Table of Contents

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

FORM 10-Q

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

For the quarterly period ended June 30, 2014

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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	☐

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 August 1, 2014:

Class	**Number of Shares Outstanding**
Common Stock, $0.0001 par value	21,790,745

Table of Contents

VITAL THERAPIES, INC.
INDEX

VITAL THERAPIES, INC.

Condensed Consolidated Balance Sheets

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

	June 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 90,840	$ 38,186
Restricted cash	1,234	963
Deferred financing costs	—	3,506
Other current assets and prepaid expenses	1,415	1,200
Total current assets	93,489	43,855
Property and equipment, net	3,264	2,467
Other assets	263	263
Total assets	$ 97,016	$ 46,585
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,461	$ 1,224
Accrued expenses	5,806	3,253
Other current liabilities	294	369
Future purchase rights liabilities	—	2,600
Total current liabilities	7,561	7,446
Other long-term liabilities	292	321
Commitments and contingencies		
Convertible preferred stock (Junior); $0.0001 par value, no shares and 3,501,401 designated at June 30, 2014 and December 31, 2013, respectively; no shares and 3,501,400 issued and outstanding at June 30, 2014 and December 31, 2013, respectively	—	1,359
Redeemable convertible preferred stock (Senior); $0.0001 par value, no shares and 17,000,000 designated at June 30, 2014 and December 31, 2013, respectively; no shares and 10,212,007 issued and outstanding at June 30, 2014 and December 31, 2013, respectively	—	82,116
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 20,000,000 and 25,000,000 (4,498,599 undesignated) authorized at June 30, 2014 and December 31, 2013, respectively; no shares issued or outstanding at June 30, 2014 and December 31, 2013	—	—
Common stock, $0.0001 par value; 130,000,000 and 29,250,000 shares authorized at June 30, 2014 and December 31, 2013, respectively; 21,790,745 and 606,238 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	2	—
Additional paid-in capital	213,146	58,413
Accumulated other comprehensive income	95	96
Accumulated deficit	(124,080)	(103,166)
Total stockholders' equity (deficit)	89,163	(44,657)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 97,016	$ 46,585

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

VITAL THERAPIES, INC.

Condensed Consolidated Statements of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	$ 9,125	$ 4,538	$ 18,345	$ 7,970
General and administrative	2,513	2,525	5,170	4,019
Total operating expenses	11,638	7,063	23,515	11,989
Loss from operations	(11,638)	(7,063)	(23,515)	(11,989)
Other income (expense):				
Interest income	4	1	7	3
Other expense, net	(5)	(4)	(7)	(4)
Revaluation of future purchase rights liabilities	1,472	922	2,600	(3,512)
Total other income (expense)	1,471	919	2,600	(3,513)
Net loss	(10,167)	(6,144)	(20,915)	(15,502)
Amortization of deemed dividend	(4,722)	(8)	(4,744)	(11)
Accretion to redemption value of redeemable convertible preferred stock	(1,362)	(1,115)	(4,410)	(2,085)
Net loss attributable to common stockholders	$ (16,251)	$ (7,267)	$ (30,069)	$ (17,598)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.91)	$ (14.33)	$ (3.24)	$ (36.12)
Weighted-average common shares outstanding, basic and diluted	17,888,171	507,055	9,273,672	487,221

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

VITAL THERAPIES, INC.

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net loss	$(10,167)	$(6,144)	$(20,915)	$(15,502)
Other comprehensive income:				
Foreign currency translation	—	3	(1)	6
Total comprehensive loss	$(10,167)	$(6,141)	$(20,916)	$(15,496)

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

VITAL THERAPIES, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (20,915)	$(15,502)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	543	337
Stock-based compensation	1,108	299
Revaluation of future purchase rights liabilities	(2,600)	3,512
Other	(52)	(20)
Changes in operating assets and liabilities:		
Other current assets and prepaid expenses	(215)	(454)
Accounts payable	337	226
Accrued expenses	2,552	1,193
Net cash used in operating activities	(19,242)	(10,409)
Cash flows from investing activities:		
Purchases of short-term investments	—	(2,999)
Sales of short-term investments	—	11,999
Increase in restricted cash	(271)	(286)
Purchases of property and equipment	(1,045)	(558)
Net cash (used in) provided by investing activities	(1,316)	8,156
Cash flows from financing activities:		
Proceeds from initial public offering, net of issuance costs	55,046	(247)
Proceeds from issuance of preferred stock, net of issuance costs	18,167	34,097
Proceeds from exercise of stock options	—	84
Proceeds from early exercise of stock options	—	279
Net cash provided by financing activities	73,213	34,213
Effect of exchange rate changes on cash and cash equivalents	(1)	2
Net change in cash and cash equivalents	52,654	31,962
Cash and cash equivalents, beginning of period	38,186	4,477
Cash and cash equivalents, end of period	$ 90,840	$ 36,439
Supplemental disclosure of noncash investing and financing activities:		
Purchase of property and equipment included in liabilities	$ 294	$ 363
Deferred financing costs included in liabilities	$ —	$ 889
Conversion of preferred stock to common stock	$110,796	$ —
Release of stock option early exercise repurchase liability	$ 52	$ —
Valuation of future purchase rights upon issuance	$ —	$ 894
Beneficial conversion underlying the senior preferred stock	$ —	$ 673
Accretion to redemption value of redeemable convertible preferred stock	$ 4,410	$ 2,085

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

VITAL THERAPIES, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of Business and Basis of Financial Statements

Description of Business

We began operations as a California corporation on May 23, 2003 through the acquisition of the assets and business of VitaGen, Inc. and in June 2003 changed our name to Vital Therapies, Inc. In January 2004, we were re-incorporated in Delaware. We are a biotherapeutic company focused on developing a cell-based therapy targeting the treatment of all forms of acute liver failure. Our product candidate, currently in Phase 3 clinical trials, the ELAD® System or ELAD, is an extracorporeal human cell-based bio-artificial 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 realized revenues from our planned principal operations. Our business, operating results, financial condition, and growth prospects are subject to significant risks and uncertainties, including failing to obtain regulatory approval to commercialize and failing to secure additional funding to complete development of and to commercialize our product. Our headquarters are located in San Diego, California.

Unaudited Interim Financial Information

The results for the three and six months ended June 30, 2014 are not necessarily indicative of results to be expected for the year ending December 31, 2014, any other interim or any future year or period. 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, 2013, included in our final prospectus filed with the Securities and Exchange Commission, or the SEC, on April 17, 2014 relating to our Registration Statement on Form S-1 (File No. 333-191711) for our initial public offering, or IPO.

Basis of Presentation and Consolidation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (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, 2013 included in this report has been derived from the audited consolidated financial statements included in the Form S-1. 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. Certain reclassifications have been made to the prior period amounts to conform to the current presentation.

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

We previously were classified as a "development stage entity" under GAAP and, as such, were required to present inception-to-date information in our statements of operations, comprehensive loss, stockholders' equity, and cash flows. In June 2014, the Financial Accounting Standards Board ("FASB") issued an accounting standards update that eliminates the concept of a development stage entity from GAAP and removes the related incremental reporting requirements, which we elected to early adopt. See Note 2 for additional information on this new standard. Accordingly, in contrast to our financial statements included in our final prospectus filed with the SEC and our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014, the condensed consolidated financial statements contained in this report do not include inception-to-date information.

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 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 and are stated at cost, which approximates market value.

Restricted Cash

Restricted cash relates to amounts reserved for various clinical trial obligations and lease arrangements at June 30, 2014 and December 31, 2013, as well as for certain provisions of the junior preferred stock agreement at December 31, 2013.

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 any period 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 any period presented.

Level 3—Unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of assets or liabilities. Our Level 3 liabilities consisted of future purchase rights liabilities during the periods presented. We had no Level 3 assets in any period presented. Upon the completion of our IPO in April 2014, the future purchase rights liabilities terminated. See “Future Purchase Rights Liabilities” below.

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

Deferred Financing Costs

Deferred financing costs represent direct costs associated with the issuance of our corporate securities. Direct costs include, but are not limited to, the legal, accounting and printing costs. Indirect costs associated with the future issuance of corporate securities are expensed as incurred. The deferred financing costs were offset against the proceeds from our IPO in April 2014.

Property and Equipment, Depreciation and Amortization

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 amortized 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 June 30, 2014.

Redeemable Convertible Preferred Stock

Our junior convertible and senior redeemable convertible preferred stock were classified as mezzanine equity instead of a component of stockholders' deficit in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities, as the preferred stock was conditionally redeemable at the holder's option or upon certain change in control events that are outside our control, including liquidation, sale, or transfer of control of the company. In conjunction with our IPO in April 2014, all shares of our junior convertible and senior redeemable convertible preferred stock were converted to common stock.

