VITAL THERAPIES INC
Form 10-K
March 04, 2019

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

FORM 10-K

(Mark One)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or

o 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.)
15222-B Avenue of Science San Diego, CA	92128
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (858) 673-6840
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No ý
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ¨ No ý

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 ý No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer ý
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company ý
	Emerging growth company ý

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based on the closing sale price of the registrant's common stock on June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, as reported on The Nasdaq Global Market, was approximately $208.6 million. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock, based on filings with the Securities and Exchange Commission, have been excluded from this computation since such persons may be deemed to be affiliates of the registrant. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

There were 42,369,694 shares of the registrant's common stock, $0.0001 par value per share, outstanding as of February 28, 2019.

Vital Therapies, Inc.
ANNUAL REPORT ON FORM 10-K
For the Fiscal Year Ended December 31, 2018
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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities and Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management, and are contained principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "could," "seeks," "estimates," "expects," "intends," "may," "p "potential," "predicts," "projects," "should," "will," "would," "might," "can," "continue" or similar expressions and the negativ those terms.

These forward-looking statements include, among other things, statements about:

- the strategies, prospects, plans, expectations and objectives of management
- the approval and timing of closing of the Transaction or any other strategic alternatives;
- the expected benefits of and potential value created by the Transaction for our stockholders;
- our ability to regain or maintain compliance with Nasdaq listing standards;
- strategies with respect to our development programs;
- our estimates regrading expenses, capital requirements, projected cash requirements and needs for additional financing;
- possible sources of funding for future operations;
- our ability to protect intellectual property rights and our intellectual property position;
- future economic conditions or performance;
- proposed products or product candidates;
- our ability to retain key personnel;
- our ability to maintain effective internal control over financial reporting; and
- beliefs and assumptions underlying any of the foregoing.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements including those described in "Risk Factors" and elsewhere in this Annual Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Annual Report. You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the Securities and Exchange Commission, or SEC, as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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PART I

Item 1. Business.

Overview

We are a biotherapeutic company that has been developing a cell-based therapy targeting the treatment of acute forms of liver failure. Our initial product candidate, the ELAD® System, or ELAD, is a human-cell-based, bio-artificial liver, which was being developed to improve rates of survival among patients with acute forms of liver failure. Since inception, we have devoted essentially all of our efforts to product development, clinical testing and pilot manufacturing and have not recognized revenues from our planned principal operations.

In September 2018, we reported top-line data from a phase 3 clinical trial of ELAD, VTL-308, in 151 subjects with severe alcoholic hepatitis. Although there was a numerical improvement in survival in the ELAD-treated group between three months and one year following randomization, the study failed to meet the primary endpoint of a significant improvement in overall survival through at least ninety-one days. The secondary endpoint of the proportion of survivors at study day ninety-one also showed no statistically significant difference between the groups. Considering these results, we do not believe the ELAD System can be approved in the United States or the European Union without additional clinical trials, if ever, and that such clinical trials would require substantial capital and time to complete. Further, as we currently have no commercial products or products in later stage development, it would be difficult to secure funding for additional clinical trials of ELAD. Consequently, we have ceased any further development of the ELAD System for the United States and Europe, substantially reduced our workforce, discontinued most of our supply and service agreements, and shifted our strategic focus to identifying and exploring strategic alternatives. This may include selling some or all of our assets, including those relating to ELAD, and options to reduce the amount of space we lease.

Our board of directors and management began evaluating our strategic options to maximize stockholder value, including the possibility of acquiring new products, seeking a merger, selling the company or all or some of its assets and/or distributing some or all of our remaining cash through either a dividend or a liquidation. As a part of the evaluation, management conducted a process of identifying and assessing potential strategic alternatives, including mergers or other transactions, with biotechnology companies.

On January 6, 2019, Vital Therapies, or the Company, Immunic AG, or Immunic, and the shareholders of Immunic entered into an Exchange Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Exchange Agreement, the shareholders of Immunic will exchange all of their shares for common stock of the Company, with Immunic becoming a wholly-owned subsidiary of Vital Therapies, referred to herein as the Transaction. Immunic is a specialist in selective oral drugs in immunology and is focused on developing novel oral therapies for chronic inflammatory and autoimmune diseases. Immunic's three development programs target inflammatory bowel diseases, multiple sclerosis, and psoriasis. Immunic's lead development program is currently in phase 2 clinical development for ulcerative colitis, with additional phase 2 trials in Crohn's disease, and multiple sclerosis, and an investigator-initiated proof of concept study in primary sclerosing cholangitis planned for 2019. If the Transaction is completed, the business of Immunic will become the business of the Company.

