these types of transactions.

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

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

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

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

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

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

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

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

Risks Related to Being a Public Company

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

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

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

For as long as we remain an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and shareholder approval of any golden parachute payments not previously approved. We will take advantage of these reporting exemptions until we are no longer an "emerging growth company."

We may remain an “emerging growth company” until as late as December 31, 2019 (the fiscal year-end following the fifth anniversary of the completion of our initial public offering), though we may cease to be an “emerging growth company” earlier under certain circumstances, including (i) if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30, in which case we would cease to be an “emerging growth company” as of the following December 31, or (ii) if our gross revenue exceeds $1 billion in any fiscal year.

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

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

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

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the 2016 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 financial statements will not be prevented or detected on a timely basis.

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

Risks Related to our Common Stock

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

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

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

The market price of our common stock has been and is likely to continue to be highly volatile. Since our initial public offering in April 2014 at a price of $12.00 per share, the sale price of stock as reported on The NASDAQ Global Market has ranged from $2.81 to $35.20, through April 30, 2017. Our announcement in 2015 that the VTI-208 clinical trial failed to meet its primary or secondary endpoints resulted in a significant decline in the market price of our common stock. In addition, as with any public company, some investors hold a short position in our common stock. Such investors have published and distributed information about our company including on current and past clinical trials. Activities by these investors may increase the volatility of the market price of our common stock, and may affect our ability to raise additional funds and to complete our clinical trials and operations.

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

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

- quarterly variations in our or our competitors' results of operations;
- developments in our industry; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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

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

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

In May 2015, we filed a shelf registration statement that permitted: (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 $75.0 million of our common stock that may be issued and sold under an "at-the-market" sales agreement with Cantor Fitzgerald & Co., or the ATM. In October 2015, we completed a follow-on public offering raising gross proceeds of $34.5 million under the shelf registration statement. During the year ended December 31, 2016, we raised gross proceeds of $12.2 million pursuant to the ATM. In March 2017, we completed an additional follow-on public offering raising gross proceeds of $40.3 million from the sale of 10.1 million shares leaving $113.1 million available under the shelf registration statement, $62.8 million of which may be offered, issued and sold under the ATM.

In addition, we have filed registration statements on Form S-8 registering a total of 5,384,695 shares of common stock subject to options or reserved for future issuance under our 2012 Stock Option Plan and 2014 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 March 31, 2017, options to purchase 3,039,736 shares of our common stock were exercisable.

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

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

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

Our officers, directors and their affiliates collectively control approximately 27.6% of our outstanding common stock, and in particular, one stockholder and his affiliates control approximately 25.8% of our outstanding common stock as of March 31, 2017. As a result, these stockholders, if they act together, will be able to exert substantial influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

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

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

Anti-takeover provisions in our amended and restated certificate of incorporation, amended and restated bylaws, and Fourth Amended and Restated Investors' Rights Agreement, as well as Delaware law, could discourage a takeover.

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

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

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

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

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

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

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

During the three months ended March 31, 2017, we did not have any sales of unregistered securities.

Item 6. Exhibits

Exhibit Number	Exhibit Title
10.18	Standard Industrial/Commercial Multi-Tenant Lease between R.E. Hazard Contracting Company and the Registrant, dated May 5, 2017.
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: May 9, 2017 By: /s/ Michael V. Swanson

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

Exhibit 10.18

INDUSTRIAL/COMMERCIAL MULTI-TENANT LEASE – NET DATED OCTOBER 18, 2016 BY AND BETWEEN VITAL THERAPIES, INC., A DELAWARE CORPORATION AND R.E. HAZARD CONTRACTING COMPANY, A CALIFORNIA CORPORATION

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INDUSTRIAL/COMMERCIAL MULTI-TENANT LEASE – NET

1. BASIC PROVISIONS

1.1 Parties

This Lease ("Lease"), dated for reference purposes only October 18, 2016, is made by and between R.E. Hazard Contracting Company, a California corporation ("Lessor") and Vital Therapies, Inc., a Delaware corporation ("Lessee"), (collectively the "Parties", or individually a "Party").

1.2 Premises and Parking

1.2.1 That certain portion of the Project (as defined below), including all improvements therein or to be provided by Lessor under the terms of this Lease, commonly known by the street address of 15222 Avenue of the Science, Suite B, located in the City of San Diego, County of San Diego, State of California, as outlined on Exhibit A attached hereto ("Premises"), and which is comprised of an agreed upon 18,134 rentable square feet.

1.2.2 In addition to Lessee's rights to use and occupy the Premises as hereinafter specified, Lessee shall have non-exclusive rights to the Common Areas (as defined in Section 2.7 below), but shall not have any rights to the roof, or exterior walls of any buildings in the Project. The Premises, the Common Areas, the land upon which they are located, along with all buildings and improvements thereon, are herein collectively referred to as the "Project," which is comprised of an agreed upon 30,948 rentable square feet (See also Section 1.14.)

1.2.3 Except as expressly provided herein, surface parking is provided free of charge with unassigned parking spaces, on first come first served basis. No vehicle maintenance shall be performed in the Project. (See also Section 2.6.)

1.3 Term

The term of the lease shall be sixty (60) months ("Original Term") commencing July 1, 2017 ("Commencement Date") and ending June 30, 2022 ("Expiration Date"). (See also Section 3.)

1.4 Early Possession

[Not applicable – intentionally omitted.]

1.5 Base Rent

Lessee shall pay Lessor $32,641.20 per month ("Base Rent"), payable on the first day of each month commencing July 1, 2017. Base Rent shall be adjusted during the Original Term as follows:

Months 1 – 12 (July 1, 2017 – June 30, 2018)	$32,641.20
Months 13 – 24 (July 1, 2018 – June 30, 2019)	$33,620.44
Months 25 – 36 (July 1, 2019 – June 30, 2020)	$34,629.05
Months 37 – 48 (July 1, 2020 – June 30, 2021)	$35,667.92
Months 49 – 60 (July 1, 2021 – June 30, 2022)	$36,737.96

Base Rent shall be abated and shall not be payable during month one and month 31 of the Original Term, provided however that during any month for which rent is abated, the remaining terms of this Lease shall remain in full force and effect.

Base Rent shall be payable as set forth in Section 4.

1.6 Lessee's Share of Common Area Operating Expenses

"Lessee's Share" of Common Area Operating Expenses pertaining to the Project shall be the percentage that the rentable square footage of the Premises is of the total rentable square footage of the Project as set forth in Section 1.2.2 (currently 58.595%%).

In the event that the rentable square footage of the Premises, the Building and/or the Project are modified by the Lessor during the term of this Lease, Lessor shall recalculate Lessee's Share to reflect such modification.

1.7 Base Rent and Other Monies Payable Upon Execution

a. Base Rent: $32,641.20 for the period of August 1 – 31, 2017.

b. Lessee's Share of Operating Expenses: $4,000 for the period from July 1, 2017 – August 31, 2017.

c. Security Deposit: $36,737.96 ("Security Deposit"). (See also Section 5)

d. Total Due Upon Execution of this Lease: $73,379.16.

1.8 Agreed Use

General pharmaceutical manufacturing and related research and development and office space. (See also Section 6)

1.9 Insuring Party

Lessor is the "Insuring Party." (See also Section 9)

1.10 Guarantor

[Not applicable – intentionally omitted.]

1.11 Options

Lessor hereby grants Lessee the Option to extend the term of this Lease for one five-year term, provided that Lessee is not in Default under this Lease either at the time it elects to exercise an Option, or at the commencement date of the extension period as applicable. See also Section 19 for additional Option terms.

1.12 Real Estate Brokers

[Not applicable – intentionally omitted.]

1.13 Attachments

Attached hereto are the following, all of which constitute a part of this Lease:

Exhibit A – "Site Plan of the Premises"

Exhibit B – "Tenant Improvements" - [Not applicable – intentionally omitted.]

Exhibit C – "Guaranty" - [Not applicable – intentionally omitted.]

Exhibit D – "Estoppel Certificate"

1.14 Right to Negotiate Additional Lease

Lessee shall have the right to negotiate a lease with respect to the premises located at 15222 Avenue of Science, Suite A, within the Project (the "Expansion Space"), if the Expansion Space becomes available at any time during the term of this Lease. (See also Section 21.)

2. PREMISES

2.1 Letting

Lessor hereby leases to Lessee, and Lessee hereby leases from Lessor, the Premises, for the term, at the rental, and upon all of the terms, covenants and conditions set forth in this Lease. While the approximate square footage of the Premises may have been used in the marketing of the Premises for purposes of comparison, the Base Rent stated herein is NOT tied to square footage and is not subject to adjustment should the actual size be determined to be different. NOTE: Lessee is advised to verify the actual size prior to executing this Lease.

2.2 Condition

Lessor shall deliver the Premises ("Unit") to Lessee broom clean and free of debris on the Commencement Date or the Early Possession Date, whichever first occurs ("Start Date"), and, so long as the required service contracts described in Section 8.1.2 below are obtained by Lessee and in effect within thirty days following the Start Date, warrants that the existing electrical, plumbing, fire sprinkler, lighting, heating, ventilating and air conditioning systems ("HVAC"), loading doors, sump pumps, if any, and all other such elements in the Unit, other than those constructed by Lessee, shall be in good operating condition on said date, that the structural elements of the roof, bearing walls and foundation of the Unit shall be free of material defects, and that the Unit does

not contain hazardous levels of any mold or fungi defined as toxic under applicable state or federal law. If a non-compliance with such warranty exists as of the Start Date, or if one of such systems or elements should malfunction or fail within the appropriate warranty period, Lessor shall, as Lessor's sole obligation with respect to such matter, except as otherwise provided in this Lease, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such non-compliance, malfunction or failure, rectify same at Lessor's expense. The warranty periods shall be as follows: (i) three months as to the HVAC systems, and (ii) 30 days as to the remaining systems and other elements of the Unit. If Lessee does not give Lessor the required notice within the appropriate warranty period, correction of any such non-compliance, malfunction or failure shall be the obligation of Lessee at Lessee's sole cost and expense (except for the repairs to the fire sprinkler systems, roof, foundations, and/or bearing walls - see Section 8).

2.3 Compliance

Lessor warrants that to the best of its knowledge the improvements on the Premises comply with the building codes that were in effect at the time that each such improvement, or portion thereof, was constructed, and also with all applicable laws, covenants or restrictions of record, regulations, and ordinances in effect on the Start Date ("Applicable Requirements"). Said warranty does not apply to the use to which Lessee will put the Premises, modifications which may be required by the Americans with Disabilities Act or any similar zoning or other laws as a result of Lessee's use (see Section 20.27), or to any Alterations or Utility Installations (as defined in Section 8.3.1) made or to be made by Lessee. If the Premises do not comply with said warranty, Lessor shall, except as otherwise provided, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such non-compliance rectify the same at Lessor's expense. If Lessee does not give Lessor written notice of a non-compliance with this warranty within six months following the Start Date, correction of that non-compliance shall be the obligation of Lessee at Lessee's sole cost and expense. If the Applicable Requirements are hereafter changed so as to require during the term of this Lease the construction of an addition to or an alteration of the Unit and/or the Premises, the remediation of any Hazardous Substance, or the reinforcement or other physical modification of the Unit or Premises ("Capital Expenditure"), Lessor and Lessee shall allocate the cost of such work as set forth in this section.

NOTE: Lessee is responsible for determining whether or not the Applicable Requirements and especially the zoning are appropriate for Lessee's intended use, and acknowledges that past uses of the Premises may no longer be allowed.

2.3.1 Subject to Section 2.3.3 below, if such Capital Expenditures are required as a result of the specific and unique use of the Premises by Lessee as compared with uses by tenants in general, Lessee shall be fully responsible for the cost thereof.

2.3.2 If such Capital Expenditure is not the result of the specific and unique use of the Premises by Lessee (such as, governmentally mandated seismic modifications), then Lessor shall pay for such Capital Expenditure and Lessee shall only be obligated to pay, each month during the remainder of the term of this Lease or any extension thereof, on the date that on which the Base Rent is due, an amount equal to the Lessee's Share of the costs multiplied by a fraction, the numerator of which shall be one (1) and the denominator of which shall be the number of months over which the capital expenditure may be depreciated by the Lessor for income tax purposes.

2.3.3 Notwithstanding the above, the provisions concerning Capital Expenditures are intended to apply only to non-voluntary, unexpected, and new Applicable Requirements. If the Capital Expenditures are instead triggered by Lessee as a result of an actual or proposed change in use, change in intensity of use, or modification to the Premises then, and in that event, Lessee shall either: (i) immediately cease such changed use or intensity of use and/or take such other steps as may be necessary to eliminate the requirement for such Capital Expenditure, or (ii) complete such Capital Expenditure at its own expense. Lessee shall not have any right to terminate this Lease.

2.4 Acknowledgements

Lessee acknowledges that: (a) it has been given an opportunity to inspect and measure the Premises, (b) it has been advised by Lessor to satisfy itself with respect to the size and condition of the Premises (including but not limited to the electrical, HVAC and fire sprinkler systems, security, environmental aspects, and compliance with Applicable Requirements and the Americans with Disabilities Act), and their suitability for Lessee's intended use, (c) Lessee has made such investigation as it deems necessary with reference to such matters and assumes all responsibility therefor as the same relate to its occupancy of the Premises, (d) it is not relying on any representation as to the size of the Premises made by Lessor, (e) the square footage of the Premises was not material to Lessee's decision to lease the Premises and pay the Rent stated herein, and (f) neither Lessor, Lessor's agents, nor Brokers have made any oral or written representations or warranties with respect to said matters other than as set forth in this Lease.

2.5 Lessee as Prior Owner/Occupant

The warranties made by Lessor in Section 1.14 shall be of no force or effect if immediately prior to the Start Date Lessee was the owner or occupant of the Premises. In such event, Lessee shall be responsible for any necessary corrective work.