Future Purchase Rights Liabilities

Our future purchase rights liabilities were initially recorded at their estimated fair value on the date of issuance as a discount on the underlying preferred stock and were re-measured to reflect changes in the estimated fair value at each reporting date, with any decrease or increase in the estimated fair value being recorded as other income or expense, respectively. The fair value of these liabilities was estimated using a binomial lattice model that was based on the characteristics of the common and preferred stock on the valuation date, probabilities related to our operations and clinical development, as well as assumptions for volatility, remaining expected life, risk-free interest rate and, in some cases, credit spread. Changes in the fair value of the future purchase rights fluctuated in conjunction with increases or decreases in the implied fair value of our common stock, and the number of preferred and common shares and future purchase rights outstanding relative to our enterprise value at each reporting date. In April 2014, the remaining future purchase rights terminated upon the conversion of all senior preferred stock to common stock in conjunction with our IPO with the remaining balance of the future purchase rights liabilities recorded as other income in our statement of operations for the period.

Research and Development

Research and development costs consist primarily of employee-related expenses, costs incurred for clinical trial sites, contractors and contract research organizations engaged in the development of the ELAD System, 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 payments made to employees and directors based on estimated fair value, net of an estimated forfeiture rate, and to consultants based on estimated fair value. Currently, our stock-based awards consist only of stock options; however, future grants under our equity compensation plans may consist of shares of restricted stock and restricted stock units. We estimate the fair value of stock options granted using the Black-Scholes-Merton, or BSM, option pricing model, which requires the use of estimates to value employee stock-based compensation at the date of grant.

We recognize stock-based compensation cost for employees and directors on a straight-line basis over the requisite service period of the award. Stock-based compensation expense is recognized only for those awards that are ultimately expected to vest. We estimate forfeitures based on an analysis of our historical employee turnover and will continue to evaluate the appropriateness of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover and other factors. We will revise the forfeiture estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Changes in forfeiture estimates, which have not been material to date, impact compensation cost in the period in which the change in estimate occurs.

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 recognized as expense in the consolidated statements of operations.

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 companies by taking the average historic price volatility for these peers for a period equivalent to the expected term of the stock option grants. The peer group was developed based on companies in the biotechnology industry whose shares are publicly-traded. 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 determined the expected life assumption 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 noted above, as applicable.

Common Stock Valuation

Due to the absence of a public market trading our common stock prior to the completion of our IPO in April 2014, it was necessary to estimate the fair value of the common stock underlying our stock-based awards when performing fair value calculations using the BSM option pricing model. The fair value of the common stock underlying our stock-based awards was assessed by our board of directors. All options to purchase shares of our common stock have been granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant.

In the absence of a public trading market for our common stock, we determined the estimated fair value of our common stock using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid Series: *Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the AICPA Practice Aid.

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 terms of the leases. In cases where our lessor grants to 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 and has been reflected as a separate component of stockholders' equity (deficit) in the accompanying condensed consolidated balance sheets.

Foreign Currency Translation and Transactions

The functional currencies of our subsidiaries in the United Kingdom and China are the local currencies. Assets and liabilities of the subsidiaries are translated at the rate of exchange at the balance sheet date. Expenses are translated at the average rate of 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 results 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 consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

We recognize net deferred tax assets to the extent we believe these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable

temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that we would be able to realize our deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. As of June 30, 2014 and December 31, 2013, we maintained a full valuation allowance against our entire balance of deferred tax assets.

We record uncertain tax positions in accordance with ASC 740 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 attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Excluded from the weighted-average number of shares outstanding are shares that have been issued upon the early exercise of stock options and are subject to future vesting, which was a total of 34,801 shares as of June 30, 2014. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Common stock equivalents are comprised of redeemable convertible preferred stock, warrants for the purchase of common stock, and options outstanding under our stock option plan. 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, which are 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 (in common stock equivalent shares):

	As of June 30,	
	2014	2013
Redeemable convertible preferred stock	—	11,313,370
Options to purchase common stock	3,174,470	2,672,904
Warrants to purchase common stock	250,646	250,646

Recently Issued Accounting Standards

In June 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-10, *"Development Stage Entities (Topic 915)—Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation,"* which eliminates the concept of a development stage entity in its entirety from current accounting guidance and provides for certain amendments to the consolidation guidance in Topic 810 in the Accounting Standards Codification, or ASC. Prior to the issuance of this guidance, we were considered a development stage entity and as a result we included certain inception-to-date disclosures in our financial statements. The guidance related to the elimination of the concept of a development stage entity is effective for public companies for annual reporting periods beginning after December 15, 2014, and interim periods therein. The amendment of the consolidation guidance in Topic 810 is effective for public companies for annual reporting periods beginning after December 15, 2015. Early adoption of the new standard is permitted. ASU No. 2014-10 was adopted by us during the quarter ended June 30, 2014. As such, all inception-to-date disclosures have been removed from these condensed consolidated financial statements.

3. Other Financial Information

Property and Equipment

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

	June 30, 2014	December 31, 2013
Manufacturing and laboratory equipment	$ 3,995	$ 3,229
Office furniture and equipment	113	112
Clinical equipment	2,111	1,606
Computer equipment and software	132	122
Leasehold improvements	3,211	2,830
Construction in progress	—	323
	9,562	8,222
Less: accumulated depreciation and amortization	(6,298)	(5,755)
Total	$ 3,264	$ 2,467

Depreciation and amortization expense was $246,000 and $174,000 for the three months ended June 30, 2014 and 2013, respectively, and $543,000 and $337,000, for the six months ended June 30, 2014 and 2013, respectively.

Accrued Expenses

Accrued expenses consist of (in thousands):

	June 30, 2014	December 31, 2013
Accrued clinical and related costs	$ 4,421	$ 2,067
Accrued financing costs	—	496
Accrued compensation and related taxes	1,238	512
Accrued other	147	178
Total	$ 5,806	$ 3,253

4. Commitments and Contingencies

Operating Leases

We lease office, manufacturing and research and development facilities, and equipment under various non-cancellable operating lease agreements through 2017. Facility leases generally provide for periodic rent increases and many contain escalation clauses and renewal options. Certain leases require us to pay property taxes and routine maintenance. Total rent expense under our operating leases was $210,000 and $149,000 for the three months ended June 30, 2014 and 2013, respectively, and $393,000 and $288,000 for the six months ended June 30, 2014 and 2013, respectively.

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 expense as deferred rent. Current and long-term deferred rent totaled $119,000 and $292,000 at June 30, 2014, and $142,000 and $321,000 at December 31, 2013, 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. Our industry is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights, as well as 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 table presents information about each major category of our financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	Fair Value Measurement at June 30, 2014			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$ 88,217	$ 88,217	$ —	$ —

	Fair Value Measurement at December 31, 2013			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$ 37,158	$ 37,158	$ —	$ —
Liabilities				
Future purchase rights	$ 2,600	$ —	$ —	$ 2,600

We report the change in fair value during each period as a nonoperating gain or loss. There were no transfers between Level 1, Level 2 or Level 3 for our assets or liabilities during the six months ended June 30, 2014.

The following table summarizes the changes in Level 3 future purchase rights liabilities measured at fair value on a recurring basis for the six months ended June 30, 2014 (in thousands):

	Fair Value of Future Purchase Rights Liabilities
Balance at January 1, 2014	$ 2,600
Revaluation of future purchase rights	(2,600)
Balance at June 30, 2014	$ —

We valued the future purchase rights liabilities as of December 31, 2013, using a binomial lattice option pricing model with the following assumptions:

	December 31, 2013
Common stock fair value	$ 5.93
Preferred stock price	$ 8.00
Volatility	85.0%
Risk-free interest rate	0.38%
Contractual life (years)	2.08
Number of nodes	25
Dividend yield	0.0%

6. Redeemable Convertible Preferred Stock

Junior Convertible Preferred Stock

In February 2012, we entered into a securities purchase agreement for the sale of junior convertible preferred stock. The junior preferred stock financing totaled $1.5 million of convertible, but not redeemable, preferred stock at approximately $0.43 a share, for an aggregate of 3,501,400 shares, to which we received net proceeds of $1.3 million. In conjunction with the completion of our IPO in April 2014, all shares of our junior convertible preferred stock were converted into common stock on a one-to-one basis and the remaining unamortized issuance costs were recognized as accretion to redemption value of the convertible preferred stock in the statement of operations.