Among other conditions, completion of the Transaction requires approval of both the issuance of the Company's common stock in the exchange and the change of control resulting from the Transaction by an affirmative vote of the holders of a majority of the shares of the Company's common stock at a special meeting of our stockholders. Additional information regarding the Transaction is included in our registration statement on Form S-4 filed with the Securities and Exchange Commission in February 2019. Subject to approval of our stockholders and other conditions, the Transaction is expected to close as early as the first half of April 2019.

If the Transaction is not completed, we will reconsider our strategic alternatives and could pursue one of the following courses of action, which we currently believe to be the most likely alternatives if the Transaction with Immunic is not completed:

- Pursue another strategic transaction. We may resume the process of evaluating a potential merger, reorganization or other business combination transaction.

- Dissolve and liquidate its assets. If we do not believe we can find a suitable alternate merger partner in the near-term, we may dissolve and liquidate our assets. We would be required to pay all of our debts and contractual obligations,

and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash remaining to distribute to stockholders after paying our obligations and setting aside funds for reserves.

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $337.4 million through December 31, 2018. In consideration of our decision to cease the further development of ELAD in the United States and Europe, we have made reductions in operating expenses as we pursue strategic alternatives for the Company. As a result, we believe that our existing cash and cash equivalents of $13.3 million as of December 31, 2018 would be sufficient to meet our known liabilities and commitments at such date; however, we expect our resource requirements to change materially to the extent we enter into and complete any strategic transactions. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The timing and amount of our actual expenditures will be based on many factors, including, but not limited to, the strategic options that we pursue, any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned, or any future research and development efforts we decide to pursue. Until the proposed Transaction with Immunic is completed, we cannot predict whether or to what extent we might resume development activities, or what our future cash needs would be for any such activities.

Our ELAD System Product Candidate

ELAD System

The ELAD System is an investigational, extracorporeal human hepatic cell-based liver treatment designed to supplement hepatic function in order to potentially improve survival rates among patients with acute forms of liver failure that was in phase 3 clinical trials. The ELAD System consists of four disposable ELAD C3A cell cartridges attached to a reusable ancillary delivery device using customized disposable tubing. The four ELAD cartridges collectively contain approximately eight thousand hollow fibers and approximately one pound of VTL C3A cells from our proprietary cell bank.

During ELAD treatment, an extracorporeal pumping unit draws blood from the subject via a central venous line which then passes into the system to generate ultra-filtrated plasma (ultrafiltrate). The subject’s ultrafiltrate is pumped through the hollow fibers of the cartridge, wherein the semipermeable membrane permits a bidirectional flow between the cells (grown between the exterior of the hollow fibers) and the ultrafiltrate (contained in the lumen of the hollow fibers). Toxins, nutrients and dissolved gases pass from the ultrafiltrate to the cells, while the potentially beneficial macromolecules and other substances synthesized by the cells simultaneously pass into the subject’s ultrafiltrate. After circulation through the ELAD C3A cell cartridges, the ultrafiltrate passes through a 0.2-μm pore size filter, is recombined with the cellular components of the subject’s blood, and is returned to the subject via the central venous line. VTL C3A cells’ metabolic byproducts are thereby returned to the subject to be utilized or to be excreted by the renal or gastrointestinal system. This circulation can be maintained continuously for the duration of the ELAD treatment for up to five days, as determined by the treating physician. The ELAD System monitors and enables adjustment of glucose and oxygen concentrations in the ultrafiltrate, as well as temperature and other parameters, in order to maintain the viability of the C3A cells.