2.6 Vehicle Parking

Lessee shall be entitled to use unreserved Parking Spaces in the Common Areas designated from time to time by Lessor for parking. Except for the two storage containers maintained by Lessee in the parking area, said parking spaces shall be used for parking by vehicles no larger than full-size passenger automobiles or pick-up trucks, herein called "Permitted Size Vehicles." Lessor may regulate the loading and unloading of vehicles by adopting Rules and Regulations as provided in Section 2.9. No vehicles other than Permitted Size Vehicles may be parked in the Common Area without the prior written permission of Lessor. In addition:

2.6.1 Lessee shall not permit or allow any vehicles that belong to or are controlled by Lessee or Lessee's employees, suppliers, shippers, customers, contractors or invitees to be loaded, unloaded, or parked in areas other than those designated by Lessor for such activities.

2.6.2 Lessee shall not service or store any vehicles in the Common Areas (except for the two storage containers referenced above).

2.6.3 If Lessee permits or allows any of the prohibited activities described in this Section 2.6, then Lessor shall have the right, without notice, in addition to such other rights and remedies that it may have, to remove or tow away the vehicle involved and charge the cost to Lessee, which cost shall be immediately payable upon demand by Lessor.

2.7 Common Areas – Definition

The term “Common Areas” is defined as all areas and facilities outside the Premises and within the exterior boundary line of the Project and interior utility raceways and installations within the Unit that are provided and designated by the Lessor from time to time for the general non-exclusive use of Lessor, Lessee and other tenants of the Project and their respective employees, suppliers, shippers, customers, contractors and invitees, including parking areas, loading and unloading areas, trash areas, roadways, walkways, driveways and landscaped areas.

2.8 Common Areas - Lessee’s Rights

Lessor grants to Lessee, for the benefit of Lessee and its employees, suppliers, shippers, contractors, customers and invitees, during the term of this Lease, the non-exclusive right to use, in common with others entitled to such use, the Common Areas as they exist from time to time, subject to any rights, powers, and privileges reserved by Lessor under the terms hereof or under the terms of any rules and regulations or restrictions governing the use of the Project. Under no circumstances shall the right herein granted to use the Common Areas be deemed to include the right to store any property, temporarily or permanently, in the Common Areas. Any such storage shall be permitted only by the prior written consent of Lessor or Lessor’s designated agent, which consent may be revoked at any time. (Lessor previously consented to the placement of two storage containers in the parking area, which consent has not been revoked.) In the event that any unauthorized storage shall occur, then Lessor shall have the right, without notice, in addition to such other rights and remedies that it may have, to remove the property and charge the cost to Lessee, which cost shall be immediately payable upon demand by Lessor. Lessee acknowledges that all driveways, parking and loading areas (not including loading docks) in the Project are to be used in common with other tenants in the Project, and their guests, customers, and suppliers, and that none of said areas are for the exclusive use of Lessee.

2.9 Common Areas - Rules and Regulations

Lessor or such other person(s) as Lessor may appoint shall have the exclusive control and management of the Common Areas and shall have the right, from time to time, to establish, modify, amend and enforce reasonable rules and regulations (“Rules and Regulations”) for the management, safety, care, and cleanliness of the grounds, the parking and unloading of vehicles and the preservation of good order, as well as for the convenience of other occupants or tenants of the Project and their invitees. Lessee agrees to abide by and conform to all such Rules and Regulations, and shall use its best efforts to cause its employees, suppliers, shippers, customers, contractors and invitees to so abide and conform. Lessor shall not be responsible to Lessee for the non-compliance with said Rules and Regulations by other tenants of the Project.

2.10 Common Areas – Changes

Lessor shall have the right, in Lessor’s sole discretion, from time to time:

2.10.1 To make changes to the Common Areas, including, without limitation, changes in the location, size, shape and number of driveways, entrances, parking spaces, parking areas, loading and unloading areas, ingress, egress, direction of traffic, landscaped areas, walkways and utility raceways;

2.10.2 To close temporarily any of the Common Areas for maintenance purposes so long as reasonable access to the Premises remains available;

2.10.3 To use the Common Areas while engaged in making additional improvements, repairs or alterations to the Project, or any portion thereof; and

2.10.4 To do and perform such other acts and make such other changes in, to or with respect to the Common Areas and Project as Lessor may, in the exercise of sound business judgment, deem to be appropriate.

3. TERM

3.1 Term

The Commencement Date, Expiration Date and Original Term of this Lease are as specified in Section 1.3.

3.2 Early Possession

[Not applicable – intentionally omitted.]

3.3 Delay In Possession

[Not applicable – intentionally omitted.]

3.4 Lessee Compliance

Lessor shall not be required to tender possession of the Premises to Lessee until Lessee complies with its obligation to provide evidence of insurance (Section 9.5). Pending delivery of such evidence, Lessee shall be required to perform all of its obligations under this Lease from and after the Start Date, including the payment of Rent, notwithstanding Lessor's election to withhold possession pending receipt of such evidence of insurance. Further, if Lessee is required to perform any other conditions prior to or concurrent with the Start Date, the Start Date shall occur but Lessor may elect to withhold possession until such conditions are satisfied.

4. RENT

4.1 Rent Defined

All monetary obligations of Lessee to Lessor under the terms of this Lease (except for the Security Deposit) are deemed to be rent ("Rent").

4.2 Common Area Operating Expenses

Lessee shall pay to Lessor during the term hereof, in addition to the Base Rent, Lessee's Share (as specified in Section 1.6) of the Common Area Operating Expenses, as hereinafter defined, during each calendar year of the term of this Lease, in accordance with the following:

4.2.1 The following costs relating to the ownership and operation of the Project are defined as "Common Area Operating Expenses":

(a) Costs relating to the operation, repair and maintenance, in neat, clean, good order and condition of the following:

(1) The Common Areas and Common Area improvements, including parking areas, loading and unloading areas, trash areas, roadways, parkways, walkways, driveways, landscaped areas, bumpers, irrigation systems, Common Area lighting facilities, fences and gates, elevators, roofs, exterior walls of the buildings, building systems and roof drainage systems.

(2) Exterior signs and any tenant directories.

(3) Any fire sprinkler systems.

(4) All other areas and improvements that are within the exterior boundaries of the Project but outside of the Premises and/or any other space occupied by a tenant.

(b) The cost of water, gas, electricity and telephone to service the Common Areas and any utilities not separately metered.

(c) The cost of trash disposal, pest control services, property management, security services, owners' association dues and fees, the cost to repaint the exterior of any structures and the cost of any environmental inspections.

(d) Reserves set aside for maintenance and repair of Common Areas and Common Area equipment.

(e) Real Property Taxes (as defined in Section 11).

(f) Any Insurance Premiums (as defined in Section 9.1).

(g) Any deductible portion of an insured loss concerning the Project or the Common Areas.

(h) Auditors', accountants' and attorneys' fees and costs related to the operation, maintenance, repair and replacement of the Project.

(i) The cost of any capital improvement to the Project not covered under the provisions of Section 2.3, provided however, that the monthly amount payable during the remainder of the term of this Lease or any extension thereof shall be limited to Lessee's Share of such capital expenditure, multiplied by a fraction, the numerator of which shall be one (1) and the denominator of which shall be the number of months over which the capital expenditure may be depreciated by the Lessor for income tax purposes.

(j) The cost of janitorial services for non-leasable areas.

(k) Costs for Lessor's management, accounting, bookkeeping, payment of Common Area Operating Expenses, collection of reimbursements and related services, which shall not cumulatively exceed five percent (5%) of total Common Area Operating Expenses on an annual basis.

(l) The cost of any other services to be provided by Lessor that are stated elsewhere in this Lease to be a Common Area Operating Expense.

4.2.2 Any Common Area Operating Expenses and Real Property Taxes that are specifically attributable to the Unit, or to any building in the Project or to the operation, repair and maintenance thereof, shall be allocated entirely to such Unit or other building. However, any Common Area Operating Expenses and Real Property Taxes that are not specifically attributable to any building or to the operation, repair and maintenance thereof, shall be equitably allocated by Lessor to all buildings in the Project.

4.2.3 The inclusion of the improvements, facilities and services set forth in Section 4.2.1 shall not be deemed to impose an obligation upon Lessor to either have said improvements or facilities or to provide those services unless the Project already has the same, Lessor already provides the services, or Lessor has agreed elsewhere in this Lease to provide the same or some of them.

4.2.4 Lessee's Share of Common Area Operating Expenses is payable monthly on the same day as the Base Rent is due hereunder. The amount of such payments shall be based on Lessor's estimate of the annual Common Area Operating Expenses, which is currently $2,000.00 per month, but is subject to modification at any time during the Term of this Lease. Within 60 days after written request (but not more than once each year) Lessor shall deliver to Lessee a reasonably detailed statement showing Lessee's Share of the actual Common Area Operating Expenses for the preceding year. If Lessee's payments during such year exceed Lessee's Share, Lessor shall credit the amount of such over-payment against Lessee's future payments. If Lessee's payments during such year were less than Lessee's Share, Lessee shall pay to Lessor the amount of the deficiency within 10 days after delivery by Lessor to Lessee of the statement.

4.2.5 Common Area Operating Expenses shall not include any expenses paid by any tenant directly to third parties, or as to which Lessor is otherwise reimbursed by any third party, other tenant, or insurance proceeds.

4.3 Payment

Lessee shall cause payment of Rent to be received by Lessor in lawful money of the United States, without offset or deduction (except as specifically permitted in this Lease), on or before the day on which it is due. In the event that any statement or invoice prepared by Lessor is inaccurate such inaccuracy shall not constitute a waiver and Lessee shall be obligated to pay the amount set forth in this Lease. Rent for any period during the term hereof which is for less than one full calendar month shall be prorated based upon the actual number of days of said month. Payment of Rent shall be made to Lessor at its address stated herein or to such other persons or place as Lessor may from time to time designate in writing. Acceptance of a payment which is less than the amount then due shall not be a waiver of Lessor's rights to the balance of such Rent, regardless of Lessor's endorsement of any check so stating. In the event that any check, draft, or other instrument of payment given by Lessee to Lessor is dishonored for any reason, Lessee agrees to pay to Lessor the sum of $25 in addition to any Late Charge and Lessor, at its option, may require all future Rent be paid by cashier's check. Payments will be applied first to accrued late charges and attorney's fees, second to accrued interest, then to Base Rent and Common Area Operating Expenses, and any remaining amount to any other outstanding charges or costs.

5. SECURITY DEPOSIT

Lessee shall deposit with Lessor upon execution hereof the Security Deposit as security for Lessee's faithful performance of its obligations under this Lease. If Lessee fails to pay Rent, or otherwise Defaults under this Lease (see Section 14.1), Lessor may use, apply or retain all or any portion of said Security Deposit for the payment of any amount already due Lessor, for Rents which will be due in the future, and/ or to reimburse or compensate Lessor for any liability, expense, loss or damage which Lessor may suffer or incur by reason thereof. If Lessor uses or applies all or any portion of the Security Deposit, Lessee shall within 10 days after written request therefor deposit monies with Lessor sufficient to restore said Security Deposit to the full amount required by this Lease. Should the Agreed Use be amended to accommodate a material change in the business of Lessee or to accommodate a sublessee or assignee, Lessor shall have the right to increase the Security Deposit to the extent necessary, in Lessor's reasonable judgment, to account for any increased wear and tear that the Premises may suffer as a result thereof. If a change in control of Lessee occurs during this Lease and following such change the financial condition of Lessee is, in Lessor's reasonable judgment, significantly reduced, Lessee shall deposit such additional monies with Lessor as shall be sufficient to cause the Security Deposit to be at a commercially reasonable level based on such change in financial condition. Lessor shall not be required to keep the Security Deposit separate from its general accounts. Within 30 days after the expiration or termination of this Lease, Lessor shall return that portion of the Security Deposit not used or applied by Lessor. No part of the Security Deposit shall be considered to be held in trust, to bear interest or to be prepayment for any monies to be paid by Lessee under this Lease.

6. USE

6.1 Use

Lessee shall use and occupy the Premises only for the Agreed Use, or any other legal use which is reasonably comparable thereto, and for no other purpose. Lessee shall not use or permit the use of the Premises in a manner that is unlawful, creates damage, waste or a nuisance, or that disturbs occupants of or causes damage to neighboring premises or properties. Other than guide, signal and Seeing Eye dogs, Lessee shall not keep or allow in the Premises any pets, animals, birds, fish, or reptiles.

6.2 Hazardous Substances

6.2.1 The term "Hazardous Substance" as used in this Lease shall mean any product, substance, or waste whose presence, use, manufacture, disposal, transportation, or release, either by itself or in combination with other materials expected to be on the Premises, is either: (i) potentially injurious to the public health, safety or welfare, the environment or the Premises, (ii) regulated or monitored by any governmental authority, or (iii) a basis for potential liability of Lessor to any governmental agency or third party under any applicable statute or common law theory. Hazardous Substances shall include, but not be limited to, hydrocarbons, petroleum, gasoline, and/or crude oil or any products, by-products or fractions thereof. Except as already consented by Lessor, Lessee shall not engage in any activity in or on the Premises which constitutes a Reportable Use of Hazardous Substances without the express prior written consent of Lessor and timely compliance (at Lessee's expense) with all Applicable Requirements. "Reportable Use" shall mean (i) the installation or use of any above or below ground storage tank, (ii) the generation, possession, storage, use, transportation, or disposal of a Hazardous Substance that requires a permit from, or with respect to which a report, notice, registration or business plan is required to be filed with, any governmental authority, and/or (iii) the presence at the Premises of a Hazardous Substance with respect to which any Applicable Requirements requires that a notice be given to

persons entering or occupying the Premises or neighboring properties. Notwithstanding the foregoing, Lessee may use any ordinary and customary materials reasonably required to be used in the normal course of the Agreed Use, ordinary office supplies (copier toner, liquid paper, glue, etc.) and common household cleaning materials, so long as such use is in compliance with all Applicable Requirements, is not a Reportable Use, and does not expose the Premises or neighboring property to any meaningful risk of contamination or damage or expose Lessor to any liability therefor. In addition, Lessor may condition its consent to any Reportable Use upon receiving such additional assurances as Lessor reasonably deems necessary to protect itself, the public, the Premises and/or the environment against damage, contamination, injury and/or liability, including, but not limited to, the installation (and removal on or before Lease expiration or termination) of protective modifications (such as concrete encasements) and/or increasing the Security Deposit.