Senior Redeemable Convertible Preferred Stock

In September 2012, we entered into a senior preferred stock purchase agreement (as amended in December 2013, the Senior Preferred Purchase Agreement) that authorized the multi-stage issuance of shares of our senior redeemable convertible preferred stock for $8.00 per share. As of December 31, 2013, we had issued 10,212,007 shares of senior redeemable convertible preferred stock under the Senior Preferred Purchase Agreement.

Pursuant to the Senior Preferred Stock Purchase Agreement, in January 2014 we issued an additional 555,000 shares of senior redeemable convertible preferred stock for proceeds of $4.3 million, net of issuance costs of $135,000. Also in January 2014, we completed the sale of 1.5 million shares of our senior redeemable convertible preferred stock at a price of $8.00 per share in a private placement to new investors for proceeds of $12.0 million, net of issuance costs of $31,000.

In February 2014, we completed a pre-emptive rights offering, triggered by the private placement to new investors in January 2014, for 241,016 shares of our senior redeemable convertible preferred stock at a price of $8.00 per share for proceeds of $1.9 million, net of issuance costs of $35,000.

In conjunction with the completion of our IPO on April 2014, all the outstanding shares of our senior redeemable convertible preferred stock were converted into common stock on a one-to-one basis and the remaining unamortized discounts and issuance costs were recognized as a deemed dividend and accretion to redemption value of the redeemable convertible preferred stock, respectively, in the statement of operations.

Future Purchase Rights/Beneficial Conversion Amounts

Pursuant to the Senior Preferred Purchase Agreement, we granted the investors in the senior preferred stock financing the right, subject to the satisfaction of certain conditions, to purchase additional shares of senior preferred stock for a purchase price of $8.00 per share at multiple subsequent closings in accordance with a schedule provided in the Senior Preferred Purchase Agreement. These future purchase rights were legally detachable from the underlying senior preferred stock and, as a result, were considered freestanding instruments accounted for separately from the senior preferred stock as a liability.

In addition, as the fair value received for certain shares of senior preferred stock sold during the year ended December 31, 2013 was less than the fair of our common stock on the date of issuance, we recorded beneficial conversion amounts associated with the rights of the holders of such preferred stock to convert their preferred stock to common stock. These beneficial conversion amounts were recorded as an offset to additional paid-in capital and were being amortized as a deemed dividend over the redemption period using an effective interest rate method.

All remaining future purchase rights associated with our preferred stock were terminated and the remaining unamortized beneficial conversion balance was recognized as a reduction to equity at the effective date of our IPO. We recognized a deemed dividend of $883,000 and $905,000 for the three and six months ended June 30, 2014, respectively, and $8,000 and $11,000 for the three and six month periods ended June 30, 2013, respectively.

Warrants

Warrants outstanding and exercisable for 250,646 shares of common stock as of June 30, 2014 have a weighted-average exercise price of $95.21 and expire between February 2016 and September 2019.

7. Common Stock

In April 2014, we completed an IPO selling 4,500,000 shares of our common stock at $12.00 per share and received net proceeds of $50.2 million after underwriters' discounts and commissions. In addition, we incurred $5.8 million in offering expenses, resulting in total costs of $9.6 million and net offering proceeds to us of $44.4 million. In May 2014, the underwriters exercised their option to purchase an additional 675,000 shares of our common stock at $12.00 per share in full. As a result, we received an additional $7.5 million in net proceeds after underwriters' discounts and commissions of $567,000 for total net proceeds of $51.9 million from the IPO.

In connection with our IPO, we filed an amended and restated certificate of incorporation to authorize 150,000,000 shares of capital stock, consisting of 20,000,000 shares of preferred stock and 130,000,000 shares of common stock.

Stock Reserved for Future Issuance

Shares reserved for future issuance at June 30, 2014 are as follows:

	Number of Shares
Common stock warrants	250,646
Common stock options outstanding	3,174,470
Common stock options available for future grant	552,067
Total common shares reserved for future issuance	3,977,183

8. Stock Compensation Plans

Equity Incentive Plans

Our 2012 Stock Option Plan, or 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 the 2012 Plan generally have a ten-year term, vest over four years and are exercisable immediately, subject to a repurchase right that lapses as the option vests. As of June 30, 2014, options for 139,071 shares of our common stock had been exercised under the 2012 Plan, of which 34,801 shares were unvested and subject to repurchase. As of June 30, 2014, we have not repurchased any shares related to these early exercises for which our repurchase liability was $175,000.

Our 2014 Equity Incentive Plan, or the 2014 Plan, became effective on the close of the IPO and replaces 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. Option grants under the 2014 Plan generally have a ten-year term and vest over four years. 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 the effective date of our IPO, and on each annual anniversary of the effective date of the IPO, 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 of our IPO; or
- an amount as our board of directors may determine.

As of June 30, 2014, the aggregate number of shares that may be issued under the 2012 and 2014 Plans is 3,726,537.

The following table summarizes employee and nonemployee stock option activity:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2014	3,098,573	$ 6.71		
Granted	121,863	$ 10.22		
Forfeited	(45,966)	$ 8.46		
Outstanding as of June 30, 2014	3,174,470	$ 6.61	8.40	$65,478,696
Options vested and expected to vest as of June 30, 2014	3,167,516	$ 6.61	8.40	$65,339,393
Options exercisable as of June 30, 2014	3,123,795	$ 6.52	8.37	$64,731,240

Stock-based Compensation Expense

The weighted-average grant date fair value of stock options granted during the six months ended June 30, 2014 and 2013 was $7.05 and $4.92, 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 nonemployees:

	Six Months Ended June 30,	
	2014	2013
Employees:		
Risk-free interest rate	1.60% - 1.83%	0.8%
Expected dividend yield	0%	0%
Expected volatility	81% - 85%	100%
Expected term of options (years)	6	5
Fair value of common stock	$7.55 - $12.49	$6.82 - $6.85
Nonemployees:		
Risk-free interest rate	0.12% - 1.13%	0.16% - 0.58%
Expected dividend yield	0%	0%
Expected volatility	76% - 85%	100%
Expected term of options (years)	1 - 4	1 - 4
Fair value of common stock	$11.31 - $27.24	$6.82 - $6.85

Valuation Analyses

Due to our management's and board of directors' decision to pursue an IPO, coupled with our belief that we could reasonably estimate the form and timing of potential liquidity events, we utilized a Probability Weighted Expected Return Method, or PWERM, to determine the fair value of our common stock in 2014 and 2013. Under this method, the implied fair value of our common stock is estimated based upon an analysis of future values assuming various outcomes. The value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available to us as well as the rights of each share class. The possible outcomes considered are based upon an analysis of future scenarios as described below:

- closing of an IPO;
- sale to a strategic acquirer;
- continuation as a private company with subsequent liquidation event; and
- dissolution.

Critical assumptions required to perform the PWERM include the following:

- Scenarios: Expected future events were identified.
- Scenario probabilities: Estimates of the probability of occurrence of each event were identified.
- Valuation: Expected future values under each scenario were estimated.
- Timing: Expected timing to the event under each scenario were estimated.
- Risk adjusted discount rates: Risk-adjusted discount rates were selected for each equity class based on the rights and preferences of each equity class and market data.
- Discounts: Appropriate minority or marketability discounts, if any, required to estimate the per share value of the various equity classes were determined.

In determining the implied fair value of our common stock in the IPO scenario, we assumed that the redeemable convertible preferred stock then outstanding would be converted into common stock. In allocating value to our common stock in the merger or sale scenario, we first allocated to our outstanding shares of redeemable convertible preferred stock the greater of the liquidation preference of the redeemable convertible preferred stock and the amount that would have been payable had all such shares of redeemable convertible preferred stock been converted to common stock.

There is inherent uncertainty in these estimates and, if we had made different assumptions, the fair value of the underlying common stock and amount of our stock-based compensation expense, net loss and net loss per share amounts would have differed.

February 12, 2014 Valuation Analysis

Our analysis considered the following probability-weighted scenarios:

Scenario	Weight
IPO by May 15, 2014	25%
Sale by September 30, 2015	10%
Private company	50%
Dissolution	15%

A discount for lack of marketability was applied for common stockholders of 8%, 20% and 28% for the IPO, sale and private company scenarios, respectively, which resulted in an implied fair value of $7.55 per share. The increase in fair value of our common stock from December 31, 2013 was primarily related to the increase in likelihood of an IPO scenario based on progress toward a public offering, coupled with a slight decrease in discount for lack of marketability for the IPO and sale scenarios. These were partially offset by dilution from the issuance of additional shares of our senior redeemable convertible preferred stock in January 2014.