Our Proprietary VTL C3A Cell Bank

The liver is a complex organ comprising several different cell types to perform the majority of its biochemical functions, with hepatocytes being most widely recognized for their roles in synthesis and metabolism. Hepatocyte viability is limited when cultured or expanded outside the body as they very quickly de-differentiate or die. Therefore, normal hepatocytes present practical and logistical obstacles for use in a liver-assist product. Cell lines derived from liver cells can alleviate many of these practical and logistical obstacles. The specific cell line that was selected for the allogeneic ELAD System, the VTL C3A cell line, is a sub-clone of a human hepatoblastoma cell line, HepG2. The C3A cell line was developed at Baylor College of Medicine and deposited at the American Type Culture Collection. The specific cells stored in our proprietary cell banks and their progeny are referred to as VTL C3A cells. Under the right conditions, VTL C3A cells rapidly proliferate, allowing growth of the large amount of cells necessary to treat the subject with a liver support system, and with cells that remain metabolically active during treatment. Each ELAD treatment uses approximately one pound of cells.

Treatment with the ELAD System is not patient-specific, and our VTL C3A cells, which are derived from a single source, are used to treat all patients. This process is known as allogeneic cellular therapy. In contrast, autologous cellular therapy uses a patient's own cells, which are manipulated in individual production batches, a costly and complex process. As a result, the production and logistics of treatment with our VTL C3A cells does not face some of the challenges commonly associated with autologous cellular therapies.

The VTL C3A cell bank has been subjected to rigorous safety testing for adventitious agents in accordance with regulatory guidance documents. This bank contains enough cells to enable our clinical development and commercialization. We own this VTL C3A cell bank exclusively and on a royalty-free basis. In addition, we have developed proprietary methods for growing, storing and optimizing the function of these cells.

ELAD Mechanism of Action

While the mechanism(s) of action for the ELAD System have not been fully elucidated, several potential mechanisms have been modeled during in vitro studies as outlined below.

The VTL C3A cells may:

1. Provide acute-phase response proteins to help dampen the pro-inflammatory environment and restore the patient's immune responses. The VTL C3A cells secrete several anti-inflammatory proteins, including alpha-1-antitrypsin (AAT) and interleukin-1 receptor antagonist (IL-1Ra), the latter of which is upregulated in response to pro-inflammatory cytokines typically found in alcoholic hepatitis patients. Further, VTL C3A cell-secreted factors were shown to reduce levels of pro-inflammatory interleukin 1-beta (IL-1beta) in activated macrophage cultures.
2. Provide factors which have been shown to prevent hepatocyte and endothelial cell death, through dampening oxidative stress and/or stimulating survival. The VTL C3A cells secrete a number of recognized factors that are involved with regeneration and have been shown, in vitro, to prevent death and promote survival of hepatocytes including soluble Fas receptor and amphiregulin (a recognized potent mitogen during liver regeneration in small-animal models of partial hepatectomy). These factors have also been shown to increase the ratio of reduced to oxidized glutathione reserves (glutathione being one of the most potent intracellular anti-oxidants). VTL C3A cells secrete a number of proteins involved in angiogenesis such as vascular endothelial growth factor, placental growth factor and angiopoietin, which may be beneficial by improving vascularity in damaged liver sinusoids as well as in other organs. VTL C3A cell-secreted proteins were shown in vitro to prevent cell death in endothelial cells and to reduce intracellular oxidative stress.
3. Produce blood coagulation factors to address blood clotting imbalances that are common in alcoholic hepatitis patients. Blood coagulation factors, Factor V, Factor VII, Factor VIII, Factor IX, Factor X, Factor XI, Factor XII, Factor XIII, fibrinogen, tissue factor, tissue factor pathway inhibitor, prothrombin, antithrombin III, Protein C, kininogen, prekallikrein, 2-macroglobulin, plasminogen and plasminogen activator inhibitor-1 have been shown to be produced by the VTL C3A cells.
4. Assist in in the restoration of liver function by providing liver-specific metabolism and detoxification capabilities. The VTL C3A cells express messenger RNA, or mRNA, for cytochrome P450, or CYP, isoenzymes CYP1A2, CYP2C9, CYP2C19, CYP2D6, CYP3A4 and CYP3A5, which are collectively responsible for metabolizing nearly 90% of all drugs. Moreover, this CYP expression appears to respond dynamically as evidenced by different expression patterns in VTL C3A cells exposed to different clinical subjects.