6.2.2 If Lessee knows, or has reasonable cause to believe, that a Hazardous Substance has come to be located in, on, under or about the Premises, other than as previously consented to by Lessor, Lessee shall immediately give written notice of such fact to Lessor, and provide Lessor with a copy of any report, notice, claim or other documentation which it has concerning the presence of such Hazardous Substance.

6.2.3 Lessee shall not cause or permit any Hazardous Substance to be spilled or released in, on, under, or about the Premises (including through the plumbing or sanitary sewer system) and shall promptly, at Lessee's expense, comply with all Applicable Requirements and take all investigatory and/or remedial action reasonably recommended, whether or not formally ordered or required, for the cleanup of any contamination of, and for the maintenance, security and/or monitoring of the Premises or neighboring properties, that was caused or materially contributed to by Lessee, or pertaining to or involving any Hazardous Substance brought onto the Premises during the term of this Lease, by or for Lessee, or any third party.

6.2.4 Lessee shall indemnify, defend and hold Lessor, its agents, employees, lenders and ground lessor, if any, harmless from and against any and all loss of rents and/or damages, liabilities, judgments, claims, expenses, penalties, and attorneys' and consultants' fees arising out of or involving any Hazardous Substance brought onto the Premises by or for Lessee, including by any third party with whom Lessee has a contract (provided, however, that Lessee shall have no liability under this Lease with respect to underground migration of any Hazardous Substance under the Premises from areas outside of the Project not caused or contributed to by Lessee). Lessee's obligations shall include, but not be limited to, the effects of any contamination or injury to person, property or the environment created or suffered by Lessee, and the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease. No termination, cancellation or release agreement entered into by Lessor and Lessee shall release Lessee from its obligations under this Lease with respect to Hazardous Substances, unless specifically so agreed by Lessor in writing at the time of such agreement.

6.2.5 Except as otherwise provided in Section 9.7, Lessor and its successors and assigns shall indemnify, defend, reimburse and hold Lessee, its employees and lenders, harmless from and against any and all environmental damages, including the cost of remediation, which suffered as a direct result of Hazardous Substances on the Premises prior to Lessee taking possession or which are caused by the gross negligence or willful misconduct of Lessor, its agents or employees. Lessor's obligations, as and when required by the Applicable Requirements, shall

include, but not be limited to, the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease.

6.2.6 Lessor shall retain the responsibility and pay for any investigations or remediation measures required by governmental entities having jurisdiction with respect to the existence of Hazardous Substances on the Premises prior to Lessee taking possession, unless such remediation measure is required as a result of Lessee's use (including "Alterations", as defined in Section 8.3.1 below) of the Premises, in which event Lessee shall be responsible for such payment. Lessee shall cooperate fully in any such activities at the request of Lessor, including allowing Lessor and Lessor's agents to have reasonable access to the Premises at reasonable times in order to carry out Lessor's investigative and remedial responsibilities.

6.2.7 If a Hazardous Substance Condition (see Section 10.1.5) occurs during the term of this Lease, unless Lessee is legally responsible therefor (in which case Lessee shall make the investigation and remediation thereof required by the Applicable Requirements and this Lease shall continue in full force and effect, but subject to Lessor's rights under Section 6.2.4 and Section 14), Lessor may, at Lessor's option, either (i) investigate and remediate such Hazardous Substance Condition, if required, as soon as reasonably possible at Lessor's expense, in which event this Lease shall continue in full force and effect, or (ii) give written notice to Lessee, within 60 days after receipt by Lessor of knowledge of the occurrence of such Hazardous Substance Condition, of Lessor's desire to terminate this Lease as of the date 60 days following the date of such notice. In the event Lessor elects to give a termination notice, Lessee may, within 10 days thereafter, give written notice to Lessor of Lessee's commitment to pay the cost of the remediation of such Hazardous Substance Condition. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days following such commitment. In such event, this Lease shall continue in full force and effect, and Lessor shall proceed to make such remediation as soon as reasonably possible after the required funds are available. If Lessee does not give such notice and provide the required funds or assurance thereof within the time provided, this Lease shall terminate as of the date specified in Lessor's notice of termination.

6.3 Lessee's Compliance with Applicable Requirements

Except as otherwise provided in this Lease, Lessee shall, at Lessee's sole expense, fully, diligently and in a timely manner, materially comply with all Applicable Requirements, the requirements of any applicable fire insurance underwriter or rating bureau, and the recommendations of Lessor's engineers and/or consultants which relate in any manner to such Applicable Requirements, without regard to whether said Applicable Requirements are now in effect or become effective after the Start Date. Lessee shall, within 10 days after receipt of Lessor's written request, provide Lessor with copies of all permits and other documents, and other information evidencing Lessee's compliance with any Applicable Requirements specified by Lessor, and shall immediately upon receipt, notify Lessor in writing (with copies of any documents involved) of any threatened or actual claim, notice, citation, warning, complaint or report pertaining to or involving the failure of Lessee or the Premises to comply with any Applicable Requirements. Likewise, Lessee shall immediately give written notice to Lessor of: (i) any water damage to the Premises and any suspected seepage, pooling, dampness or other condition conducive to the production of mold; or (ii) any mustiness or other odors that might indicate the presence of mold in the Premises.

6.4 Inspection; Compliance

Lessor and Lessor's "Lender" (as defined in Section 18.1) and consultants shall have the right to enter into Premises at any time, in the case of an emergency, and otherwise at reasonable times after reasonable notice, for the purpose of inspecting the condition of the Premises and for verifying compliance by Lessee with this Lease. The cost of any such inspections shall be paid by Lessor, unless a violation of Applicable Requirements, or a Hazardous Substance Condition (see Section 10.1), is found to exist or be imminent, or the inspection is requested or ordered by a governmental authority. In such case, Lessee shall upon request reimburse Lessor for the cost of such inspection, so long as such inspection is reasonably related to the violation or contamination. In addition, Lessee shall provide copies of all relevant material safety data sheets (MSDS) to Lessor within 10 days of the receipt of written request therefor.

7. TENANT IMPROVEMENTS

[Not applicable – intentionally omitted.]

8. MAINTENANCE; REPAIRS; UTILITY INSTALLATIONS; TRADE FIXTURES AND ALTERATIONS

8.1 Lessee's Obligations

8.1.1 Subject to the provisions of Section 2.2 (Condition), 2.3 (Compliance), Section 2.5 (Lessee as Prior Owner/Occupant) 6.3 (Lessee's Compliance with Applicable Requirements), 8.2 (Lessor's Obligations), 10 (Damage or Destruction), and 15 (Condemnation), Lessee shall, at Lessee's sole expense, keep the Premises, Utility Installations (intended for Lessee's exclusive use, no matter where located), and Alterations in good order, condition and repair (whether or not the portion of the Premises requiring repairs, or the means of repairing the same, are reasonably or readily accessible to Lessee, and whether or not the need for such repairs occurs as a result of Lessee's use, any prior use, the elements or the age of such portion of the Premises), including, but not limited to, all equipment or facilities, such as plumbing, HVAC equipment, electrical, lighting facilities, boilers, pressure vessels, fixtures, interior walls, interior surfaces of exterior walls, ceilings, floors, windows, doors, plate glass, and skylights but excluding any items which are the responsibility of Lessor pursuant to Section 8.2. Lessee, in keeping the Premises in good order, condition and repair, shall exercise and perform good maintenance practices, specifically including the procurement and maintenance of the service contracts required by Section 8.1.2 below. Lessee's obligations shall include restorations, replacements or renewals when necessary to keep the Premises and all improvements thereon or a part thereof in good order, condition and state of repair.

8.1.2 Lessee shall, at Lessee's sole expense, procure and maintain contracts, with copies to Lessor, in customary form and substance for, and with contractors specializing and experienced in the maintenance of the following equipment and improvements, if any, if and when installed on the Premises: (i) HVAC equipment, (ii) boiler and pressure vessels, and (iii) clarifiers. However, Lessor reserves the right, upon notice to Lessee, to procure and maintain any or all of such service contracts, and Lessee shall reimburse Lessor, upon demand, for the cost thereof.

8.1.3 If Lessee fails to perform Lessee's obligations under this Section 8.1, Lessor may enter upon the Premises after 10 days' prior written notice to Lessee (except in the case of an emergency, in which case no notice shall be required), perform such obligations on Lessee's behalf, and put the Premises in good order, condition and repair, and Lessee shall promptly pay to Lessor a sum equal to the cost thereof.

8.1.4 Subject to Lessee's indemnification of Lessor as set forth in Section 9.7 below, and without relieving Lessee of liability resulting from Lessee's failure to exercise and perform good maintenance practices, if an item described in Section 8.1.2 cannot be repaired other than at a cost which is in excess of 50% of the cost of replacing such item, then such item shall be replaced by Lessor, and the cost thereof shall be prorated between the Parties.

8.2 Lessor's Obligations

Subject to the provisions of Sections 2.2 (Condition), 2.3 (Compliance), 4.2 (Common Area Operating Expenses), 6 (Use), 8.1 (Lessee's Obligations), 10 (Damage or Destruction) and 15 (Condemnation), Lessor, subject to reimbursement pursuant to Section 4.2, shall keep in good order, condition and repair the foundations, exterior walls, structural condition of interior bearing walls, exterior roof, fire sprinkler system, Common Area fire alarm and/or smoke detection systems, fire hydrants, parking lots, walkways, parkways, driveways, landscaping, fences, signs and utility systems serving the Common Areas and all parts thereof, as well as providing the services for which there is a Common Area Operating Expense pursuant to Section 4.2. Lessor shall be obligated to paint the exterior, but not the interior surfaces of exterior walls. Lessor shall not be obligated to maintain, repair or replace windows, doors or plate glass of the Premises. Lessee expressly waives the benefit of any statute now or hereafter in effect to the extent it is inconsistent with the terms of this Lease.

8.3 Utility Installations; Trade Fixtures; Alterations

8.3.1 The term "Utility Installations" refers to all floor and window coverings, air and/or vacuum lines, power panels, electrical distribution, security and fire protection systems, communication cabling, lighting fixtures, HVAC equipment, plumbing, and fencing in or on the Premises. The term "Trade Fixtures" shall mean Lessee's machinery and equipment that can be removed without doing material damage to the Premises. The term "Alterations" shall mean any modification of the improvements, other than Utility Installations or Trade Fixtures, whether by addition or deletion. "Lessee Owned Alterations and/or Utility Installations" are defined as Alterations and/or Utility Installations made by Lessee that are not yet owned by Lessor pursuant to Section 8.4.1.

8.3.2 Lessee shall not make any Alterations or Utility Installations to the Premises without Lessor's prior written consent. Lessee may, however, make non-structural Alterations or Utility Installations to the interior of the Premises (excluding the roof) without such consent but upon notice to Lessor, as long as they are not visible from the outside, do not involve puncturing, relocating or removing the roof or any existing walls, will not affect the electrical, plumbing, HVAC, and/or life safety systems, and the cumulative cost thereof during this Lease does not exceed a sum equal to three month's Base Rent in the aggregate or a sum equal to one month's Base Rent in any one year. Notwithstanding the foregoing, Lessee shall not make or permit any roof penetrations and/or install anything on the roof without the prior written approval of Lessor. Lessor may, as a precondition to granting such approval, require Lessee to also seek bids from contractor(s) chosen and/or approved by Lessor. Any Alterations or Utility Installations that Lessee shall desire to make and which require the consent of the Lessor shall be presented to Lessor in written form with detailed plans. Consent shall not be unreasonably withheld or delayed, but shall be deemed conditioned upon Lessee's: (i) acquiring all applicable governmental permits, (ii) furnishing Lessor with copies of both the permits and the plans and specifications prior to commencement of the work, and (iii) compliance with all conditions of said permits and other Applicable

Requirements in a prompt and expeditious manner. Any Alterations or Utility Installations shall be performed in a workmanlike manner with good and sufficient materials. Lessee shall promptly upon completion furnish Lessor with as-built plans and specifications. For work which costs an amount in excess of one month's Base Rent, Lessor may condition its consent upon Lessee providing a lien and completion bond in an amount equal to 150% of the estimated cost of such Alteration or Utility Installation and/or upon Lessee's posting an additional Security Deposit with Lessor.

8.3.3 Lessee shall pay, when due, all claims for labor or materials furnished or alleged to have been furnished to or for Lessee at or for use on the Premises, which claims are or may be secured by any mechanic's or materialmen's lien against the Premises or any interest therein. Lessee shall give Lessor not less than 10 days' notice prior to the commencement of any work in, on or about the Premises, and Lessor shall have the right to post notices of non-responsibility. If Lessee shall contest the validity of any such lien, claim or demand, then Lessee shall, at its sole expense defend and protect itself, Lessor and the Premises against the same and shall pay and satisfy any such adverse judgment that may be rendered thereon before the enforcement thereof. If Lessor shall require, Lessee shall furnish a surety bond in an amount equal to 125% of the amount of such contested lien, claim or demand, indemnifying Lessor against liability for the same.

8.4 Ownership; Removal; Surrender; and Restoration

8.4.1 Subject to Lessor's right to require removal or elect ownership as hereinafter provided, all Alterations and Utility Installations made by Lessee shall be the property of Lessee, but considered a part of the Premises. Lessor may, at any time, elect in writing to be the owner of all or any specified part of the Lessee Owned Alterations and Utility Installations. Unless otherwise instructed per Section 8.4.2 hereof, all Lessee Owned Alterations and Utility Installations shall, at the expiration or termination of this Lease, become the property of Lessor and be surrendered by Lessee with the Premises.

8.4.2 Lessor, unless otherwise agreed in writing, may require that any or all Lessee Owned Alterations or Utility Installations be removed by the expiration or termination of this Lease. Lessor may require the removal at any time of all or any part of any Lessee Owned Alterations or Utility Installations made without the required consent.