March 31, 2014 Valuation Analysis

Our analysis considered the following probability-weighted scenarios:

Scenario	Weight
IPO by April 15, 2014	65%
Sale by September 30, 2015	10%
Private company	15%
Dissolution	10%

A discount for lack of marketability was applied for common stockholders of 2%, 17% and 27% for the IPO, sale and private company scenarios, respectively, which resulted in an implied fair value of $11.30 per share. The increase in fair value of our common stock from December 31, 2013 and February 12, 2014, was related to the increase in likelihood of an IPO scenario as significant progress had been completed toward a public offering and the decrease in discount for lack of marketability for the IPO scenario that reflected the proximity to the projected time to liquidity. These were slightly offset by dilution from the issuance of additional shares of our senior redeemable convertible preferred stock in January and February 2014, as applicable.

Total stock-based compensation expense for employee and nonemployee stock awards to employees and nonemployees recognized in our condensed consolidated statements of operations is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Employees:				
Research and development	$ 174	$ 40	$ 323	$ 57
General and administrative	209	118	404	166
Total	$ 383	$ 158	$ 727	$ 223
Nonemployees:				
Research and development	$ 275	$ 35	$ 360	$ 70
General and administrative	16	1	21	6
Total	$ 291	$ 36	$ 381	$ 76

As of June 30, 2014, there was $4.5 million of total compensation cost related to unvested stock option awards not yet recognized, which is expected to be recognized over a remaining weighted-average vesting period of 2.5 years.

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

The following Management's 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 final prospectus filed with the Securities and Exchange Commission (SEC) on April 17, 2014, relating to our Registration Statement on Form S-1 (File No. 333-191711) for our initial public offering. 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 therapeutics 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 regarding: markets for the ELAD® System; strategy and timing of clinic trials, regulatory requirements, 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 achieve and 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 rely 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.

Overview

We are a biotherapeutic company focused on developing a cell-based therapy targeting the treatment of all forms of acute liver failure. Our product candidate, the ELAD System, is an extracorporeal bio-artificial liver therapy designed to allow the patient's own liver to regenerate to a healthy state, or to stabilize the patient until transplant. The ELAD System is the only bio-artificial liver support system containing immortal human liver-derived cells, or 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 30,000 patients annually in the United States experience forms of acute liver failure, such as acute-on-chronic, surgically-induced and fulminant liver failures, for which the ELAD System may be a life-saving therapy. Outside of liver transplant, which is severely limited by availability of organs and not available to many patients, the current standard-of-care for acute 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 United States 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 United States, 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.

We are currently enrolling patients in one Phase 3 clinical trial, have regulatory allowance and five sites open for enrollment in a second Phase 3 trial, and also have initiated a Phase 2 clinical trial, each in forms of acute liver failure. In March 2013, we initiated VTI-208, a Phase 3 randomized, controlled clinical trial in 200 subjects with alcohol-induced liver decompensation, or AILD. As of August 5, 2014, 138 subjects had been enrolled in this trial and 49 clinical sites were open for enrollment. In addition, we have obtained regulatory allowance in the United States, United Kingdom, Spain and Australia to begin enrolling patients

in our second Phase 3 randomized, controlled clinical trial, VTI-210, in subjects with severe acute alcoholic hepatitis, or AAH. We recently requested regulatory guidance from the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA) on VTI-210 and, based on the response, we are modifying the trial protocol to stratify subjects into groups based on AAH diagnosis either by biopsy or by clinical grounds without biopsy, and are modifying the statistical plan to allow for an event-driven clinical design with a minimum of 150 subjects. We expect the enrollment of subjects in the modified VTI-210 protocol to begin in the second half of 2014 and as of August 5, 2014, five clinical sites were open for enrollment. Finally, we have enrolled our first patient in VTI-212, a single-arm clinical trial, which is being modified to enroll 40 subjects with fulminant hepatic failure, or FHF, and surgery-induced acute liver failure, or SILF.

Vital Therapies, Inc. was formed in May 2003 to acquire the assets of VitaGen (formerly Hepatix) in a bankruptcy proceeding. Our predecessor companies developed the ELAD System, completing two pilot trials in acute liver failure and two randomized, controlled Phase 1 and Phase 2 trials in FHF, but failed to attract funds sufficient to continue development of the ELAD system. Beginning in June 2003, we refocused the company to pursue regulatory approval and commercialization of the ELAD System in China. In 2007, we completed a pivotal trial in acute liver failure in subjects with viral hepatitis in China, and we submitted an application for marketing in China. Our application is still under review in China; however, we do not expect approval in China until we have approval in the United States.

We restarted our clinical program in the United States and Europe in 2008. Since then, we have run two Phase 2 trials and selected AILD and AAH as indications for our Phase 3 pivotal trial program in the United States and Europe. We have also made significant improvements in the ELAD System bedside unit and our proprietary cartridge cell growth production process, including (i) the incorporation of an updated version of the cardiovascular base unit that has improved features, functionality and reliability; (ii) new and improved cartridges for ultrafiltrate, cell filters and the ELAD cartridges; (iii) tubing sets that have been optimized to recirculate smaller volumes of ultrafiltrate and blood through the system to reduce the risk of clotting and other potential adverse side effects; and (iv) improvements to our cell culture and growth processes to reduce cost and increase manufacturing efficiency and yield.

We have incurred net losses since inception of $124.1 million through June 30, 2014. We anticipate that we will continue to incur increasing losses for at least the next several years. Due to the uncertainties involved with biological product development and the clinical trial process, we cannot predict the timing or accuracy of future expenses, when product approval for the ELAD System might occur, or when profitability may be achieved or sustained.

In April 2014, we completed our initial public offering, or IPO, of 4,500,000 shares of common stock at an offering price of $12.00 per share. We received net proceeds of approximately $44.4 million, after deducting underwriting discounts, commissions and offering-related transaction costs. In May 2014, the underwriters exercised their option to purchase an additional 675,000 shares of our common stock at $12.00 per share in full. As a result, we received an additional $7.5 million in net proceeds after underwriters' discounts and commissions, for total net proceeds of $51.9 million from the offering.

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 and regulatory 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 and maintenance of facilities and equipment, and depreciation of fixed assets; and
- costs associated with other research and regulatory activities.

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

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 related facility costs, stock-based compensation, and professional fees for legal, consulting, accounting and tax services.

Comparison of the Three Months Ended June 30, 2014

The following table summarizes our operating expenses for the three months ended June 30, 2014 and 2013.

	Three Months Ended June 30,		Change	
	2014	2013	$	%
(dollars in thousands)	(unaudited)			
Operating expenses:				
Research and development	$ 9,125	$ 4,538	$4,587	101%
General and administrative	2,513	2,525	(12)	(— %)
Total operating expenses	$ 11,638	$ 7,063	$4,575	65%

The $4.6 million increase in research and development expense during the three months ended June 30, 2014 as compared to the three months ended June 30, 2013 was primarily associated with an increase in our Phase 3 clinical trial activities. The increase during the three months ended June 30, 2014 was principally attributable to increases of $1.2 million in fees paid to CROs, clinical sites and other related costs, $1.5 million in salaries and wages, stock-based compensation and other compensation related costs due to increased headcount, $835,000 in third-party consulting, $593,000 in manufacturing supplies and related costs, $119,000 in travel expenses and $317,000 of facilities related costs, which includes depreciation, computer and equipment costs, utilities and lease expenses.

The $12,000 decrease in general and administrative expense during the three months ended June 30, 2014 as compared to the three months ended June 30, 2013 was primarily attributable to increases of $352,000 in salaries and wages, stock-based compensation, and other compensation related expenses due to increased headcount to support our operations, $160,000 for insurance coverage increases associated with becoming a publicly-traded company, and $71,000 associated with computer and equipment costs, other facilities related costs and depreciation. These increases were offset by decreases of $216,000 primarily associated with lower recruiting expenses, $117,000 in consulting fees due to the completion of our IPO in April 2014, and $264,000 related to lower corporate legal expenses and audit fees.

Separate from operating expenses, the $1.5 million of other income recognized for the revaluation of future purchase rights liabilities for the three months ended June 30, 2014 was the result of the termination of the remaining purchase rights liabilities upon the conversion of all senior preferred stock to common stock in conjunction with the completion of our IPO. This compares to $922,000 recognized as other income for the revaluation of future purchase rights liabilities for the three months ended June 30, 2013.

Comparison of Six Months Ended June 30, 2014 and 2013

The following table summarizes our operating expenses for the six months ended June 30, 2014 and 2013.