While a statistically significant reduction in bilirubin has been demonstrated in subjects over the three to five days of ELAD treatment, because the VTL C3A cells lack the transporters required for unconjugated bilirubin uptake, the metabolic pathway of bilirubin reduction is not supported through our in vitro studies. However, bilirubin has been shown to be non-specifically sequestered by the VTL C3A cell membranes, which may help contribute to reducing overall bilirubin levels in ELAD-treated subjects.

VTL C3A cells have also been shown to express mRNA for bile acid gene targets involved in synthesis, conjugation and transport functions. Bile acid metabolism appears to be moderate in comparison to the cholestatic environment (a condition in which substances normally excreted into bile are retained) of patients with alcoholic hepatitis, based on initial studies; however, total bile acid levels trended lower, decreased more rapidly, and showed enhanced secondary bile acid conjugation over 5 days in a survey of subjects receiving ELAD treatment compared to control subjects.

Differentiating Factors of the ELAD System

Unlike other potential therapies developed for acute forms of liver failure in the past, we believe the ELAD System has a unique combination of attributes:

- Biologically active. The ELAD System contains biologically active VTL C3A cells and is designed to replicate many liver functions. We believe that an acellular solution to liver failure is unlikely to effectively replace lost liver

function. A cellular approach, capable of replicating key biologic processes, might provide the requisite flexibility and breadth of function to supplement liver function and improve survival in patients with acute liver failure.

- Human cellular therapy. The ELAD System is based on human cells, which confer a considerable advantage over non-human, animal-based cell therapies. Given the widespread availability of animal tissues, much work has been done on the use of animal liver cells, often derived from pigs, to treat humans with liver failure. While immunological risk is always present in cellular therapy, the use of non-human animal tissues presents greater immunological risk compared to human cellular therapy. Humans possess naturally occurring antibodies that react with antigens on porcine cell surfaces. These antibodies can mount an immediate attack in the presence of porcine cells, causing these cells to rapidly lose function and die. Moreover, repeated treatments with a porcine cell may cause subsequent immune responses to become increasingly severe. The infusion of porcine enzymes into a patient's blood stream also poses immunologic risk.

Liver Failure

The liver performs a wide variety of vital life functions including metabolic, regulatory, detoxification and synthetic activities. The primary liver cell, the hepatocyte, is believed to be responsible for approximately 500 or more specific biologic processes. In addition, the liver also serves as a reservoir for immune cells which clear the blood of pathogens. As a result, the liver's failure to perform its normal role can have devastating or fatal consequences. Causes of liver failure are numerous, and the condition is typically described in terms of rapidity of onset. The two main categories are acute liver failure and chronic liver failure.

Severe Alcoholic Hepatitis (sAH)

Alcoholic hepatitis arises when the cause of the acute liver decompensation appears to be directly related to excessive consumption of alcohol. Severe alcoholic hepatitis, or sAH, is defined as progressive inflammatory liver disease, leading to an acute form of alcohol-induced liver injury that occurs with the consumption of large amounts of alcohol in patients with relatively mild, underlying chronic alcoholic liver disease.

Various degrees of fibrosis and hepatitis are present in sAH patients. Those patients with characteristics of acute alcoholic hepatitis, or AAH, and a Maddrey Discriminant Function (a calculation used to predict the prognosis of alcoholic hepatitis) of ≥32 are deemed to have sAH. Other AAH patients (non-AAH Liver Disease) may have underlying chronic liver disease due to other etiologies, but the cause of their acute decompensation is considered to be related to excessive alcohol consumption. In sAH, there appears to be sufficient hepatocyte mass to allow hepatic regeneration and reversal of the decompensation. It can be discriminated from patients with end-stage liver disease by measurements of liver size using imaging techniques such as ultrasound or CT scan as they tend to present with enlarged livers, rather than with the shrunken livers characteristic of subjects with end-stage liver disease.