8.4.3 Lessee shall surrender the Premises by the Expiration Date or any earlier termination date, with all of the improvements, parts and surfaces thereof broom clean and free of debris, and in good operating order, condition and state of repair, ordinary wear and tear excepted. "Ordinary wear and tear" shall not include any damage or deterioration that would have been prevented by good maintenance practice. Notwithstanding the foregoing, if this Lease is for 12 months or less, then Lessee shall surrender the Premises in the same condition as delivered to Lessee on the Start Date with NO allowance for ordinary wear and tear. Lessee shall repair any damage occasioned by the installation, maintenance or removal of Trade Fixtures, Lessee owned Alterations and/or Utility Installations, furnishings, and equipment as well as the removal of any storage tank installed by or for Lessee. Lessee shall also completely remove from the Premises any and all Hazardous Substances brought onto the Premises by or for Lessee, or by any third party with which Lessee has a contract (except Hazardous Substances which were deposited via underground migration from areas outside of the Premises) even if such removal would require Lessee to perform or pay for work that exceeds statutory requirements. Trade Fixtures shall remain the property of Lessee and shall be removed by Lessee. Any personal property of Lessee not

removed on or before the Expiration Date or any earlier termination date shall be deemed to have been abandoned by Lessee and may be disposed of or retained by Lessor as Lessor may desire. The failure by Lessee to timely vacate the Premises pursuant to this Section 8.4.3 without the express written consent of Lessor shall constitute a holdover under the provisions of Section 20.9 below.

9. INSURANCE; INDEMNITY

9.1 Payment of Premiums

The cost of the premiums for the insurance policies to be carried by Lessor ("Insurance Premiums"), pursuant to Sections 9.2.2, 9.3.1 and 9.3.2 shall be a Common Area Operating Expense. Premiums for policy periods commencing prior to, or extending beyond, the term of this Lease shall be prorated to coincide with the corresponding Start Date or Expiration Date.

9.2 Liability Insurance

9.2.1 Carried by Lessee. Lessee shall obtain and keep in force a Commercial General Liability policy of insurance protecting Lessee and Lessor, as an additional insured, against claims for bodily injury, personal injury and property damage based upon or arising out of the ownership, use, occupancy or maintenance of the Premises and all areas appurtenant thereto. Such insurance shall be on an occurrence basis providing single limit coverage in an amount not less than $1,000,000 per occurrence with an annual aggregate of not less than $2,000,000. Lessee shall add Lessor and Cypress View Properties, Inc., as additional insureds by means of an endorsement at least as broad as the Insurance Service Organization's "Additional Insured-Managers or Lessors of Premises" Endorsement. The policy shall not contain any intra-insured exclusions as between insured persons or organizations, but shall include coverage for liability assumed under this Lease as an "insured contract" for the performance of Lessee's indemnity obligations under this Lease. The limits of said insurance shall not, however, limit the liability of Lessee nor relieve Lessee of any obligation hereunder. Lessee shall provide an endorsement on its liability policy(ies) that provides that its insurance shall be primary to and not contributory with any similar insurance carried by Lessor, whose insurance shall be considered excess insurance only.

9.2.2 Carried by Lessor. Lessor shall maintain liability insurance as described in Section 9.2.1, in addition to, and not in lieu of, the insurance required to be maintained by Lessee. Lessee shall not be named as an additional insured therein.

9.2.3 Carried by Lessee's Contractors. Unless otherwise agreed to in writing by Lessor, if Lessee engages a contractor ("Contractor") to perform work on the Premises, whether such work is a Tenant Improvement, Trade Fixture, Alteration or otherwise, the Contractor shall procure and maintain for the duration of the contract, insurance against claims for injuries to persons or damages to the Premises which may arise from or in connection with the performance of the work hereunder by the Contractor, his agents, representatives, employees, or subcontractors. Such insurance shall include Builder's Risk (Course of Construction) insurance utilizing an "All Risk" (Special Perils) coverage form, with limits equal to the completed value of the project and no coinsurance penalty provisions. The Lessor shall be named as Loss Payee for the Builder's Risk insurance.

9.3 Property Insurance - Building, Improvements and Rental Value

9.3.1 Lessor shall obtain and keep in force a policy or policies of insurance in the name of Lessor, with loss payable to Lessor, any ground-lessor, and to any Lender insuring loss or damage to the Premises. The amount of such insurance shall be equal to the full insurable replacement cost of the Premises, as the same shall exist from time to time, or the amount required by any Lender, but in no event more than the commercially reasonable and available insurable value thereof. If the coverage is available and commercially appropriate, such policy or policies shall insure against all types of direct physical loss or damage (except the perils of flood and/or earthquake unless required by a Lender), including coverage for debris removal and the enforcement of any Applicable Requirements requiring the upgrading, demolition, reconstruction or replacement of any portion of the Premises as the result of a covered loss. Said policy or policies shall also contain an agreed valuation provision in lieu of any coinsurance clause, waiver of subrogation, and inflation guard protection causing an increase in the annual property insurance coverage amount by a factor of not less than the adjusted U.S. Department of Labor Consumer Price Index for All Urban Consumers for the city nearest to where the Premises are located. Lessee Owned Alterations and Utility Installations, Trade Fixtures, and Lessee's personal property shall be insured by Lessee not by Lessor unless the item in question has become the property of Lessor under the terms of this Lease.

9.3.2 Lessor shall also obtain and keep in force a policy or policies in the name of Lessor with loss payable to Lessor and any Lender, insuring the loss of the full Rent for one year ("Rental Value Insurance"). Said insurance shall contain an agreed valuation provision in lieu of any coinsurance clause, and the amount of coverage shall be adjusted annually to reflect the projected Rent otherwise payable by Lessee, for the next 12-month period.

9.3.3 Lessee shall pay for any increase in the premiums for the property insurance of the Unit, and for the Common Areas or other buildings in the Project if said increase is caused by Lessee's acts, omissions, use or occupancy of the Premises.

9.4 Lessee's Property; Business Interruption Insurance; Worker's Compensation Insurance

9.4.1 Lessee shall obtain and maintain insurance coverage on all of Lessee's personal property, Trade Fixtures, and Lessee Owned Alterations and Utility Installations. Such insurance shall be full replacement cost coverage with a deductible of not to exceed $2,500 per occurrence. The proceeds from any such insurance shall be used by Lessee for the replacement of personal property, Trade Fixtures and Lessee Owned Alterations and Utility Installations.

9.4.2 Lessee shall obtain and maintain loss of income and extra expense insurance in amounts as will reimburse Lessee for direct or indirect loss of earnings attributable to all perils commonly insured against by prudent lessees in the business of Lessee or attributable to prevention of access to the Premises as a result of such perils.

9.4.3 Lessee shall obtain and maintain Worker's Compensation Insurance in such amount as may be required by Applicable Requirements. Such policy shall include a 'Waiver of Subrogation' endorsement. Lessee shall provide Lessor with a copy of such endorsement along with the certificate of insurance or copy of the policy required by Section 9.5.

9.4.4 Lessor makes no representation that the limits or forms of coverage of insurance specified herein are adequate to cover Lessee's property, business operations or obligations under this Lease.

9.5 Insurance Policies

Insurance required herein shall be by companies maintaining during the policy term a "General Policyholders Rating" of at least A-, VII, as set forth in the most current issue of "Best's Insurance Guide", or such other rating as may be required by a Lender. Lessee shall not do or permit to be done anything which invalidates the required insurance policies. Lessee shall provide, prior to the Start Date, certificates with copies of the required endorsements evidencing the existence and amounts of the required insurance. No such policy shall be cancelable except after 30 days prior written notice to Lessor, provided that a policy shall be cancelable after 10 days for non-payment of premium. Lessee shall, no more than 10 days after the expiration of such policies, furnish Lessor with evidence of renewals or "insurance binders" evidencing renewal thereof, or Lessor may order such insurance and charge the cost thereof to Lessee, which amount shall be payable by Lessee to Lessor upon demand. Such policies shall be for a term of at least one year, or the length of the remaining term of this Lease, whichever is less. If either Party shall fail to procure and maintain the insurance required to be carried by it, the other Party may, but shall not be required to, procure and maintain the same.

9.6 Waiver of Subrogation

Without affecting any other rights or remedies, Lessee and Lessor each hereby release and relieve the other, and waive their entire right to recover damages against the other, for loss of or damage to its property arising out of or incident to the perils required to be insured against herein. The effect of such releases and waivers is not limited by the amount of insurance carried or required, or by any deductibles applicable hereto. The Parties agree to have their respective property damage insurance carriers waive any right to subrogation that such companies may have against Lessor or Lessee, as the case may be, so long as the insurance is not invalidated thereby.

9.7 Indemnity

Except for Lessor's gross negligence or willful misconduct, Lessee shall indemnify, protect, defend and hold harmless the Premises, Lessor and its agents, Lessor's master or ground lessor, partners and Lenders, from and against any and all claims, loss of rents and/or damages, liens, judgments, penalties, attorneys' and consultants' fees, expenses and/or liabilities arising out of, involving, or in connection with, the use and/or occupancy of the Premises by Lessee. If any action or proceeding is brought against Lessor by reason of any of the foregoing matters, Lessee shall upon notice defend the same at Lessee's expense by counsel chosen by Lessee or its insurer and reasonably satisfactory to Lessor and Lessor shall cooperate with Lessee in such defense. Lessor need not have first paid any such claim in order to be defended or indemnified.

9.8 Exemption of Lessor and its Agents from Liability

Notwithstanding the negligence or breach of this Lease by Lessor or its agents, neither Lessor nor its agents shall be liable under any circumstances for: (i) injury or damage to the person or goods, wares, merchandise or other property of Lessee, Lessee's employees, contractors, invitees, customers, or any other person in or about the Premises, whether such damage or injury is caused by or results from fire, steam, electricity, gas, water or rain, indoor air quality, the presence of mold or from the breakage, leakage, obstruction or other defects of pipes, fire sprinklers, wires, appliances, plumbing, HVAC or lighting fixtures, or from any other cause, whether the said injury or damage results from conditions arising upon the Premises or upon other portions of the Project, or from other sources or places, (ii) any damages arising from any act or neglect of any other tenant

of Lessor or from the failure of Lessor or its agents to enforce the provisions of any other lease in the Project, or (iii) injury to Lessee's business or for any loss of income or profit therefrom. Instead, it is intended that Lessee's sole recourse in the event of such damages or injury be to file a claim on the insurance policy(ies) that Lessee is required to maintain pursuant to the provisions of Section 9.

9.9 Failure to Provide Insurance

Lessee acknowledges that any failure on its part to obtain or maintain the insurance required herein will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, for any month or portion thereof that Lessee does not maintain the required insurance and/or does not provide Lessor with the required binders or certificates evidencing the existence of the required insurance, the Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 15% of the then existing Base Rent or $200, whichever is greater. The parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to maintain the required insurance. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach (see Section 14.1) with respect to the failure to maintain such insurance, prevent the exercise of any of the other rights and remedies granted hereunder, nor relieve Lessee of its obligation to maintain the insurance specified in this Lease.

10. DAMAGE OR DESTRUCTION

10.1 Definitions

10.1.1 "Premises Partial Damage" shall mean damage or destruction to the improvements on the Premises, other than Lessee Owned Alterations and Utility Installations, which can reasonably be repaired in three months or less from the date of the damage or destruction, and the cost thereof does not exceed a sum equal to six month's Base Rent. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

10.1.2 "Premises Total Destruction" shall mean damage or destruction to the improvements on the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which cannot reasonably be repaired in three months or less from the date of the damage or destruction and/or the cost thereof exceeds a sum equal to six month's Base Rent. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

10.1.3 "Insured Loss" shall mean damage or destruction to improvements on the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which was caused by an event required to be covered by the insurance described in Section 9.3.1, irrespective of any deductible amounts or coverage limits involved.

10.1.4 "Replacement Cost" shall mean the cost to repair or rebuild the improvements owned by Lessor at the time of the occurrence to their condition existing immediately prior thereto, including demolition, debris removal and upgrading required by the operation of Applicable Requirements, and without deduction for depreciation.

10.1.5 “Hazardous Substance Condition” shall mean the occurrence or discovery of a condition involving the presence of, or a contamination by, a Hazardous Substance, in, on, or under the Premises which requires restoration.

10.2 Partial Damage - Insured Loss

If a Premises Partial Damage that is an Insured Loss occurs, then Lessor shall, at Lessor’s expense, repair such damage (but not Lessee’s Trade Fixtures or Lessee Owned Alterations and Utility Installations) as soon as reasonably possible and this Lease shall continue in full force and effect; provided, however, that Lessee shall, at Lessor’s election, make the repair of any damage or destruction the total cost to repair of which is $10,000 or less, and, in such event, Lessor shall make any applicable insurance proceeds available to Lessee on a reasonable basis for that purpose. Notwithstanding the foregoing, if the required insurance was not in force or the insurance proceeds are not sufficient to affect such repair, the Insuring Party shall promptly contribute the shortage in proceeds as and when required to complete said repairs. In the event, however, such shortage was due to the fact that, by reason of the unique nature of the improvements, full replacement cost insurance coverage was not commercially reasonable and available, Lessor shall have no obligation to pay for the shortage in insurance proceeds or to fully restore the unique aspects of the Premises unless Lessee provides Lessor with the funds to cover same, or adequate assurance thereof, within 10 days following receipt of written notice of such shortage and request therefor. If Lessor receives said funds or adequate assurance thereof within said 10 day period, the party responsible for making the repairs shall complete them as soon as reasonably possible and this Lease shall remain in full force and effect. If such funds or assurance are not received, Lessor may nevertheless elect by written notice to Lessee within 10 days thereafter to: (i) make such restoration and repair as is commercially reasonable with Lessor paying any shortage in proceeds, in which case this Lease shall remain in full force and effect, or (ii) have this Lease terminate 30 days thereafter. Lessee shall not be entitled to reimbursement of any funds contributed by Lessee to repair any such damage or destruction. Premises Partial Damage due to flood or earthquake shall be subject to Section 10.3, notwithstanding that there may be some insurance coverage, but the net proceeds of any such insurance shall be made available for the repairs if made by either Party.