	Six Months Ended June 30,		Change	
	2014	2013	$	%
(dollars in thousands)	(unaudited)			
Operating expenses:				
Research and development	$18,345	$ 7,970	$10,375	130%
General and administrative	5,170	4,019	1,151	29%
Total operating expenses	$23,515	$11,989	$11,526	96%

The $10.4 million increase in research and development expense during the six months ended June 30, 2014 as compared to the six months ended June 30, 2013 was principally associated with an increase in our Phase 3 clinical trial activities. The higher costs were primarily attributable to increases of $3.5 million in fees paid to CROs, clinical sites and other related costs, $2.9 million in salaries and wages, stock-based compensation and other compensation related costs due to increased headcount, $1.8 million in consulting fees, $1.0 million in manufacturing supplies and related costs, $471,000 in travel and seminar expenses and $616,000 in facilities related costs, which includes depreciation, computer and equipment costs, utilities and lease expenses.

The $1.2 million increase in general and administrative expense during the six months ended June 30, 2014 as compared to the six months ended June 30, 2013 was primarily attributable to a $836,000 increase in salaries and wages, stock-based compensation, and other compensation related expenses due to increased headcount to support our operations, an increase of $179,000 in audit and corporate legal expenses, $256,000 for higher insurance costs associated with coverage related to becoming a publicly-traded company, and an increase of $153,000 associated with computer and equipment costs, other facilities related costs and depreciation, related to our increases in headcount, offset by a $317,000 decrease primarily related to lower recruiting expenses.

Separate from operating expenses, the $2.6 million recognized as other income for the revaluation of future purchase rights liabilities for the six months ended June 30, 2014 reflects the termination of the remaining purchase rights liabilities in conjunction with the completion of our IPO in April 2014. The $3.5 million of other expense reflects the revaluation of future purchase rights liabilities for the six months ended June 30, 2013.

Liquidity and Capital Resources

To date, we have not generated significant revenues attributable to the ELAD System. We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $124.1 million as of June 30, 2014. We expect that our research and development and general and administrative expenses will continue to increase through the completion of our Phase 3 clinical trials and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through a combination of equity offerings, debt financings, government or other third-party financing, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

In April 2014, we completed our initial public offering selling 4,500,000 shares of our common stock at $12.00 per share. In May 2014, the underwriters exercised their option to purchase an additional 675,000 shares of our common stock at $12.00 per share. In total, we received net proceeds of $57.8 million after underwriters' discounts and commissions. In addition, we have incurred $5.8 million in offering expenses, resulting in total fees and costs of $10.2 million and net offering proceeds to us of $51.9 million.

As of June 30, 2014, we had cash and cash equivalents of approximately $90.8 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 June 30, 2014, such balances were held in cash and money market funds.

The following table shows a summary of our cash flows for the six months ended June 30, 2014 and 2013.

	Six Months Ended June 30,	
	2014	2013
	(In thousands) (unaudited)	
Cash (used in) provided by:		
Operating activities	$(19,242)	$(10,409)
Investing activities	(1,316)	8,156
Financing activities	73,213	34,213

Operating Activities

During the six months ended June 30, 2014, operating activities used $19.2 million of cash. The use of cash was primarily related to our net loss of $20.9 million adjusted for noncash income of $2.6 million related to the revaluation of future purchase rights liabilities, noncash charges of $543,000 and $1.1 million for depreciation and stock-based compensation, respectively, and $2.7 million of net changes in our operating assets and liabilities. Net cash provided by changes in our operating assets and liabilities during the six months ended June 30, 2014 consisted primarily of an increase of $337,000 in accounts payable and $2.6 million in accrued liabilities, reflecting an increase in clinical activities and related research and development expenditures, partially offset by an increase of $215,000 from other current assets and prepaid expenses. The net increase in other current assets and prepaid expenses was attributable to a reduction in prepaid clinical costs of $636,000 related to the utilization of prepayments to our CROs, offset by an increase of $779,000 related to prepaid expenses primarily attributable to the purchase of corporate insurance policies.

During the six months ended June 30, 2013, operating activities used $10.4 million of cash. The use of cash was primarily related to our net loss of $15.5 million, partially offset by noncash charges of $3.5 million related to the revaluation of future purchase rights liabilities, $337,000 and $299,000 for depreciation and stock-based compensation, respectively, and $965,000 of net changes in our operating assets and liabilities. Net cash provided by changes in our operating assets and liabilities during the six months ended June 30, 2013 consisted primarily of an increase of $1.4 million in accounts payable and accrued liabilities, due principally to the timing of payments made by us to vendors, partially offset by an increase of $198,000 related to a lease deposit and $256,000 of prepaid clinical and other costs.

Investing Activities

During the six months ended June 30, 2014, investing activities used $1.3 million of cash, primarily related to $1.0 million in purchases of capital equipment for manufacturing and clinical areas and a net increase of $271,000 in restricted cash requirements. The net increase in our restricted cash is related to an increase in our clinical trial obligations of $558,000, which was offset by $288,000 related to the elimination of certain restrictions associated with the Junior Preferred Stock Purchase Agreement.

During the six months ended June 30, 2013, investing activities provided $8.2 million of cash, primarily related to a $9 million decrease in short-term investments, partially offset by $558,000 in purchases of capital equipment, and a $286,000 increase in restricted cash requirements associated with our clinical trial obligations and the Junior Preferred Stock Purchase Agreement.

Financing Activities

During the six months ended June 30, 2014, financing activities provided $73.2 million of cash, which included $55.0 million in net proceeds from our IPO and $18.2 million in net proceeds from the sale of senior redeemable convertible preferred stock. In April 2014, we completed our IPO selling 4,500,000 shares of our common stock at $12.00 per share with the underwriters exercising their option to purchase an additional 675,000 shares for $12.00 per share in May 2014 for total net proceeds of $55.0 million during the second quarter of 2014. The sale of senior redeemable convertible preferred stock occurred during the first quarter of 2014 and included the issuance of 555,000 shares of senior redeemable convertible preferred stock at $8.00 per share for net proceeds of $4.3 million under our Senior Preferred Stock Purchase Agreement. Additionally, in January 2014, we completed a private placement to new investors of 1.5 million shares of our senior redeemable convertible preferred stock at a price of $8.00 per share for net proceeds of $12.0 million. A pre-emptive rights offering, triggered by the private placement, raised a further $1.9 million in net proceeds from the sale of 241,016 shares of our senior redeemable convertible preferred stock at a price of $8.00 per share.

During the six months ended June 30, 2013, financing activities provided $34.2 million of cash, net of offering costs, primarily related to the sale of additional shares of our senior preferred stock at $8.00 per share. An additional $363,000 was received from the exercise of stock options during this same period.

Based on our current business plan, we believe that our existing cash and cash equivalents as of June 30, 2014 will be sufficient to fund our operations into the second quarter of 2016. In particular, we believe that the net proceeds from the initial public offering and our existing cash and cash equivalents will be sufficient to complete enrollment and receive data from our VTI-208 Phase 3 clinical trial. In addition, we project such funds may also be sufficient to complete enrollment and receive topline data from our VTI-212 Phase 2 clinical trial. Based on our current business plan and assuming a minimum 150 patient trial, we expect additional funding will be required before preliminary results from VTI-210 will be available. The amounts and timing of our actual expenditures depend on numerous factors, including the rate of subject enrollment in our clinical trials, filing requirements with various regulatory agencies, clinical trial results, and any unforeseen cash needs.

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:

- 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 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 on the ELAD System and any future product candidates.

Off-Balance Sheet Arrangements

Through June 30, 2014, 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 United States 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 second quarter of 2014, 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 final prospectus filed with the Securities and Exchange Commission (SEC) on April 17, 2014, relating to our Registration Statement on Form S-1 (File No. 333-191711) for a more complete discussion of our critical accounting policies and estimates.

Recently Issued Accounting Standards

In June 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-10*, "Development Stage Entities (Topic 915)—Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation,"* which eliminates the concept of a development stage entity in its entirety from current accounting guidance, and provides for certain amendments to the consolidation guidance in Topic 810 in the Accounting Standards Codification, or ASC. Prior to the issuance of this guidance, we were considered a development stage entity and as a result we included certain inception-to-date disclosures in our financial statements. The guidance related to the elimination of the concept of a development stage entity is effective for public companies for annual reporting periods beginning after December 15, 2014, and interim periods therein. The amendment of the consolidation guidance in Topic 810 is effective for public companies for annual reporting periods beginning after December 15, 2015. Early adoption of the new standard is permitted. ASU No. 2014-10 was adopted by us during the quarter ended June 30, 2014. As such, all inception-to-date disclosures have been removed from these condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There has been no material change in the Company's assessment of its sensitivity to market risk since our presentation set forth in "Quantitative and Qualitative Disclosures About Market Risk" in our final prospectus filed with the Securities and Exchange Commission (SEC) on April 17, 2014, relating to our Registration Statement on Form S-1 (File No. 333-191711).