Treatment options for patients with sAH are limited. In particular sAH patients with a Maddrey Discriminant Function of >32 have a poor prognosis, with 90-day survival of around 50%. Regimens that have been used for at least the last 40 years, including corticosteroids, theophylline with corticosteroids, pentoxifylline and infliximab, have had no significant effect on the long-term survival of patients with sAH. Steroid use has been associated with an increased rate of infections, a frequent complication of liver failure. Other contraindications to steroid use in patients with sAH include active gastrointestinal bleeding, renal failure, acute pancreatitis, active tuberculosis, uncontrolled diabetes and psychosis. Subjects who do not respond to seven days of steroid therapy have a particularly dismal prognosis, with six-month survival rates of less than 25%. A major study of more than 1,100 subjects with a clinical diagnosis of sAH demonstrated a reduction in 28-day mortality in subjects administered steroids that did not reach statistical significance, with no improvement in survival at 90 days or one year. This study also revealed no survival benefit at any time point for pentoxifylline relative to placebo. Under current guidelines, transplantation is generally not recommended for subjects with sAH.

Acute-on-Chronic Liver Failure (ACLF)

Hepatocellular damage, secondary to a variety of insults (infectious agents, alcohol, exogenous drugs autoimmunity, non-alcoholic fatty liver disease, non-alcoholic steatohepatitis etc.), can result in chronic liver disease, if the underlying etiology is not effectively treated. This condition is characterized histopathologically by increasing degrees of fibrosis and cirrhosis, and frequently remains subclinical or undiagnosed. Often as a result of a secondary insult, the liver can decompensate, leading to a life-threatening disorder known as acute-on-chronic liver failure, or ACLF.

The damage to the liver from continuing insults causes the gradual development of fibrosis in the liver over time, which results in a decrease of both liver function and the ability to regenerate after decompensation. The fibrosis

progresses to cirrhosis when this process continues for many years. The progression of fibrosis to cirrhosis results in a shrunken liver, distortion of hepatic lobules, and continued loss of hepatocytes (due to replacement with fibrotic tissue) that leads to progressive and recurrent episodes of decompensation. This progressive loss of hepatocyte mass impairs the liver's inherent ability to regenerate following decompensation.

Fulminant Hepatic Failure (FHF)

Another form of acute liver failure is fulminant hepatic failure, or FHF, a relatively rare condition characterized by a rapid deterioration of liver function with altered mental state and coagulopathy in individuals without known pre-existing liver disease. The most frequent causes include drug or toxin-induced liver injury, viral hepatitis, autoimmune disease and hypoperfusion. Two thousand cases of FHF are estimated to occur in the U.S. each year. The standard of care includes liver transplantation, and these patients get priority on the liver transplant list although they tend to progress very rapidly and may succumb to their disease before a suitable organ becomes available.

Post-Surgical Liver Failure

Another form of acute liver failure can arise following surgical procedures. For example post-surgical liver failure can arise due to:

1. Primary Graft Non-Function, which occurs when a newly transplanted liver fails to function. This is a life threatening medical emergency, and can lead to death if a new organ does not become available quickly.
2. Small-For-Size or Split Liver Transplant occurs when the transplanted liver is functioning, but may be too small to sustain the patient, either because only a small donor liver was available, or because a live person donated a portion of their liver for transplantation.
3. Liver Cancer Resection. Primary liver cancer can sometimes be cured by resecting the cancerous part of the liver after which the remaining liver regenerates to full size. Currently, surgeons will typically only resect up to 50% of the liver in order to avoid death from liver failure. However, more extensive resections occasionally occur, and resection of smaller portions can also lead to liver failure.

Chronic Liver Failure

Chronic liver failure refers to a gradual loss of liver function and is usually characterized by the presence of widespread cirrhosis, which refers to the replacement of normal liver tissue by fibrosis, scar tissue and regenerative nodules. As normal liver tissue is destroyed, the organ gradually fails to perform its normal metabolic, regulatory and synthetic functions. Unfortunately, damage from cirrhosis cannot be reversed, and lost liver function can only be regained through transplantation.

Limitations of Currently Available Treatment Options for Acute Forms of Liver Failure

Given the liver’s complexity, there are no simple or widely effective medical solutions to acute forms of liver failure. The only long-term cure for acute liver failure is surgical transplantation. As published by the U.S. Department of Health and Human Services' Organ Procurement and Transplantation Network, there were 8,082 liver transplants performed in the U.S. in 2017. There are approximately 14,000 patients currently on the transplant waiting list and approximately 1,200 patients die while waiting each year. Similarly, there are approximately 7,000 liver transplants performed per year in Europe. Outside of transplant, current therapy is defined by the treating facility and is mostly supportive and designed to manage the symptoms and complications associated with acute forms of liver failure.