10.3 Partial Damage - Uninsured Loss

If a Premises Partial Damage that is not an Insured Loss occurs, unless caused by a negligent or willful act of Lessee (in which event Lessee shall make the repairs at Lessee’s expense), Lessor may either: (i) repair such damage as soon as reasonably possible at Lessor’s expense, in which event this Lease shall continue in full force and effect, or (ii) terminate this Lease by giving written notice to Lessee within 30 days after receipt by Lessor of knowledge of the occurrence of such damage. Such termination shall be effective 60 days following the date of such notice. In the event Lessor elects to terminate this Lease, Lessee shall have the right within 10 days after receipt of the termination notice to give written notice to Lessor of Lessee’s commitment to pay for the repair of such damage without reimbursement from Lessor. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days after making such commitment. In such event this Lease shall continue in full force and effect, and Lessor shall proceed to make such repairs as soon as reasonably possible after the required funds are available. If Lessee does not make the required commitment, this Lease shall terminate as of the date specified in the termination notice.

10.4 Total Destruction

Notwithstanding any other provision hereof, if a Premises Total Destruction occurs, this Lease shall terminate 60 days following such Destruction. If the damage or destruction was caused by the gross negligence or willful misconduct of Lessee, Lessor shall have the right to recover Lessor's damages from Lessee, except as provided in Section 9.6.

10.5 Damage Near End of Term

If at any time during the last six months of this Lease there is damage for which the cost to repair exceeds one month's Base Rent, whether or not an Insured Loss, Lessor may terminate this Lease effective 60 days following the date of occurrence of such damage by giving a written termination notice to Lessee within 30 days after the date of occurrence of such damage. Notwithstanding the foregoing, if Lessee at that time has an exercisable option to extend this Lease or to purchase the Premises, then Lessee may preserve this Lease by, (a) exercising such option and (b) providing Lessor with any shortage in insurance proceeds (or adequate assurance thereof) needed to make the repairs on or before the earlier of (i) the date which is 10 days after Lessee's receipt of Lessor's written notice purporting to terminate this Lease, or (ii) the day prior to the date upon which such option expires. If Lessee duly exercises such option during such period and provides Lessor with funds (or adequate assurance thereof) to cover any shortage in insurance proceeds, Lessor shall, at Lessor's commercially reasonable expense, repair such damage as soon as reasonably possible and this Lease shall continue in full force and effect. If Lessee fails to exercise such option and provide such funds or assurance during such period, then this Lease shall terminate on the date specified in the termination notice and Lessee's option shall be extinguished.

10.6 Abatement of Rent; Lessee's Remedies

10.6.1 In the event of Premises Partial Damage or Premises Total Destruction or a Hazardous Substance Condition for which Lessee is not responsible under this Lease, the Rent payable by Lessee for the period required for the repair, remediation or restoration of such damage shall be abated in proportion to the degree to which Lessee's use of the Premises is impaired, but not to exceed the proceeds received from the Rental Value Insurance. All other obligations of Lessee hereunder shall be performed by Lessee, and Lessor shall have no liability for any such damage, destruction, remediation, repair or restoration except as provided herein.

10.6.2 If Lessor is obligated to repair or restore the Premises and does not commence, in a substantial and meaningful way, such repair or restoration within 90 days after such obligation shall accrue, Lessee may, at any time prior to the commencement of such repair or restoration, give written notice to Lessor and to any Lenders of which Lessee has actual notice, of Lessee's election to terminate this Lease on a date not less than 60 days following the giving of such notice. If Lessee gives such notice and such repair or restoration is not commenced within 30 days thereafter, this Lease shall terminate as of the date specified in said notice. If the repair or restoration is commenced within such 30 days, this Lease shall continue in full force and effect. "Commence" shall mean either the unconditional authorization of the preparation of the required plans, or the beginning of the actual work on the Premises, whichever first occurs.

10.7 Termination; Advance Payments

Upon termination of this Lease pursuant to Section 6.2.7 or Section 10, an equitable adjustment shall be made concerning advance Base Rent and any other advance payments made

by Lessee to Lessor. Lessor shall, in addition, return to Lessee so much of Lessee's Security Deposit as has not been, or is not then required to be, used by Lessor.

11. REAL PROPERTY TAXES

11.1 Definition of "Real Property Taxes"

As used herein, the term "Real Property Taxes" shall include any form of assessment; real estate, general, special, ordinary or extraordinary, or rental levy or tax (other than inheritance, income or estate taxes); improvement bond; and/or license fee imposed upon or levied against any legal or equitable interest of Lessor in the Project, Lessor's right to other income therefrom, and/or Lessor's business of leasing, by any authority having the direct or indirect power to tax and where the funds are generated with reference to the Project address and where the proceeds so generated are to be applied by the city, county or other local taxing authority of a jurisdiction within which the Project is located. The term "Real Property Taxes" shall also include any tax, fee, levy, assessment or charge, or any increase therein: (i) imposed by reason of events occurring during the term of this Lease, including but not limited to, a change in the ownership of the Project, (ii) a change in the improvements thereon, and/or (iii) levied or assessed on machinery or equipment provided by Lessor to Lessee pursuant to this Lease. In calculating Real Property Taxes for any calendar year, the Real Property Taxes for any real property tax year shall be included in the calculation of Real Property Taxes for such calendar year based upon the number of days which such calendar year and tax year have in common.

11.2 Payment of Taxes

Except as otherwise provided in Section 11.3, Lessor shall pay the Real Property Taxes applicable to the Project, and said payments shall be included in the calculation of Common Area Operating Expenses in accordance with the provisions of Section 4.2.

11.3 Additional Improvements

Common Area Operating Expenses shall not include Real Property Taxes specified in the tax assessor's records and work sheets as being caused by additional improvements placed upon the Project by other lessees or by Lessor for the exclusive enjoyment of such other lessees. Notwithstanding Section 11.2 hereof, Lessee shall, however, pay to Lessor at the time Common Area Operating Expenses are payable under Section 4.2, the entirety of any increase in Real Property Taxes if assessed solely by reason of Alterations, Trade Fixtures or Utility Installations placed upon the Premises by Lessee or at Lessee's request or by reason of any alterations or improvements to the Premises made by Lessor subsequent to the execution of this Lease by the Parties.

11.4 Joint Assessment

If the Premises is not separately assessed, Real Property Taxes allocated to the Premises shall be an equitable proportion of the Real Property Taxes for all of the land and improvements included within the tax parcel assessed, such proportion to be determined by Lessor from the respective valuations assigned in the assessor's work sheets or such other information as may be reasonably available. Lessor's reasonable determination thereof, in good faith, shall be conclusive.

11.5 Personal Property Taxes

Lessee shall pay prior to delinquency all taxes assessed against and levied upon Lessee Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all personal property of Lessee contained in the Premises. When possible, Lessee shall cause its Lessee Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all other personal property to be assessed and billed separately from the real property of Lessor. If any of Lessee's said property shall be assessed with Lessor's real property, Lessee shall pay Lessor the taxes attributable to Lessee's property within 10 days after receipt of a written statement setting forth the taxes applicable to Lessee's property.

12. UTILITIES AND SERVICES

Lessee shall pay for all water, gas, heat, light, power, telephone, trash disposal and other utilities and services supplied to the Premises, together with any taxes thereon. Notwithstanding the provisions of Section 4.2, if at any time in Lessor's sole judgment, Lessor determines that Lessee is using a disproportionate amount of water, electricity or other commonly metered utilities, or that Lessee is generating such a large volume of trash as to require an increase in the size of the trash receptacle and/or an increase in the number of times per month that it is emptied, then Lessor may increase Lessee's Base Rent by an amount equal to such increased costs. There shall be no abatement of Rent and Lessor shall not be liable in any respect whatsoever for the inadequacy, stoppage, interruption or discontinuance of any utility or service due to riot, strike, labor dispute, breakdown, accident, repair or other cause beyond Lessor's reasonable control or in cooperation with governmental request or directions.

13. ASSIGNMENT AND SUBLETTING

13.1 Lessor's Consent Required

13.1.1 Lessee shall not voluntarily or by operation of law assign, transfer, mortgage or encumber (collectively, "assign or assignment") or sublet all or any part of Lessee's interest in this Lease or in the Premises without Lessor's prior written consent, which shall not be unreasonably withheld or delayed.

13.1.2 Unless Lessee is a corporation and its stock is publicly traded on a national stock exchange, a change in the control of Lessee shall constitute an assignment requiring consent. The transfer, on a cumulative basis, of 50% or more of the voting control of Lessee shall constitute a change in control for this purpose.

13.1.3 The involvement of Lessee or its assets in any transaction, or series of transactions (by way of merger, sale, acquisition, financing, transfer, leveraged buy-out or otherwise), whether or not a formal assignment or hypothecation of this Lease or Lessee's assets occurs, which results or will result in a reduction of the Net Worth of Lessee by an amount greater than 25% of such Net Worth as it was represented at the time of the execution of this Lease or at the time of the most recent assignment to which Lessor has consented, or as it exists immediately prior to said transaction or transactions constituting such reduction, whichever was or is greater, shall be considered an assignment of this Lease to which Lessor may withhold its consent. "Net Worth of Lessee" shall mean the net worth of Lessee established under generally accepted accounting principles.

13.1.4 An assignment or subletting without consent shall, at Lessor's option, be a Default curable after notice per Section 14.4, or a noncurable Breach. If Lessor elects to treat

such unapproved assignment or subletting as a noncurable Breach, Lessor may, upon 30 days written notice, terminate the attempted assignment or sublease and Lessee shall then remain liable for all of its obligations under this Lease, unless otherwise agreed by Lessor.

13.1.5 Lessee's remedy for any breach of Section 13.1 by Lessor shall be limited to compensatory damages and/or injunctive relief.

13.1.6 Lessor may reasonably withhold consent to a proposed assignment or subletting if Lessee is in Default at the time consent is requested.

13.1.7 Notwithstanding the foregoing, allowing a de minimis portion of the Premises, i.e., 20 square feet or less, to be used by a third-party vendor in connection with the installation, for example, of a vending machine or priority mail box, shall not constitute a subletting.

13.2 Terms and Conditions Applicable to Assignment and Subletting

13.2.1 Regardless of Lessor's consent, no assignment or subletting shall: (i) be effective without the express written assumption by such assignee or sublessee of the obligations of Lessee under this Lease, (ii) release Lessee of any obligations hereunder, or (iii) alter the primary responsibility of Lessee for the payment of Rent or for the performance of any other obligations to be performed by Lessee.

13.2.2 Lessor may accept Rent or performance of Lessee's obligations from any person other than Lessee pending approval or disapproval of an assignment. Neither a delay in the approval or disapproval of such assignment nor the acceptance of Rent or performance shall constitute a waiver or estoppel of Lessor's right to exercise its remedies for Lessee's Default or Breach.

13.2.3 Lessor's consent to any assignment or subletting shall not constitute a consent to any subsequent assignment or subletting.

13.2.4 In the event of any Default or Breach by Lessee, Lessor may proceed directly against Lessee or anyone else responsible for the performance of Lessee's obligations under this Lease, including any assignee or sublessee, without first exhausting Lessor's remedies against any other person or entity responsible therefor to Lessor, or any security held by Lessor.

13.2.5 Each request for consent to an assignment or subletting shall be in writing, accompanied by information relevant to Lessor's determination as to the financial and operational responsibility and appropriateness of the proposed assignee or sublessee, including but not limited to the intended use and/or required modification of the Premises, if any, together with a fee of $500 as consideration for Lessor's considering and processing said request. Lessee agrees to provide Lessor with such other or additional information and/or documentation as may be reasonably requested. (See also Section 20.18)

13.2.6 Any assignee of, or sublessee under, this Lease shall, by reason of accepting such assignment, entering into such sublease, or entering into possession of the Premises or any portion thereof, be deemed to have assumed and agreed to conform and comply with each and every term, covenant, condition and obligation herein to be observed or performed by Lessee during the term of said assignment or sublease, other than such obligations as are contrary to or

inconsistent with provisions of an assignment or sublease to which Lessor has specifically consented to in writing.

13.2.7 Lessor's consent to any assignment or subletting shall not transfer to the assignee or sublessee any Option granted to the original Lessee by this Lease unless such transfer is specifically consented to by Lessor in writing. (See Section 19.1.)

13.2.8 If Lessee assigns and/or sublets any portion(s) of its interest in this Lease or in the Premises with Lessor's consent, any consideration received by Lessee for said assignment and/or subletting, after deducting any real estate broker's commissions incurred solely for the purpose of and in connection with the assignment or subletting, shall be divided equally with Lessor to the extent it exceeds the consideration due Lessor from Lessee under this Lease ("Net Rent Premium"). The amount due Lessor shall be paid to Lessor within ten (10) days after its receipt by Lessee. Lessee shall act as Lessor's agent in collecting such amounts from any such assignee or sublessee.

13.3 Additional Terms and Conditions Applicable to Subletting

The following terms and conditions shall apply to any subletting by Lessee of all or any part of the Premises and shall be deemed included in all subleases under this Lease whether or not expressly incorporated therein:

13.3.1 Lessee hereby assigns and transfers to Lessor all of Lessee's interest in all Rent payable on any sublease, and Lessor may collect such Rent and apply same toward Lessee's obligations under this Lease; provided, however, that until a Breach shall occur in the performance of Lessee's obligations, Lessee may collect said Rent. In the event that the amount collected by Lessor exceeds Lessee's then outstanding obligations any such excess shall be refunded to Lessee. Lessor shall not, by reason of the foregoing or any assignment of such sublease, nor by reason of the collection of Rent, be deemed liable to the sublessee for any failure of Lessee to perform and comply with any of Lessee's obligations to such sublessee. Lessee hereby irrevocably authorizes and directs any such sublessee, upon receipt of a written notice from Lessor stating that a Breach exists in the performance of Lessee's obligations under this Lease, to pay to Lessor all Rent due and to become due under the sublease. Sublessee shall rely upon any such notice from Lessor and shall pay all Rents to Lessor without any obligation or right to inquire as to whether such Breach exists, notwithstanding any claim from Lessee to the contrary.

13.3.2 In the event of a Breach by Lessee, Lessor may, at its option, require sublessee to attorn to Lessor, in which event Lessor shall undertake the obligations of the sublessor under such sublease from the time of the exercise of said option to the expiration of such sublease; provided, however, Lessor shall not be liable for any prepaid rents or security deposit paid by such sublessee to such sublessor or for any prior Defaults or Breaches of such sublessor.

13.3.3 Any matter requiring the consent of the sublessor under a sublease shall also require the consent of Lessor.

13.3.4 No sublessee shall further assign or sublet all or any part of the Premises without Lessor's prior written consent.