Item 4. Controls and Procedures

Internal Controls and Procedures

In connection with past audits of our financial statements, our independent registered public accounting firm identified and reported adjustments to management. Certain of these adjustments were deemed to be the result of internal control deficiencies that constitute material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. If one or more material weaknesses persist or if we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report our financial results could be adversely affected.

We have not maintained an effective control environment in that the design and execution of our controls was limited due to the lack of a proper segregation of duties resulting from inadequate staffing levels, the ineffective review over financial transactions and the inadequate maintenance of our books and records. The lack of adequate staffing levels resulted in insufficient time spent on review and approval of certain information used to prepare our financial statements and the maintenance of effective controls to adequately monitor and review significant transactions for financial statement completeness and accuracy. Such examples include the correct financial statement classification, the valuation of financing transactions entered into during the period, and maintenance of documentation in support of such transactions. These control deficiencies, although varying in severity, contributed to the material weaknesses in the control environment noted by our independent registered public accounting firm.

Although remediation efforts are still in progress, management is taking steps to address the causes of our audit adjustments and to improve our internal control over financial reporting, including the implementation of new accounting processes and control

procedures and the identification of gaps in our skills base and the expertise of our staff as required to meet the financial reporting requirements of a public company. We have hired additional accounting personnel who are degreed accountants, which has enabled us to expedite our month-end close process, thereby facilitating the timely preparation of financial reports and to strengthen our segregation of duties. We intend to hire incremental qualified staff as part of a comprehensive review of our internal controls and formalization of our review and approval processes. As a part of these efforts, we may identify additional control deficiencies, which could give rise to significant deficiencies and other material weaknesses in addition to the material weaknesses previously identified.

We are in the very early stages of the costly and challenging process of compiling the systems and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing or any required remediation in a timely fashion. During the evaluation and testing process, if 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 designed and operating effectively, 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.

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 of the Sarbanes-Oxley Act until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an "emerging growth company" if we take advantage of the exemptions contained in the Jumpstart Our Business Startups Act, or 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. To comply with the requirements of being a public company, we may need to undertake various actions, such as implementing new internal controls and procedures or hiring accounting or internal audit staff.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2014. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure 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 SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, 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 objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level because of the material weaknesses in our internal controls over financial reporting as described above. Notwithstanding the existence of the material weaknesses described above, management believes that the consolidated financial statements in this Form 10-Q fairly present, in all material respects, our financial position, results of operations and cash flows for the interim and annual periods presented in accordance with generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) occurred during the three months ended June 30, 2014 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 party to any litigation and we are not aware of any pending or threatened litigation against us that we believe would adversely affect our business, operating results, financial condition or cash flows.

Item 1A. Risk Factors

Before deciding to invest in our company or deciding to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report and in our final prospectus filed with the Securities and Exchange Commission (SEC) on April 17, 2014, relating to our Registration Statement on Form S-1 (File No. 333-191771) for our initial public offering. The risks and uncertainties described below and in our other filings are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business. If any of these known or unknown risks or uncertainties actually occurs, our business, financial condition and results of operations could be seriously harmed. In that event, the market price for our common stock could decline and you may lose your investment.

Risks Related to Our Business

We are a clinical-stage company with no approved products, which makes assessment of our future viability 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. We have not yet demonstrated an ability to obtain regulatory approval, manufacture commercial-scale products, 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 acute liver failure. 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 indications of AILD, AAH, FHF and SILF in the United States 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 clinical trials necessary to support regulatory approval in any jurisdiction. For example, the U.S. Food and Drug Administration, or the FDA, has expressed concern about the open-label design of study VTI-208, our pivotal study in AILD, and the need to apply a consistent standard-of-care and to standardize post-discharge care, both being issues that could significantly confound the study results, impact morbidity and mortality and cause the FDA or other regulatory authorities to require that we repeat clinical trials with different trial designs. 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 should fail 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 must be evaluated in light of the uncertainties and complexities affecting a clinical-stage combination product biologic and medical device company. We have not completed clinical development for any of the ELAD System's potential indications in the United States or Europe where the ELAD System is regulated as a combination biologic and medical device, and a combined somatic cell Advanced Therapy Medicinal Product, respectively. We are conducting two Phase 3 clinical trials and a Phase 2/3 clinical program designed to establish the safety and efficacy of the ELAD System and to support approval in the United States and Europe. These clinical trials are expected to be performed in subjects with AILD, AAH, FHF and SILF. 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, the FDA has noted its view that preliminary clinical evidence, at this time, does not indicate that the ELAD System may demonstrate a substantial improvement over standard-of-care. There is no guarantee that our clinical trials will be completed in a timely fashion or succeed. Our ability ultimately to reach profitability is critically dependent on our future success in obtaining regulatory approval for the ELAD System. However, there is no guarantee that our clinical trials will be successful, or that regulators will approve the ELAD System in a timely manner, or at all.

If we fail to obtain regulatory approval as anticipated in the United States 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. Our ability to obtain regulatory approval of the ELAD System depends on, among other things, successful completion of clinical trials, and demonstrating efficacy with statistical significance and safety in humans. The results of our current and future clinical trials may not meet the FDA, the European Medicines Agency, or EMA, or other regulatory agencies' requirements to approve the ELAD System for marketing under any specific indication, and these regulatory agencies may otherwise determine that our manufacturing processes or facilities are insufficient to support approval. For example, the FDA has noted its view that preliminary clinical evidence, at this time, does not indicate that the ELAD System may demonstrate a substantial improvement over standard-of-care. 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, which could delay or prevent approval. If we fail to obtain regulatory approval in a timely manner, our commercialization of the ELAD System would be 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 therapy.

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 and includes consideration of factors such as cost effectiveness and patient benefit. There is great pressure from government and third-party payors 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 have commissioned a report from pricing study and reimbursement specialists, which concludes that we should target a commercial price between $150,000 and $275,000 for ELAD therapy in the United States, we do not know whether this price is achievable or sustainable. We have not yet determined a target commercial price for ELAD therapy outside of the United States, but believe it may be difficult to sustain a commercial price at or above the commercial price in the United States. We will have no control over the pricing that is set by the government or private insurers, 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, we cannot predict if such private payors will be prepared to pay an acceptable price.

If we are unable to implement our sales, marketing, distribution, training and support strategies or enter into agreements with third parties to perform these functions in markets outside of the United States 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 and do not plan to introduce the ELAD System, if approved, into the United States or other foreign jurisdictions until late 2016 at the earliest. Our commercial success will depend on our ability to market and receive adequate reimbursement of 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.

In the future, we expect to build a targeted sales, marketing, training and support infrastructure to market the ELAD System in the United States and Europe and to establish collaborations opportunistically to market, distribute and support the ELAD System outside of the United States 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 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 $32.7 million for the year ended December 31, 2013, and $20.9 million for the six months ended June 30, 2014. As of June 30, 2014, we have an accumulated deficit

of $124.1 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. We do not expect to earn revenues until late 2016 at the earliest, and 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, 2013, we had net operating loss, or NOL, carryforwards of approximately $37.3 million and $35.8 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 an ownership change in connection with or after our initial public offering, 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. 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, or 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 development programs for the ELAD System.

We rely on information technology systems to keep financial records, maintain laboratory and corporate records, communicate with staff and external parties and operate other critical functions. Despite the implementation of security measures, our internal computer systems and those used by our clinical investigators, contract research organizations, or CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. The techniques that could be used by criminal elements or foreign governments to attack these computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. Activities in China may be particularly at risk. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. While, to our knowledge, we have not experienced any such 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 activities. For example, the loss of clinical trial data from ongoing or 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 the future development of the ELAD System could be delayed.

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.