Pharmaceuticals

N-acetylcysteine is approved by the FDA for the prevention of acute liver injury following the ingestion of toxic amounts of acetaminophen. Other treatments, including steroids and pentoxifylline, are often used off-label to manage symptoms associated with acute forms of liver failure, although steroids in particular have been shown to increase the risk of potentially fatal infections. Results from the Steroids or Pentoxifylline for Alcoholic Hepatitis study, or STOPAH, were presented at the American Association for the Study of Liver Disease, or AASLD, meeting in November 2014. STOPAH enrolled 1,103 subjects with sAH at 65 sites in the U.K., but failed to demonstrate any significant benefit in the primary analysis of overall survival for subjects treated with either steroids, pentoxifylline or a combination of the two at one, three or twelve months, as compared with placebo. In a secondary, multivariate analysis of the data, a small benefit was observed for those subjects taking steroids at one month, although this benefit was not seen in multivariate analyses at either three months or at twelve months. Despite the availability of these treatments, the one-year mortality rate for acute forms of liver failure remains above 50%. We are not aware of any mechanisms for pharmacologically addressing liver failure specifically or restoring lost liver function.

Liver Support Devices

Two commercially available liver dialysis systems, MARS from Baxter (formerly Gambro) and Prometheus from Fresenius, have undergone extensive clinical development. Another company, Hepa Wash GmbH has begun a limited

market introduction of an albumin dialysis system in Europe, and HepaNet has introduced the OPAL system, an evolution of the MARS albumin dialysis system in Germany. All rely on not only traditional dialysis circuits to remove water-soluble toxins,

but also albumin dialysis circuits to remove albumin-bound molecules. To our knowledge none of these non-cellular systems has shown an improvement in long-term survival among patients with liver failure. It was also recently reported that a team from the Institute for Liver and Digestive Health, University College London and Yaqrit Ltd had initiated a clinical trial in decompensated liver disease for a novel liver dialysis (non-bioartificial) system to be known as YAQ-002 incorporating albumin dialysis along with selective adsorption technology. There are also reports of a human cell-based system under development in China, but the clinical status of this program has not been confirmed.

Clinical Experience with the ELAD System

Over 500 subjects have been treated with the ELAD System at sites in the U.S., Europe, China, and Australia, among other countries.

The ELAD System's Clinical Development in sAH

VTL-308

In May 2016, we commenced our pivotal VTL-308 clinical study. VTL308 was a phase 3 randomized, open-label, multicenter, controlled, pivotal study, designed to evaluate the ELAD System in subjects with severe alcoholic hepatitis, or sAH, who met criteria based on the data from the pre-specified and post-hoc analyses of our VTI-208 clinical trial (see below). VTL-308 compared the efficacy and safety of the ELAD System plus standard-of-care to standard-of-care alone in adults, under the age of 50 and without secondary organ failure, with liver failure from sAH. VTL-308 enrolled 151 subjects and the study's primary endpoint was a Kaplan-Meier analysis of overall survival performed after the last subject to be enrolled had been followed for at least ninety days. Secondary endpoints were to evaluate the proportion of survivors at study days 28 and 91, as well as the proportion of subjects achieving a certain threshold of bilirubin reduction and surviving without transplant.

The key changes in the VTL-308 clinical trial from the VTI-208 clinical trial protocol included restrictions on subjects' age, Model for End-stage Liver Disease (MELD) score and the three components of the MELD score associated with kidney dysfunction (creatinine), blood clotting dysfunction (INR) and liver function (bilirubin). The VTL-308 inclusion criteria were established to reflect the same study population as that enrolled in a subset of the VTI-208 population with baseline criteria including MELD <30, age <50, INR ≤2.5, creatinine <1.3mg/dL and serum total bilirubin ≥16mg/dL. When we applied the baseline criteria used in the VTL-308 clinical trial to the subjects in the VTI-208 clinical trial on a post-hoc basis, the study would have reached a nominal p-value of <0.01 with respect to overall survival. These VTI-208 analyses provided the rationale for the VTL-308 clinical trial in sAH. A subject's MELD score is a tool for characterizing the severity of liver disease and for providing a prognosis for survival.