13.3.5 Lessor shall deliver a copy of any notice of Default or Breach by Lessee to the sublessee, who shall have the right to cure the Default of Lessee within the grace period, if

any, specified in such notice. The sublessee shall have a right of reimbursement and offset from and against Lessee for any such Defaults cured by the sublessee.

14. DEFAULT; BREACH; REMEDIES

14.1 Default; Breach

A "Default" is defined as a failure by the Lessee to comply with or perform any of the terms, covenants, conditions or Rules and Regulations under this Lease. A "Breach" is defined as the occurrence of one or more of the following Defaults, and the failure of Lessee to cure such Default within any applicable grace period:

14.1.1 The abandonment of the Premises; or the vacating of the Premises without providing a commercially reasonable level of security, or where the coverage of the property insurance described in Section 9.3 is jeopardized as a result thereof, or without providing reasonable assurances to minimize potential vandalism.

14.1.2 The failure of Lessee to make any payment of Rent or any Security Deposit required to be made by Lessee hereunder, whether to Lessor or to a third party, when due; or the failure of Lessee to provide reasonable evidence of insurance or surety bond, or to fulfill any obligation under this Lease which endangers or threatens life or property, where such failure continues for a period of five business days following written notice to Lessee. THE ACCEPTANCE BY LESSOR OF A PARTIAL PAYMENT OF RENT OR SECURITY DEPOSIT SHALL NOT CONSTITUTE A WAIVER OF ANY OF LESSOR'S RIGHTS, INCLUDING LESSOR'S RIGHT TO RECOVER POSSESSION OF THE PREMISES.

14.1.3 The failure of Lessee to allow Lessor and/or its agents access to the Premises, the commission of waste, an act or acts constituting public or private nuisance, and/or an illegal activity on the Premises by Lessee, where such actions continue for a period of three business days following written notice to Lessee.

14.1.4 The failure by Lessee to provide (i) reasonable written evidence of compliance with Applicable Requirements, (ii) the service contracts, (iii) the rescission of an unauthorized assignment or subletting, (iv) an Estoppel Certificate or financial statements, (v) a requested subordination, (vi) any document requested under Section 20.21, (vii) material data safety sheets (MSDS), or (viii) any other documentation or information which Lessor may reasonably require of Lessee under the terms of this Lease, where any such failure continues for a period of 10 days following written notice to Lessee.

14.1.5 A Default by Lessee as to the terms, covenants, conditions or provisions of this Lease, or of the rules adopted under Section 2.9 hereof, other than those described in Sections 14.1.1, 14.1.2, 14.1.3 or 14.1.4, above, where such Default continues for a period of 30 days after written notice; provided, however, that if the nature of Lessee's Default is such that more than 30 days are reasonably required for its cure, then it shall not be deemed to be a Breach if Lessee commences such cure within said 30 day period and thereafter diligently prosecutes such cure to completion.

14.1.6 The occurrence of any of the following events: (i) the making of any general arrangement or assignment for the benefit of creditors; (ii) becoming a "debtor" as defined in 11 U.S.C. § 101 or any successor statute thereto (unless, in the case of a petition filed against Lessee,

the same is dismissed within 60 days); (iii) the appointment of a trustee or receiver to take possession of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where possession is not restored to Lessee within 30 days; or (iv) the attachment, execution or other judicial seizure of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where such seizure is not discharged within 30 days; provided, however, in the event that any provision of this subsection is contrary to any applicable law, such provision shall be of no force or effect, and not affect the validity of the remaining provisions.

14.1.7 The discovery that any financial statement of Lessee given to Lessor was materially false.

14.2 Remedies

If Lessee fails to perform any of its affirmative duties or obligations, within 30 days (see Section 14.1.5) after written notice (or in case of an emergency, without notice), Lessor may, at its option, perform such duty or obligation on Lessee's behalf, including but not limited to the obtaining of reasonably required bonds, insurance policies, or governmental licenses, permits or approvals. Lessee shall pay to Lessor an amount equal to 115% of the costs and expenses incurred by Lessor in such performance upon receipt of an invoice therefor. In the event of a Breach, Lessor may, with or without further notice or demand, and without limiting Lessor in the exercise of any right or remedy which Lessor may have by reason of such Breach:

14.2.1 Terminate Lessee's right to possession of the Premises by any lawful means, in which case this Lease shall terminate and Lessee shall immediately surrender possession to Lessor. In such event Lessor shall be entitled to recover from Lessee: (i) the unpaid Rent which had been earned at the time of termination; (ii) the worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that the Lessee proves could have been reasonably avoided; (iii) the worth at the time of award of the amount by which the unpaid rent for the balance of the term after the time of award exceeds the amount of such rental loss that the Lessee proves could be reasonably avoided; and (iv) any other amount necessary to compensate Lessor for all the detriment proximately caused by the Lessee's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, including but not limited to the cost of recovering possession of the Premises, expenses of reletting, including necessary demolition and alteration of the Premises, reasonable attorneys' fees, and that portion of any leasing commission paid by Lessor in connection with this Lease applicable to the unexpired term of this Lease. Efforts by Lessor to mitigate damages caused by Lessee's Breach of this Lease shall not waive Lessor's right to recover any damages to which Lessor is otherwise entitled. If termination of this Lease is obtained through the provisional remedy of unlawful detainer, Lessor shall have the right to recover in such proceeding any unpaid Rent and damages as are recoverable therein, or Lessor may reserve the right to recover all or any part thereof in a separate suit. If a notice and grace period required under Section 14.1 was not previously given, a notice to pay rent or quit, or to perform or quit given to Lessee under the unlawful detainer statute shall also constitute the notice required by Section 14.1. In such case, the applicable grace period required by Section 14.1 and the unlawful detainer statute shall run concurrently, and the failure of Lessee to cure the Default within the greater of the two such grace periods shall constitute both an unlawful detainer and a Breach of this Lease entitling Lessor to the remedies provided for in this Lease and/or by said statute.

14.2.2 Continue the Lease and Lessee's right to possession and recover the Rent as it becomes due, in which event Lessee may sublet or assign, subject only to reasonable limitations. Acts of maintenance, efforts to relet, and/or the appointment of a receiver to protect the Lessor's interests, shall not constitute a termination of the Lessee's right to possession.

14.2.3 Pursue any other remedy now or hereafter available under the laws or judicial decisions of the state wherein the Premises are located. The expiration or termination of this Lease and/or the termination of Lessee's right to possession shall not relieve Lessee from liability under any indemnity provisions of this Lease as to matters occurring or accruing during the term hereof or by reason of Lessee's occupancy of the Premises.

14.3 Inducement Recapture

Any agreement for free or abated rent or other charges, or for the giving or paying by Lessor to or for Lessee of any cash or other bonus, inducement or consideration for Lessee's entering into this Lease, all of which concessions are hereinafter referred to as "Inducement Provisions", shall be deemed conditioned upon Lessee's full and faithful performance of all of the terms, covenants and conditions of this Lease. Upon Breach of this Lease by Lessee, any such Inducement Provision shall automatically be deemed deleted from this Lease and of no further force or effect, and any rent, other charge, bonus, inducement or consideration theretofore abated, given or paid by Lessor under such an Inducement Provision shall be immediately due and payable by Lessee to Lessor, notwithstanding any subsequent cure of said Breach by Lessee. The acceptance by Lessor of rent or the cure of the Breach which initiated the operation of this section shall not be deemed a waiver by Lessor of the provisions of this section unless specifically so stated in writing by Lessor at the time of such acceptance.

14.4 Late Charges

Lessee hereby acknowledges that late payment by Lessee of Rent will cause Lessor to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult to ascertain. Such costs include, but are not limited to, processing and accounting charges, and late charges which may be imposed upon Lessor by any Lender. Accordingly, if any Rent shall not be received by Lessor within five days after such amount shall be due, then, without any requirement for notice to Lessee, Lessee shall immediately pay to Lessor a one-time late charge equal to 5% of each such overdue amount or $100, whichever is greater. The parties hereby agree that such late charge represents a fair and reasonable estimate of the costs Lessor will incur by reason of such late payment. Acceptance of such late charge by Lessor shall in no event constitute a waiver of Lessee's Default or Breach with respect to such overdue amount, nor prevent the exercise of any of the other rights and remedies granted hereunder. In the event that a late charge is payable hereunder, whether or not collected, for three consecutive installments of Base Rent, then notwithstanding any provision of this Lease to the contrary, Base Rent shall, at Lessor's option, become due and payable quarterly in advance.

14.5 Interest

Any monetary payment due Lessor hereunder, other than late charges, not received by Lessor when due shall bear interest from the 31st day after it was due. The interest ("Interest") charged shall be computed at the rate of 10% per annum but shall not exceed the maximum rate allowed by law. Interest is payable in addition to the potential late charge provided for in Section 14.4.

14.6 Breach by Lessor

14.6.1 Lessor shall not be deemed in breach of this Lease unless Lessor fails within a reasonable time to perform an obligation required to be performed by Lessor. For purposes of this Section, a reasonable time shall in no event be less than 30 days after receipt by Lessor, and any Lender whose name and address shall have been furnished to Lessee in writing for such purpose, of written notice specifying wherein such obligation of Lessor has not been performed; provided, however, that if the nature of Lessor's obligation is such that more than 30 days are reasonably required for its performance, then Lessor shall not be in breach if performance is commenced within such 30 day period and thereafter diligently pursued to completion.

14.6.2 In the event that neither Lessor nor Lender cures said breach within 30 days after receipt of said notice, or if having commenced said cure they do not diligently pursue it to completion, then Lessee may elect to cure said breach at Lessee's expense and offset from Rent the actual and reasonable cost to perform such cure, provided however, that such offset shall not exceed an amount equal to the greater of one month's Base Rent or the Security Deposit, reserving Lessee's right to reimbursement from Lessor for any such expense in excess of such offset. Lessee shall document the cost of said cure and supply said documentation to Lessor.

15. CONDEMNATION

15.1 Effect on Lease

If all of the Premises, is taken under the power of eminent domain or sold under the threat of the exercise of said power ("Condemnation"), this Lease shall terminate as of the date the condemning authority takes title or possession, whichever first occurs. If title to a portion of the Premises or the land on which the Premises are located is taken by Condemnation, and the remainder will not, in Lessor's reasonable judgment, after consultation with Lessee, be suitable for Lessee's continued use for the purposes permitted by this Lease, this Lease shall terminate as of the date the condemning authority takes title or possession, whichever first occurs, provided that Lessor gives written notice of such termination to Lessee no later than thirty (30) days after the date of such taking. If title to a portion of the Premises or the land on which the Premises are located is taken by Condemnation, and the remainder will, in Lessor's reasonable judgment (after consultation with Lessee), be suitable for Lessee's continued use for the purposes permitted by this Lease, then Lessor shall repair the damage caused by the partial taking, if any, and this Lease shall not terminate and shall remain in full force and effect as to the portion of the Premises remaining, except that the Base Rent payable hereunder shall be reduced in proportion to the reduction in utility of the Premises caused by such Condemnation. Lessee acknowledges and agrees that a change in access to the land on which the Premises are located or minor adjustments to parking, shall not constitute a taking and shall not entitle Lessee to any reduction in Base Rent.

15.2 Allocation of Condemnation Award

Lessee hereby assigns to Lessor its interest, if any, in any award which may be made as a result of any Condemnation, without regard to whether this Lease is terminated, except for any apportionment that directly applies to, or any separate award made to Lessee for Lessee's tenant improvements, moving costs or loss of Lessee's business goodwill. Any condemnation award(s) and/or payment(s) for the taking or damaging of all or any portion of the Premises under the power of eminent domain, or any payment made under threat of the exercise of such power, shall be the sole and exclusive property of Lessor, whether such award shall be made as compensation for

the taking of all or any portion of the Premises or any portion of the land on which the Premises are located, diminution in value of the leasehold (including without limitation any "bonus value" of the Lease), the value of the part taken, or for severance damages; provided, however, that Lessee shall be entitled to any apportionment that directly applies to, or any compensation separately awarded for Lessee's tenant improvements, relocation expenses and/or loss of business goodwill. All "improvements pertaining to the realty" as defined in the Eminent Domain Law (Code of Civil Procedure sections 1230.10 et seq.), which Lessee specifically acknowledges and agrees shall include without limitation Alterations and Utility Installations made to the Premises by Lessee, and all fixtures that cannot be removed without doing material damage to the Premises, shall, for purposes of Condemnation, be considered the property of the Lessor and Lessor shall be entitled to any and all compensation which is payable therefor.

16. CONFIDENTIAL INFORMATION, INDEMNITIES OF RELATIONSHIPS

16.1 Confidential Information

Lessor and Lessee acknowledge that this Lease, and all material information exchanged during the negotiations related to this Lease, is confidential information, including, but not limited to: the existence and content of this Lease, the Lessee's financial statements, the identity of the brokers, and all written, printed, graphic, or electronic information furnished by any party (collectively, "Confidential Information"). Except to the extent disclosure is required by law, including the Securities and Exchange Commission, NASDAQ or other public company regulatory body, the parties shall keep all Confidential Information in strict confidence, and shall not disclose any Confidential Information to any third party other than Lessee's or Lessor's independent auditors, financial and legal advisors, those selected to review Common Area Operating Expenses and taxes, and legal and space-planning consultants; provided, however, that Lessee may disclose the terms to prospective subtenants or assignees. No Confidential Information or other information regarding this Lease shall be reported or otherwise released. This provision shall survive the termination or expiration of this Lease, for a period of no less than one year.

16.2 Indemnities

Lessee and Lessor do each hereby agree to indemnify, protect, defend and hold the other harmless from and against liability for compensation or charges which may be claimed by any broker other than those set forth in Section 1.12, finder or other similar party by reason of any dealings or actions of the indemnifying Party, including any costs, expenses, attorneys' fees reasonably incurred with respect thereto.

17. ESTOPPEL CERTIFICATES AND FINANCIAL STATEMENTS

17.1 Obligation to Provide Estoppel Certificate

Each Party (as "Responding Party") shall within 10 days after written notice from the other Party (the "Requesting Party") execute, acknowledge and deliver to the Requesting Party a statement in writing in form similar to the "Estoppel Certificate" form attached hereto as Exhibit D, plus such additional information, confirmation and/or statements as may be reasonably requested by the Requesting Party.