We are currently undertaking our first pivotal clinical trials for the ELAD System. While the endpoints and populations for the pivotal trials are derived from results of initial studies and medical literature, in none of those prior studies have we demonstrated an effect in the population and on the endpoints prospectively described in the study plan. The pivotal trials are primarily based on trends derived from post-hoc, retrospective analyses of data subsets. Our prior clinical trials of the ELAD System in AILD were not powered to, and did not demonstrate, statistically significant improvement over the standard-of-care in the primary endpoint of 90-day survival. Similarly, our prior clinical trials of the ELAD System in 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. Although we did complete a pivotal clinical program in acute liver failure in China in 2007, the underlying clinical trial was terminated early by the lead hospital due to achievement of safety and efficacy goals and a determination that it was unethical to continue. We are now in the process of conducting a pivotal program for the United States and Europe. We have not yet completed a pivotal clinical trial program of the size and complexity of our currently planned pivotal program for the United States, Europe, and Australia and we cannot provide any guarantee that we will successfully complete such a program. If this pivotal program is completed, there can be no assurance that the data generated can be used to support marketing approval for any indication in the United States or Europe. If our Phase 3 clinical trials do not achieve statistical significance for the primary endpoint, we will not receive marketing approval and we will not be able to commercialize the ELAD System.

The results of previous clinical trials may not be predictive of future results.

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 current and future clinical trials, there can be no guarantee that these lessons are correct or that we will effectively incorporate them into the design of current and future clinical trials. For example, our primary endpoint in VTI-208, 90-day survival, is based on the results of a subset of subjects in VTI-206. Though that subset showed a trend toward increased survival at 90-days, it consisted of only 29 subjects. The FDA has noted its belief that this preliminary clinical evidence does not indicate that our product may demonstrate a substantial improvement over the current standard-of-care. We cannot provide any guarantee that our current and 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 have 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 will include concurrent control subjects in a 1:1 ratio with treated subjects and all subjects will be included in the statistical analysis. Also, each study is designed to enroll subjects with an expected death rate between 50% and 75% in 30 to 90 days without the ELAD System therapy. It is necessary to select subjects with these death rates in order to be able to determine whether the ELAD System has an effect on treated subjects with a manageable number of subjects in the clinical trial. We monitor certain baseline characteristics of the subjects we are enrolling in our studies (such as age and mean model for end-stage liver disease, or MELD, score) to assess that the population characteristics are similar to those from prior studies in which death rates were in the target range. Although subjects enrolled thus far in VTI-208 have similar ages and MELD scores to AILD subjects enrolled in VTI-206, there is no assurance that this will continue to be the case or that these parameters are sufficient to predict survival. 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 be demonstrate statistically significant efficacy of the ELAD System therapy to gain approval.

Random variation or changes in standard-of-care could cause our clinical trials to fail.

Regulatory authorities worldwide have adopted the standard that, to gain marketing approval, clinical trials should produce a result that has less than a 5% probability of being due to random variation. There is no assurance that any of our 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, FDA has expressed concern that the VTI-208 study may not be adequately designed to provide convincing evidence of efficacy if there are significant differences in how the ELAD System subjects and controls are treated during the treatment period and after hospital discharge. 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. Any of these factors, which are beyond our control, could materially and adversely affect the results 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 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 towards very sick patients who are likely to die if left untreated. Patients in acute liver failure 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 cause a decline in blood platelets, which can lead to coagulation problems and uncontrolled bleeding because platelets are critical to the formation of blood clots. Patients with acute liver failure generally have serious blood clotting problems since the liver produces most 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, some patients require an infusion of small amounts of anti-coagulant therapy, which can aggravate bleeding. Because every patient is different, the need for anti-coagulant therapy is not predictable and must be established during therapy, a process that can affect the course of the therapy. The risk of uncontrolled bleeding may be addressed during the ELAD System therapy by administering platelet transfusions to patients whose platelets drop below a safe level. 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 hemolysis which, if not arrested, can be fatal. The incidence of hemolysis is about 1-2% in the acute liver failure patients enrolled in our trials to date.

Human liver-derived C3A cells have been shown in animal studies to have the capacity to grow into a tumor mass under certain conditions. Although this has not been seen in the subjects treated with the ELAD System to date, 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. 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 our control, including:

- timeliness of contracting with clinical trial sites, and obtaining approval of the trial by the institutional review boards, or IRBs, at each site;
- 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 for prospective subjects.

Additionally, even if we are able to identify an appropriate subject population for a clinical trial, there can be no assurance that the subjects will complete the study.

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

Our current and future clinical trials may require amendment or be delayed, 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 System pursuant to required quality standards for use in our clinical trials and by third-party manufacturers in supplying necessary and suitable components for the system;
- delays or failure in transporting the ELAD System 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;
- regulators or clinical site Ethics Committees or IRBs may 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 of our clinical trials may conclude that the ELAD System lacks sufficient clinical efficacy or presents unacceptable safety risks.

Should any of our clinical trials fail to provide evidence of safety and efficacy sufficient to satisfy the requirements of the regulatory authorities, the ELAD System will not be approved. If we experience delays in the completion of, or termination of, any clinical trial of the ELAD System, the commercial prospects of the ELAD System will be harmed, and our ability to generate revenues will be delayed or eliminated. In addition, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and delay or jeopardize our ability to commercialize the ELAD System. Any of these occurrences may 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 the United States, the ELAD System is regulated as a combination biologic and medical device. Before the ELAD System can be marketed in the United States, we must submit and the FDA must approve a Biologic License Application, or a BLA. In addition, the device components of the ELAD System must be found acceptable as part of the BLA. Because the ELAD System is a novel therapy involving a combination biologic and medical device, 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 treatment and controls 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 clinical benefits;

- 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. For example, the FDA has stated there are insufficient preclinical and clinical data to determine whether the ELAD System has the potential to provide a clinically meaningful improvement in liver function;
- 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, which 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 VTI-208 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 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, including VTI-208, is a statistical and clinical success, a second confirmatory trial that substantiates positive results may be necessary to support a BLA; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

The FDA has expressed concern that the VTI-208 study may not be adequately designed to provide convincing evidence of efficacy if there are significant differences in how the ELAD System subjects and control subjects are treated during the study and after discharge from the hospital. Differences in length of hospital stay, rates of hospital re-admission, alcohol recidivism rates, nutritional support, and concomitant medications could significantly confound the 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.

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

Outside the United States, 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 will 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.

Risks Related to the Medical Device Components of the ELAD System

If we or our third-party manufacturers fail to comply with the Quality System Regulation in the United States 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 cardiopulmonary bypass system that has been replaced with an updated system.

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 cardiopulmonary bypass surgery. Our prior clinical trials have been carried out using an ELAD System bedside unit based on Sorin's S3 system. However, Sorin has stopped selling the S3 system from the market 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 are being used in our ongoing clinical trials. There can be no assurance that regulatory authorities will view the S3 and S5 systems interchangeably, or that Sorin will cooperate with us or provide us with the documentation necessary to obtain regulatory approval or commercialize the device.

One of the ELAD System component suppliers is subject to an FDA consent decree which, if not lifted, would force us to find another supplier for these components.

One of the components of the ELAD System bedside unit is manufactured by Terumo Cardiovascular Systems, or Terumo. In March 2011, Terumo entered into a consent decree with the FDA which limits its ability to ship products from certain of its manufacturing facilities including the one that manufactures the component we use. We have signed a Certificate of Medical Necessity that allows us to continue to use those components we already own while Terumo works to resolve the issues associated with the consent decree. Once the consent decree is lifted Terumo has indicated that it will resume shipping of this component. Should Terumo not be able to fulfill the requirements of the consent decree, we will have to source these components from an alternative supplier. There is no guarantee that Terumo will be able to fulfill the requirements of the consent decree, or that an alternative supplier can be found or will agree to acceptable terms.

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 the BLA for the ELAD System. If the manufacturers of those components make modifications, discontinue or are unable to supply sufficient quantities of such components, 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 manufacturing of tubing which is a component of the ELAD System. If we cannot obtain sufficient quantities of this tubing on timely basis, we may have to delay enrollment in our clinical trials until additional supplies become available or we could be required to validate an alternative tubing to use, which may also delay our clinical trials and increase our costs. If 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 effectively used 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, we will be using the components for purposes outside the scope of the cleared indications. Other device components have no regulatory approvals. We will need to conduct additional bench testing to bridge the differences between the cleared indications for use and the proposed use in the ELAD System or to obtain approval. The failure to provide adequate bridging information or to obtain approval for these device components could delay or prevent approval of the ELAD System.

Risks Related to the Cellular Component of 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 and the bioreactors that have been developed to grow and store the ELAD cartridges. We are currently developing additional sources of supply for these components sufficient to support future clinical development and, ultimately, commercialization of the ELAD System. If we were to 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, newborn calf serum, which is a component of the cell growth media, is used in the manufacture of the ELAD System. 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 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 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, once 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.