In September 2018, we reported top-line data from VTL-308. Although there was a numerical improvement in survival in the ELAD-treated group between three months and one year following randomization, the study failed to meet the primary endpoint of a significant improvement in overall survival through at least ninety-one days. The secondary endpoint of the proportion of survivors at study day ninety-one also showed no statistically significant difference between the groups.

VTI-208

In March 2013, we initiated VTI-208, a phase 3 randomized, controlled, open-label clinical trial with a targeted enrollment of 200 subjects with alcohol-induced liver decompensation. The primary endpoint of VTI-208 was overall survival up to at least study day ninety-one. The VTI-208 clinical trial completed enrollment in January 2015 with 203 subjects having been enrolled at 40 clinical sites in U.S., United Kingdom, or U.K., and Australia.

In August 2015, we announced that the VTI-208 clinical trial did not achieve its primary endpoint of overall survival through study day 91. The VTI-208 study included 96 and 107 subjects randomized to ELAD treatment and control (standard of care only) groups, respectively, in the intention-to-treat, or ITT, population. Although overall survival in the ITT population was not statistically different between groups, in a pre-specified subset of 120 subjects with MELD scores <28 that consisted of 51 and 69 subjects in the ELAD-treated and control groups, respectively, the Kaplan-Meier analysis of overall survival did approach statistical significance. In another pre-specified exploratory analysis of 101 subjects with less than the median age of 46.9 years, the Kaplan-Meier analysis of overall survival also favored the ELAD-treated subjects. Analyses of 83 subjects with MELD scores >28 and of 102 subjects greater that the median age both favored the control subjects.

VTI-210

In November 2014, we commenced enrollment in a phase 3 randomized, controlled, open-label clinical trial, VTI-210, in subjects with sAH, who were believed are at a substantially increased risk of mortality as compared to VTI-208. The VTI-210 clinical trial was based on a design suggested by the European regulatory authority and sought to only include subjects who had failed conventional therapy. However, the trial was voluntarily discontinued by us after only 18 subjects were enrolled when our August 2015 analysis of the VTI-208 data suggested that the VTI-210 enrollment criteria were unlikely to lead to a successful trial outcome. In particular, within the VTI-208 data set, healthy secondary organ function at baseline appeared to be

a critical determinant of positive outcome with ELAD. In contrast, the VTI-210 criteria allowed subjects to be enrolled with severe secondary organ dysfunction.

It was not possible to draw any conclusions from the small sample of subjects enrolled in VTI-210; however, there were no significant differences in mortality between the ELAD-treated and control groups either at day 28 or day 91, with three deaths in each group at day 28 and one additional death in the ELAD-treated group at day 91. Additional deaths occurred in both groups after 91 days, consistent with the very low survival expectations of patients who have failed conventional therapy. The adverse event profile was consistent with findings in other ELAD studies and typical for subjects treated with extracorporeal therapies.

VTI-212

We also enrolled four subjects in VTI-212, an open-label phase 2 study designed to be part of a Phase 2/3 clinical program in subjects with either fulminant hepatic failure or surgery-induced acute liver failure. We began this study in June 2014 with a Phase 2 single-arm component with a targeted enrollment of 40 subjects, which could later be followed by a randomized, controlled Phase 3 component. Considering the results of the VTI-208 clinical trial and in an effort to focus our resources, we discontinued the VTI-212 clinical trials in late 2015.

The ELAD System's Clinical Development in Acute Flare of Viral Hepatitis

VTIC-301

Between 2006 and 2007, we enrolled 69 subjects with acute-on-chronic liver failure (ACLF) in a randomized, controlled open-label trial at two hospitals in Beijing, China. Inclusion criteria focused the trial's enrollment on subjects anticipated to have a 50% chance of death by 84 days, and the majority of enrolled subjects were experiencing an acute flare of viral hepatitis. The study was designed to enroll 120 subjects but was terminated early by one of the hospital's ethics committee because, in light of the results discussed below, it would have been unethical to continue to treat control subjects with standard of care alone. Endpoints included survival at 14, 28, 56 and 84 days, as analyzed using a log-rank method.