17.2 Remedies for Failure to Provide Estoppel Certificate.

If the Responding Party shall fail to execute or deliver the Estoppel Certificate within such 10-day period, the Requesting Party may execute an Estoppel Certificate stating that: (i) the Lease is in full force and effect without modification except as may be represented by the Requesting Party, (ii) there are no uncured defaults in the Requesting Party's performance, and (iii) if Lessor is the Requesting Party, not more than one month's rent has been paid in advance. Prospective purchasers and encumbrancers may rely upon the Requesting Party's Estoppel Certificate, and the Responding Party shall be estopped from denying the truth of the facts contained in said Certificate. In addition, Lessee acknowledges that any failure on its part to provide such an Estoppel Certificate will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, should the Lessee fail to execute and/or deliver a requested Estoppel Certificate in a timely fashion the monthly Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 5% of the then existing Base Rent or $100, whichever is greater until such time as the Estoppel Certificate is executed and delivered. The Parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to provide the Estoppel Certificate. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach with respect to the failure to provide the Estoppel Certificate nor prevent the exercise of any of the other rights and remedies granted hereunder.

17.3 Additional Provisions Regarding Lessor Finance, Refinance or Sale of Premises

If Lessor desires to finance, refinance, or sell the Premises, or any part thereof, Lessee shall within 10 days after written notice from Lessor deliver to any potential lender or purchaser designated by Lessor such financial statements as may be reasonably required by such lender or purchaser, including but not limited to Lessee's financial statements for the past three years. All such financial statements shall be received by Lessor and such lender or purchaser in confidence and shall be used only for the purposes herein set forth.

18. SUBORDINATION; ATTORNMENT; NON-DISTURBANCE

18.1 Subordination

This Lease and any Option granted hereby shall be subject and subordinate to any ground lease, mortgage, deed of trust, or other hypothecation or security device (collectively, "Security Device"), now or hereafter placed upon the Premises, to any and all advances made on the security thereof, and to all renewals, modifications, and extensions thereof. Lessee agrees that the holders of any such Security Devices (in this Lease together referred to as "Lender") shall have no liability or obligation to perform any of the obligations of Lessor under this Lease. Any Lender may elect to have this Lease and/or any Option granted hereby superior to the lien of its Security Device by giving written notice thereof to Lessee, whereupon this Lease and such Options shall be deemed prior to such Security Device, notwithstanding the relative dates of the documentation or recordation thereof.

18.2 Attornment

In the event that Lessor transfers title to the Premises, or the Premises are acquired by another upon the foreclosure or termination of a Security Device to which this Lease is subordinated (i) Lessee shall, subject to the non-disturbance provisions of Section 18.3, attorn to such new

owner, and upon request, enter into a new lease, containing all of the terms and provisions of this Lease, with such new owner for the remainder of the term hereof, or, at the election of the new owner, this Lease will automatically become a new lease between Lessee and such new owner, and (ii) Lessor shall thereafter be relieved of any further obligations hereunder and such new owner shall assume all of Lessor's obligations, except that such new owner shall not: (a) be liable for any act or omission of any prior lessor or with respect to events occurring prior to acquisition of ownership; (b) be subject to any offsets or defenses which Lessee might have against any prior lessor, (c) be bound by prepayment of more than one month's rent, or (d) be liable for the return of any security deposit paid to any prior lessor which was not paid or credited to such new owner.

18.3 Non-Disturbance

With respect to Security Devices entered into by Lessor after the execution of this Lease, Lessee's subordination of this Lease shall be subject to receiving a commercially reasonable non-disturbance agreement (a "Non-Disturbance Agreement") from the Lender which Non-Disturbance Agreement provides that Lessee's possession of the Premises, and this Lease, including any options to extend the term hereof, will not be disturbed so long as Lessee is not in Breach hereof and attorns to the record owner of the Premises.

18.4 Self-Executing

The agreements contained in this Section 18 shall be effective without the execution of any further documents; provided, however, that, upon written request from Lessor or a Lender in connection with a sale, financing or refinancing of the Premises, Lessee and Lessor shall execute such further writings as may be reasonably required to separately document any subordination, attornment and/or Non-Disturbance Agreement provided for herein.

19. OPTIONS

19.1 General Provisions Applicable to Options

19.1.1 "Option" shall mean: (a) the right to extend or reduce the term of or renew this Lease or to extend or reduce the term of or renew any lease that Lessee has on other property of Lessor; (b) the right of first refusal or first offer to lease either the Premises or other property of Lessor; (c) the right to purchase, the right of first offer to purchase or the right of first refusal to purchase the Premises or other property of Lessor.

19.1.2 Any Option granted to Lessee in this Lease is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and, if requested by Lessor, with Lessee certifying that Lessee has no intention of thereafter assigning or subletting.

19.1.3 In the event that Lessee has any multiple Options to extend or renew this Lease, a later Option cannot be exercised unless the prior Options have been validly exercised.

19.2 Effect of Default on Options

19.2.1 Lessee shall have no right to exercise an Option: (i) during the period commencing with the giving of any notice of Default and continuing until said Default is cured, (ii) during the period of time any Rent that is then due is unpaid (without regard to whether notice

thereof is given Lessee), (iii) during the time Lessee is in Breach of this Lease, or (iv) in the event that Lessee has been given three or more notices of separate Default, whether or not the Defaults are cured, during the 12 month period immediately preceding the exercise of the Option.

19.2.2 The period of time within which an Option may be exercised shall not be extended or enlarged by reason of Lessee's inability to exercise an Option because of the provisions of Section 19.2.1.

19.2.3 An Option shall terminate and be of no further force or effect, notwithstanding Lessee's due and timely exercise of the Option, if, after such exercise and prior to the commencement of the extended term or completion of the purchase, (i) Lessee fails to pay Rent for a period of 30 days after such Rent becomes due (without any necessity of Lessor to give notice thereof), or (ii) if Lessee commits a Breach of this Lease.

19.3 Option Exercise Procedures

19.3.1 If Lessee elects to exercise an Option, it shall do so by delivery of written notice of such election to Lessor not less than six (6) and no more than the twelve (12) months prior to the expiration date of the Original Term or extension period, as applicable.

19.3.2 The Base Rent and method of annual increases thereto for the extension period shall be the then fair market rental rate and method for annual increases for comparable space in the area.

19.3.3 The fair market rental and method for annual increases shall be mutually agreed upon by Lessor and Lessee within thirty (30) days after Lessor's receipt of Lessee's written notice of the exercise of the Option (the "Agreement Period").

19.3.4 If Lessor and Lessee are unable to so agree within the Agreement Period, each shall select an appraiser and, within fifteen (15) days after the expiration of the Agreement Period, shall notify the other of the name, business address and telephone number of the appraiser so selected. Said two (2) appraisers shall, within thirty (30) days after the expiration of the Agreement Period, jointly select a third appraiser and shall notify Lessor and Lessee of the name, business address and telephone number of said appraiser. Each of the three (3) appraisers shall, within forty-five (45) days after expiration of the Agreement Period, make a good faith determination of the then fair market rental rate of the Premises and the method for annual increases in said rate and shall notify Lessor, Lessee, and each other appraiser of such determinations. If all appraisers do not agree on the fair market rental rate and method for annual increases, the common decision of two (2) of them shall be determinative. If two (2) of the three (3) appraisers are unable to so agree, the fair market rental rate that is neither the highest nor lowest of the three (3) determinations shall be the Base Rent and the method for annual increases shall be the method specified by the appraiser whose determination of fair market rental is used. Notwithstanding anything to the contrary in this Lease, Base Rent during an extension period shall not be less than Base Rent in effect for the last year of the Original Term or, if applicable, the extension period then ending.

19.3.5 Lessor and Lessee shall each cooperate with all reasonable requests by any of the appraisers in order to assist the appraisers in the timely performance of their duties hereunder. To be eligible to serve as an appraiser, one must be a licensed real estate broker in California with a minimum of five (5) years continuous experience in the leasing of similar space in the area, and must be actively engaged in such activity at the time of his or her selection.

Lessor and Lessee shall each pay the fees and expenses of its own appraiser and one-half (1/2) of the fees and expenses of the third appraiser.

20. MISCELLANEOUS PROVISIONS

20.1 Definition of Lessor

The term “Lessor” as used herein shall mean the owner or owners at the time in question of the fee title to the Premises, or, if this is a sublease, of the Lessee’s interest in the prior lease. In the event of a transfer of Lessor’s title or interest in the Premises or this Lease, Lessor shall deliver to the transferee or assignee (in cash or by credit) any unused Security Deposit held by Lessor. Upon such transfer or assignment and delivery of the Security Deposit, as aforesaid, the prior Lessor shall be relieved of all liability with respect to the obligations and/or covenants under this Lease thereafter to be performed by the Lessor. Subject to the foregoing, the obligations and/or covenants in this Lease to be performed by the Lessor shall be binding only upon the Lessor as hereinabove defined.

20.2 Severability

The invalidity of any provision of this Lease, as determined by a court of competent jurisdiction, shall in no way affect the validity of any other provision hereof.

20.3 Days

Unless otherwise specifically indicated to the contrary, the word “days” as used in this Lease shall mean and refer to calendar days.

20.4 Limitation on Liability

The obligations of Lessor under this Lease shall not constitute personal obligations of Lessor, or its partners, members, directors, officers or shareholders, and Lessee shall only look to the owner of the Premises, for the satisfaction of any liability of Lessor with respect to this Lease, and shall not seek recourse against Lessor’s partners, members, directors, officers or shareholders, or any of their personal assets for such satisfaction.

20.5 Time of Essence

Time is of the essence with respect to the performance of all obligations to be performed or observed by the Parties under this Lease.

20.6 No Prior or Other Agreements

This Lease contains all agreements between the Parties with respect to any matter mentioned herein, and no other prior or contemporaneous agreement or understanding shall be effective. Lessor and Lessee each represents and warrants to the other that it has made, and is relying solely upon, its own investigation as to the nature, quality, character and financial responsibility of the other Party to this Lease and as to the use, nature, quality and character of the Premises.

20.7 Notices

20.7.1 All notices required or permitted by this Lease or applicable law shall be in writing and may be delivered in person (by hand or by courier), sent by regular, certified or registered mail or U.S. Postal Service Express Mail, with postage prepaid, or as an attachment to an email or other electronic transmission to two or more members or officers of a Party, and shall be deemed sufficiently given if served in a manner specified in this Section 20.7. The addresses noted adjacent to a Party's signature on this Lease shall be that Party's address for delivery or mailing of notices. Either Party may by written notice to the other specify a different address for notice, except that upon Lessee's taking possession of the Premises, the Premises shall constitute Lessee's address for notice. A copy of all notices to Lessor shall be concurrently transmitted to such party or parties at such addresses as Lessor may from time to time hereafter designate in writing.

20.7.2 Any notice sent by registered or certified mail, return receipt requested, shall be deemed given on the date of delivery shown on the receipt card, or if no delivery date is shown, the postmark thereon. If sent by regular mail the notice shall be deemed given 72 hours after the same is addressed as required herein and mailed with postage prepaid. Notices delivered by United States Express Mail or overnight courier that guarantees next day delivery shall be deemed given 24 hours after delivery of the same to the Postal Service or courier. Notices transmitted by electronic transmission or similar means shall be deemed delivered upon telephone confirmation of receipt (confirmation report from fax machine is sufficient), provided a copy is also delivered via delivery or mail. If notice is received on a Saturday, Sunday or legal holiday, it shall be deemed received on the next business day.

20.8 Waivers

20.8.1 No waiver by Lessor of the Default or Breach of any term, covenant or condition hereof by Lessee, shall be deemed a waiver of any other term, covenant or condition hereof, or of any subsequent Default or Breach by Lessee of the same or of any other term, covenant or condition hereof. Lessor's consent to, or approval of, any act shall not be deemed to render unnecessary the obtaining of Lessor's consent to, or approval of, any subsequent or similar act by Lessee, or be construed as the basis of an estoppel to enforce the provision or provisions of this Lease requiring such consent.

20.8.2 The acceptance of Rent by Lessor shall not be a waiver of any Default or Breach by Lessee. Any payment by Lessee may be accepted by Lessor on account of monies or damages due Lessor, notwithstanding any qualifying statements or conditions made by Lessee in connection therewith, and such statements and/or conditions shall be of no force or effect whatsoever unless specifically agreed to in writing by Lessor at or before the time of deposit of such payment.

20.8.3 THE PARTIES AGREE THAT THE TERMS OF THIS LEASE SHALL GOVERN WITH REGARD TO ALL MATTERS RELATED THERETO AND HEREBY WAIVE THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE TO THE EXTENT THAT SUCH STATUTE IS INCONSISTENT WITH THIS LEASE.

20.9 No Right To Holdover

Lessee has no right to retain possession of the Premises or any part thereof beyond the expiration or termination of this Lease. In the event that Lessee holds over, then the Base Rent shall be increased to 110% of the Base Rent applicable immediately preceding the expiration or termination, and shall increase to 150% of the Base Rent starting the fourth month after expiration

or termination. Nothing contained herein shall be construed as consent by Lessor to any holding over by Lessee. During this Holdover period, the Lease shall revert to a month-to-month occupancy and the existing Lease terms in all other respects shall survive. If the Parties agree to a new Lease or extension of the existing Lease, then the commencement date shall be the date agreed to in the new Lease. No Holdover rent premium shall be returned to the Lessee.

20.10 Cumulative Remedies

No remedy or election hereunder shall be deemed exclusive but shall, wherever possible, be cumulative with all other remedies at law or in equity.

20.11 Covenants and Conditions; Construction of Agreement

All provisions of this Lease to be observed or performed by Lessee are both covenants and conditions. In construing this Lease, all headings and titles are for the convenience of the Parties only and shall not be considered a part of this Lease. Whenever required by the context, the singular shall include the plural and vice versa. This Lease shall not be construed as if prepared by one of the Parties, but rather according to its fair meaning as a whole, as if both Parties had prepared it.