In order to support our ongoing clinical programs, we will need to increase production of our ELAD System. Similarly, 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 United States and abroad. These activities involve significant expense, including the construction 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, our anticipated growth will place additional strain on our organization, employees and third-party suppliers, resulting in an increased need for us to carefully monitor quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

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 to 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 United States and the United Kingdom, 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 Phase 3 clinical trials and long-term commercial demand, we may 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 and could affect treatment outcomes. For instance, while patients treated with the ELAD System typically only require a single set of cartridges, some patients require more than one set during their three to ten day 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 specification set for a supplier and confirmed by us in our quality control procedures, but it is possible that unanticipated complications will emerge.

Risks Related to the ELAD System's Future Commercialization

It is difficult to forecast future performance; our financial results may fluctuate unpredictably.

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 United States 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.

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 acute 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 patient 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 will 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 valuable employees and thereby lose our advantage in the marketplace.

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.

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

The biotherapeutic and medical device industries are highly competitive and we face potential competition from pharmaceutical companies, specialty pharmaceutical, medical device and biotechnology companies worldwide. Given the significant unmet medical need for novel therapies to treat acute liver failure, many companies, universities and research organizations are actively engaged in the discovery, research and development of potential therapies in this field. Several of these entities are engaged in research on cell-based approaches to acute liver failure. Although we are not aware of any ongoing human clinical trials involving potentially competitive product candidates, such trials could be taking place or could begin in the near future. We are not aware of any company that is in human clinical trials with a human cell-based product for the treatment of acute liver failure. At least four companies have prior research work on various human hepatocyte cell lines including Exten Industries, Hepalife Technologies, Fresenius, and Hybrid Organ GmbH. In addition, the University College London, and the University of Amsterdam and its spinout Hep-Art Medical Devices are actively pursuing animal research in this area. Several companies have also attempted to develop extracorporeal therapy based upon primary porcine hepatocytes, although ongoing research in this area is difficult to ascertain. Two commercially available liver dialysis systems, from Gambro and Fresenius, have undergone extensive clinical development, although both have failed to show an improvement in long-term survival among patients with acute liver failure. Both rely on not only traditional dialysis circuits to remove water-soluble toxins, but also albumin dialysis circuits to remove albumin-bound molecules. In addition, there are several drugs available to treat symptoms associated with acute liver failure, including steroids, pentoxifylline and N-acetylcysteine. These three drugs, alone or in combination, are used frequently in patients with acute liver failure. While we are not aware of any of these other

entities being close to undergoing human clinical trials with a human cell-based product for the treatment of acute liver failure, 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, which could harm our business.

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 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 ten 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 and may not be accurate.

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 United States 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 United States, 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 and state 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 programs;
- 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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 rule, such as health plans, clearinghouses and healthcare providers;
- 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; and
- 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.

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 program, 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 United States 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 United States or internationally and the amount of reimbursement available from third-party payors. For instance, under the ACA, there is a new 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 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 United States. 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, in the past six years 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 United States 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 United States 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 United States 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 United States 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 are 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 United States 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 have not maintained, and currently do not maintain, any liability, hazard or other insurance covering our services, business, operations, errors, acts or omissions, personnel or properties in China, or in any other countries where we may 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 United Kingdom 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 United States 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.

Risks Related to Intellectual Property

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

We hold a patent in the United States 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 have been granted a patent with claims covering an extracorporeal device configuration, which we believe includes our ELAD System, independent of 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 and Taiwan and remain under review in certain other jurisdictions, including Europe, Brazil, China, India and the Philippines. In addition to these two U.S. patents, as of May 6, 2014, we hold three additional patents in the U.S., and additional patent applications related to developments in the ELAD System are pending. 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 ELAD System. Furthermore, even if our patents are held to be valid and broadly interpreted, third parties may find legitimate ways to

compete with the ELAD System by inventing around our patent. 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 United States 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 prosecute our patents would 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 United States 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 now more 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 United States 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 the 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 United States 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

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

We will need to raise substantial additional capital to:

- complete our ongoing and future 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 approval of our clinical trial applications, the rate of initiation of our clinical sites and the rate of enrollment of our clinical trials;

- the cost of filing and prosecuting patent applications;
- the cost of defending, in litigation or otherwise, 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 additional 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 commitments or agreements relating to any of these types of transactions.

We cannot assure you that we will 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 proceeds from our initial public offering 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 acquisitions or collaborative projects.

Risks Related to Being a Public Company

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

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly 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 may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. Although we have already hired additional employees 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 revenue-generating 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.

However, 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 on executive compensation and shareholder approval of any golden parachute payments not previously approved. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company."

We would cease to be an "emerging growth company" upon the earliest of: (1) the first fiscal year following the fifth anniversary of our initial public offering, (2) the first fiscal year after our annual gross revenue is $1.0 billion or more, (3) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities and (4) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

As a public company it will be more expensive for us to 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 could 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.

We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may decline or be more volatile.

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 will be 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. We may not complete our analysis of our system of internal control over financial reporting in a timely manner, or these internal controls may not be determined to be designed or operating effectively, which 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 first fiscal year beginning after the closing of our initial public offering. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting.

We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing or any required remediation in a timely fashion. During the evaluation and testing process, if 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 Securities and Exchange Commission, or SEC.

We will be 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 the later of the year following our first annual report required to be filed with the SEC, and the date we are no longer an "emerging growth company" if we take advantage of 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. To comply with the requirements of being a public company, we may need to undertake various actions, such as implementing new internal controls and procedures or hiring accounting or internal audit staff.

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

We have not maintained an effective control environment to ensure that the design and execution of our controls has 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 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, such 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.

We are in the process of implementing measures designed to improve our internal control over financial reporting to remediate the control deficiencies that led to our material weakness. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or to avoid potential future material weaknesses. In addition, neither our management nor independent registered public accounting firm has ever 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 we or 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 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 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.

We expect that the price of our common stock will fluctuate substantially.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

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

- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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 us may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in 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.

As of June 30, 2014, we have 21,790,745 shares of common stock outstanding, 19,085,648 of which are subject to 180-day contractual lock-ups entered into in connection with our initial public offering that expire in October 2014 and 2,705,097 are freely tradable. Following the expiration of the lock-up (or earlier if permitted by the managing underwriters), those shares of our common stock will be eligible for sale in the public market, subject in some cases to the volume and other restrictions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, as well as our insider trading policy. Sales of our common stock by our current stockholders may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, and make it more difficult for you to sell shares of our common stock.

In addition, on June 6, 2014, we filed a registration statement on Form S-8 registering 3,732,152 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 this registration statement on Form S-8 will be available for sale in the public market subject to vesting arrangements and the exercise of such options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144. As of June 30, 2014, options to purchase 3,123,795 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 United States. Any 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 you 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 principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

With the completion of our initial public offering in April 2014 and the underwriters over-allotment in May 2014, our officers, directors and principal stockholders and their affiliates collectively control approximately 38.1% of our outstanding common stock, and in particular, one stockholder and his affiliates control approximately 30.4% of our outstanding common stock as of June 30, 2014. As a result, these stockholders, if they act together, can 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 of our initial public offering for working capital and general corporate purposes.

The net proceeds of our initial public offering will be allocated to research and development activities, preparation for commercialization and general corporate purposes. Our management has broad discretion over the use and investment of the net proceeds of our initial public offering within those categories, and accordingly investors will need to rely upon the judgment of our management with respect to the use of proceeds, with only limited information concerning management's specific intentions.

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 40% of our directors.

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

Use of Proceeds

In April 2014, we completed our initial public offering of 4,500,000 shares of our common stock at a price of $12.00 per share. In May 2014, the underwriters exercised their over-allotment option and purchased an additional 675,000 shares of common stock at $12.00 per share. In total, we received aggregate gross proceeds of $62.1 million. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-191711), which was declared effective by the SEC on April 16, 2014.

BofA Merrill Lynch and Credit Suisse Securities (USA) LLC acted as joint book-running managers for the offering and William Blair & Company, LLC and Canaccord Genuity Inc. acted as co-managers.

The underwriting discounts and commissions in connection with the offering totaled $4.3 million. In addition, we incurred $5.8 million in offering expenses, resulting in total fees and costs of $10.2 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, was $51.9 million.

There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on April 17, 2014. We have invested the remaining proceeds from the offering in money market funds. The amount and timing of our actual expenditures depend on numerous factors, including the ongoing status of and results from clinical trials, as well as any unforeseen cash needs. Accordingly, our management will have broad discretion in the application of the net proceeds.

Item 6. Exhibits

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

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference

** XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

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.

Date: August 6, 2014

VITAL THERAPIES, INC.

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

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)) 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) 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

c) 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: August 6, 2014

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)) 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) 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

c) 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: August 6, 2014

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 June 30, 2014 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: August 6, 2014

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 June 30, 2014 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: August 6, 2014

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