20.12 Binding Effect; Choice of Law

This Lease shall be binding upon the Parties, their personal representatives, successors and assigns and be governed by the laws of the State in which the Premises are located. Any litigation between the Parties hereto concerning this Lease shall be initiated in the county in which the Premises are located.

20.13 Attorneys' Fees

If any Party brings an action or proceeding involving the Premises whether founded in tort, contract or equity, or to declare rights hereunder, the Prevailing Party (as hereafter defined) in any such proceeding, action, or appeal thereon, shall be entitled to reasonable attorneys' fees. Such fees may be awarded in the same suit or recovered in a separate suit, whether or not such action or proceeding is pursued to decision or judgment. The term, "Prevailing Party" shall include, without limitation, a Party who substantially obtains or defeats the relief sought, as the case may be, whether by compromise, settlement, judgment, or the abandonment by the other Party of its claim or defense. The attorneys' fees award shall not be computed in accordance with any court fee schedule, but shall be such as to fully reimburse all attorneys' fees reasonably incurred. In addition, Lessor shall be entitled to attorneys' fees, costs and expenses incurred in the preparation and service of notices of Default and consultations in connection therewith ($200 is a reasonable minimum per occurrence for such services and consultation).

20.14 Lessor's Access; Showing Premises; Repairs

Lessor and Lessor's agents shall have the right to enter the Premises at any time, in the case of an emergency, and otherwise at reasonable times after reasonable prior notice for the purpose of showing the same to prospective purchasers, lenders, or tenants, and making such alterations, repairs, improvements or additions to the Premises as Lessor may deem necessary or desirable and the erecting, using and maintaining of utilities, services, pipes and conduits through

the Premises and/or other premises as long as there is no material adverse effect on Lessee's use of the Premises. All such activities shall be without abatement of rent or liability to Lessee.

20.15 Auctions

Lessee shall not conduct, nor permit to be conducted, any auction upon the Premises without Lessor's prior written consent. Lessor shall not be obligated to exercise any standard of reasonableness in determining whether to permit an auction.

20.16 Signs

Lessor may place on the Premises ordinary "For Sale" signs at any time and ordinary "For Lease" signs during the last six months of the term hereof. Lessee shall not place any sign upon the Project without Lessor's prior written consent. All signs must comply with all applicable government and zoning requirements.

20.17 Termination; Merger

Unless specifically stated otherwise in writing by Lessor, the voluntary or other surrender of this Lease by Lessee, the mutual termination or cancellation hereof, or a termination hereof by Lessor for Breach by Lessee, shall automatically terminate any sublease or lesser estate in the Premises; provided, however, that Lessor may elect to continue any one or all existing subtenancies. Lessor's failure within 10 days following any such event to elect to the contrary by written notice to the holder of any such lesser interest, shall constitute Lessor's election to have such event constitute the termination of such interest.

20.18 Consents

Except as otherwise provided herein, wherever in this Lease the consent of a Party is required to an act by or for the other Party, such consent shall not be unreasonably withheld or delayed. Lessor's actual reasonable costs and expenses (including but not limited to architects', attorneys', engineers' and other consultants' fees) incurred in the consideration of, or response to, a request by Lessee for any Lessor consent, including but not limited to consents to an assignment, a subletting or the presence or use of a Hazardous Substance, shall be paid by Lessee upon receipt of an invoice and supporting documentation therefor. Lessor's consent to any act, assignment or subletting shall not constitute an acknowledgment that no Default or Breach by Lessee of this Lease exists, nor shall such consent be deemed a waiver of any then-existing Default or Breach, except as may be otherwise specifically stated in writing by Lessor at the time of such consent. The failure to specify herein any particular condition to Lessor's consent shall not preclude the imposition by Lessor at the time of consent of such further or other conditions as are then reasonable with reference to the particular matter for which consent is being given. In the event that either Party disagrees with any determination made by the other hereunder and reasonably requests the reasons for such determination, the determining party shall furnish its reasons in writing and in reasonable detail within 10 business days following such request.

20.19 Quiet Possession

Subject to payment by Lessee of the Rent and performance of all of the covenants, conditions and provisions on Lessee's part to be observed and performed under this Lease, Lessee shall have quiet possession and quiet enjoyment of the Premises during the term hereof.

20.20 Security Measures

Lessee hereby acknowledges that the Rent payable to Lessor hereunder does not include the cost of guard service or other security measures, and that Lessor shall have no obligation whatsoever to provide same. Lessee assumes all responsibility for the protection of the Premises, Lessee, its agents and invitees and their property from the acts of third parties.

20.21 Reservations

Lessor reserves the right: (i) to grant, without the consent or joinder of Lessee, such easements, rights and dedications that Lessor deems necessary, (ii) to cause the recordation of parcel maps and restrictions, and (iii) to create and/or install new utility raceways, so long as such easements, rights, dedications, maps, restrictions, and utility raceways do not unreasonably interfere with the use of the Premises by Lessee. Lessee agrees to sign any documents reasonably requested by Lessor to effectuate such rights.

20.22 Performance Under Protest

If at any time a dispute shall arise as to any amount or sum of money to be paid by one Party to the other under the provisions hereof, the Party against whom the obligation to pay the money is asserted shall have the right to make payment "under protest" and such payment shall not be regarded as a voluntary payment and there shall survive the right on the part of said Party to institute suit for recovery of such sum. If it shall be adjudged that there was no legal obligation on the part of said Party to pay such sum or any part thereof, said Party shall be entitled to recover such sum or so much thereof as it was not legally required to pay. A Party who does not initiate suit for the recovery of sums paid "under protest" within 6 months shall be deemed to have waived its right to protest such payment.

20.23 Authority; Multiple Parties; Execution

20.23.1 If either Party hereto is a corporation, trust, limited liability company, partnership, or similar entity, each individual executing this Lease on behalf of such entity represents and warrants that he or she is duly authorized to execute and deliver this Lease on its behalf. Each Party shall, within 30 days after request, deliver to the other Party satisfactory evidence of such authority.

20.23.2 If this Lease is executed by more than one person or entity as "Lessee", each such person or entity shall be jointly and severally liable hereunder. It is agreed that any one of the named Lessees shall be empowered to execute any amendment to this Lease, or other document ancillary thereto and bind all of the named Lessees, and Lessor may rely on the same as if all of the named Lessees had executed such document.

20.23.3 This Lease may be executed by the Parties in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

20.24 Offer

Preparation of this Lease by either party or their agent and submission of same to the other Party shall not be deemed an offer to lease to the other Party. This Lease is not intended to be binding until executed and delivered by all Parties hereto.

20.25 Amendments

This Lease may be modified only in writing, signed by the Parties in interest at the time of the modification. As long as they do not materially change Lessee's obligations hereunder, Lessee agrees to make such reasonable non-monetary modifications to this Lease as may be reasonably required by a Lender in connection with the obtaining of normal financing or refinancing of the Premises.

20.26 Waiver of Trial By Jury

THE PARTIES HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING INVOLVING THE PROPERTY OR ARISING OUT OF THIS AGREEMENT.

20.27 Accessibility; Americans with Disabilities Act

20.27.1 The Premises have not undergone an inspection by a Certified Access Specialist (CASp). A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises.

20.27.2 Since compliance with the Americans with Disabilities Act (ADA) is dependent upon Lessee's specific use of the Premises, Lessor makes no warranty or representation as to whether or not the Premises comply with ADA or any similar legislation. In the event that Lessee requests a CASp inspection and/or Lessee's use of the Premises requires modifications or additions to the Premises in order to be in ADA compliance (or other construction-related accessibility standards, if applicable), Lessee agrees to make any such necessary modifications and/or additions at Lessee's expense.

21. RIGHT TO NEGOTIATE LEASE FOR EXPANSION SPACE

21.1 Exercise of First Offer

During the term of this Lease and subject to the terms of this Section 21, Lessee shall have the right to negotiate a lease for the Expansion Space, if available for lease. The Expansion Space will not be considered "available for lease" if Lessor and the lessee under any expiring lease (the "Prior Lessee") of such space desire to renew or extend the Prior Lessee's lease under a properly exercised option that was granted to the Prior Lessee before the Effective Date.

21.2 Notice to Lessee

If the Expansion Space becomes available for lease, Lessor will provide Lessee with a notice ("Notice") of that availability. The right to lease the Expansion Space will apply only to the entire space described in the Notice. Lessee has the right, within ten (10) business days following receipt of the Notice, to elect, by written notice to Lessor, to begin negotiations to lease the Expansion Space from the Lessor.

21.3 Period for Negotiation

Promptly after receipt of Lessee's exercise of its right to negotiate a lease for the Expansion Space, the parties shall commence good faith negotiations exclusively with each other for a period not to exceed ninety (90) days after acceptance of the Notice. The parties may mutually agree to extend this ninety (90) day period at any time.

21.4 Failure of Parties to Negotiate Lease

21.4.1 If Lessor does not receive written confirmation of Lessee's intent to negotiate a lease for Suite A within said ten (10) business day period, or if the parties do not enter into a lease for Suite A within said ninety (90) day period, and do not mutually agree to extend such period, Lessor shall be free to enter into lease for Suite A with a third party on terms (considered as a whole) no more favorable to the third party than Lessor had last offered to Lessee.

21.4.2 If Lessor executes a lease for the Expansion Space with a third party, all rights of Lessee with respect to that Expansion Space under this section will cease, provided that if the Expansion Space becomes available for lease again at a future date, the provisions of this Section will again be applicable.

21.5 No Right to Expansion Space if in Default

In no event will Lessee have the right to exercise the right to negotiate a lease for the Expansion Space if Lessee is then in default under this Lease beyond any applicable notice and cure periods.

LESSOR AND LESSEE HAVE CAREFULLY READ AND REVIEWED THIS LEASE AND EACH TERM AND PROVISION CONTAINED HEREIN, AND BY THE EXECUTION OF THIS LEASE SHOW THEIR INFORMED AND VOLUNTARY CONSENT THERETO. THE PARTIES HEREBY AGREE THAT, AT THE TIME THIS LEASE IS EXECUTED, THE TERMS OF THIS LEASE ARE COMMERCIALLY REASONABLE AND EFFECTUATE THE INTENT AND PURPOSE OF LESSOR AND LESSEE WITH RESPECT TO THE PREMISES.

The Parties hereto have executed this Lease at the place and on the dates specified above their respective signatures.

(SIGNATURES CONTINUED ON NEXT PAGE)

LESSOR: RE HAZARD CONTRACTING COMPANY,
a California corporation

/s/ Robert Pizzuto

By: Robert Pizzuto

Its: Vice President

Lessor's Address for Notices: c/o Cypress View Properties, Inc.

Attn: Larry Figueroa
401 B Street, Suite 2400

San Diego, CA 92101

619-795-8578
larry@cypressview.com

LESSEE: Vital Therapies, Inc., a Delaware corporation

By: /s/ Duane Nash

Name: Duane Nash

Title: President

By: /s/ Aron Stern

Name: Aron Stern

Title: Chief Administrative Officer

Lessee's Address for Notices: 15010 Avenue of the Science, Suite 200

San Diego, CA 92128

EXHIBIT A – “Site Plan of the Premises”

EXHIBIT B – “Tenant Improvements” - [Not applicable – intentionally omitted.]

EXHIBIT C – “Guaranty” - [Not applicable – intentionally omitted.]

EXHIBIT D – “Estoppel Certificate”

STANDARD ESTOPPEL CERTIFICATE - BY LESSEE

To Whom It May Concern:

Re: Industrial/Commercial Multi-Tenant Lease – Gross Modified Dated October 18, 2016 ("Lease") By And Between Vital Therapies, Inc., a Delaware corporation (“Lessee”) and R.E Hazard Contracting Company, a California corporation (“Lessor”), concerning the real property commonly known as 15222 Avenue of the Science, Suite B, San Diego, California (the “Premises”)

Lessee hereby certifies as follows:

1. A true copy of the Lease is attached as Exhibit A. Other than the document included in Exhibit A there are no oral or written agreements or understandings between the Lessor and Lessee with respect to the Premises.

2. The Lease term commenced on July 1, 2017, and will continue for sixty (60) months, until June 30, 2022.

3. The current monthly rent and Lessor’s Share of Operating Expenses (as defined in the Lease), if any, are as follows:

	Amount	**Day of Month Due**	**Amount Paid YTD**
Rent			
Operating Expenses			

No rents or Operating Expenses have been prepaid except as reflected in the Lease.

4. The current amount of security deposit held by Lessor is $_____.

5. The improvements and space required to be provided by Lessor have been furnished and completed in all respects to the satisfaction of Lessee, and all promises of an inducement by Lessor have been fulfilled.

6. Lessee has no knowledge of any uncured defaults by Lessor or Lessee under the Lease.

7. There are no disputes between Lessor and Lessee concerning the Lease, the Premises or the improvements therein or thereon.

8. Lessee is in full and complete possession of the Premises and has not assigned or sublet any portion of the Premises.

9. Lessee has no knowledge of any prior sale, transfer, assignment or encumbrance of the Lessor's interest in the Lease.

10. Lessee has made no alterations or additions to the Premises not contemplated in the Lease.

11. If alterations or additions have been made by Lessee, Lessee represents that to the best of its knowledge, all such alterations and additions were done in accordance with the terms of the Lease and in compliance with all applicable laws, rules and regulations.

12. Lessee is not currently the subject of a bankruptcy proceeding and to the best of its knowledge Lessor is involved in such a proceeding.

13. Lessee is aware that buyers, lenders and others will rely upon the statements made in this Estoppel Certificate, and has therefore adjusted the language hereof as necessary to make it an accurate statement of the current facts concerning the Lease.

LESSEE: Vital Therapies, Inc., a Delaware corporation

Dated: By: _____

Name:_____

Title: _____

Exhibit 31.1

CERTIFICATIONS

I, Terence E. Winters, Ph.D., 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: May 9, 2017

By: /s/ Terence E. Winters, Ph.D.
Terence E. Winters, Ph.D.
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: May 9, 2017

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 March 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Terence E. Winters, Ph.D., 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: May 9, 2017

By: /s/ Terence E. Winters, Ph.D.
Terence E. Winters, Ph.D.
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 March 31, 2017 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: May 9, 2017

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