A significant protocol amendment was enacted after the enrollment of the first 49 subjects, in which inclusion criteria were changed, reducing the severity of disease, and a shorter ELAD System treatment time was recommended. This change in study design resulted in far fewer deaths or transplants in the second subset of 20 ELAD-treated and control subjects. A revised statistical plan was prepared to accommodate these differences in subject populations. Separate analyses were performed on the 49-subject subset and the full 69-subject population, and additional statistical analysis techniques were proposed, such as the use of Wilcoxon rank-sum techniques to analyze continuous variables such as survival time.

Analysis of the first 49 subjects (32 subjects randomized to be treated with the ELAD System for three days along with standard of care for the treating institution and 17 subjects randomized to be treated with standard of care alone) revealed the following:

- significant differences in 28 and 56-day survival using the log-rank test (p=0.015 and 0.026, respectively); (log-rank was not significant at 14 and 84 days, p=0.074 and 0.058, respectively);
- significant differences in 84-day survival using the Wilcoxon test (HR=0.45; p=0.049); and
- no unexpected safety issues.

Generally, the serious adverse events reported in this study were reflective of the severity of disease and co-morbidities present in the patient population. There were 16 post-treatment adverse events in eight of the 32 treated subjects that the investigators reported as possibly or probably related to treatment.

Analysis of all 68 subjects treated (44 subjects randomized to be treated with the ELAD System for one to three days along with standard of care for the treating institution and 25 subjects randomized to be treated with standard of care alone; note one control subject withdrew consent immediately following randomization and is not included in this analysis, so only 24 controls are included for a total of 68 subjects) revealed the following:

- Significant differences in 28-day survival using the log-rank test (p=0.015);
- No significant differences in 14, 56 and 84-day survival using the log-rank test; and
- No unexpected safety issues.

Based on these results, it was concluded that the Wilcoxon test is a more sensitive technique to elucidate differences between groups in the ELAD System clinical trials, and that a more severely diseased population and more extended treatment times should be evaluated in future clinical studies.

These China pivotal trial data formed the basis of a submission for marketing approval to the China FDA, or CFDA, in September 2007. It should also be noted that this study was not designed, and will not be used, as a pivotal trial to support approval of the ELAD System in the U.S. and Europe.

Subsequent to the completion of the VTIC-301 clinical study, an additional protocol was prepared by the treating physicians to explore the long-term survival of subjects enrolled in this study. Following the grant of informed consent, subjects enrolled in VTIC-301 were contacted and invited to return to the treating hospital for examination for recurrence of liver disease or the incidence of cancer. This study was carried out in 23 and 22 subjects, respectively, three and five years following initial randomization.

These data from the first 49 subjects suggest that the survival benefit (statistically significant at three years and five years, Kaplan Meier: $p<0.05$, log-rank) afforded to those subjects treated with the ELAD System is maintained over a three and five-year period relative to those subjects in the control group.

These follow-up analyses were not prospectively defined in the VTIC-301 protocols.

The results of VTIC-301 were submitted to the CFDA for marketing approval in September 2007. However, a regulation enacted in 2009 prevents the approval of novel foreign medical products until they are approved in their home markets first. Accordingly, we would not expect activity or approval by the regulatory authorities in China unless and until we could obtain approval in the U.S.

Manufacturing and Supply

The manufacture of the ELAD System is comprised of our proprietary VTL C3A cells, cartridges and the bedside unit. The system contains both reusable and disposable medical device components. We source most of the components from third-party suppliers. In a few cases, we have manufactured a device or a device component ourselves. Based on discussions with the regulatory authorities, we have determined that the ELAD System is a combination biologic-device, and as such both biologic and device components would have to be submitted as part of a biologics license application filing for review and approval prior to the granting of a marketing authorization for the product.

All biopharmaceutical production activities must be conducted under current Good Manufacturing Practice, (cGMP), the standards established by the FDA for pharmaceutical and biologics production. Medical devices must be manufactured in accordance with pertinent device regulations. The equipment used in the manufacturing process is based on custom designs typically encountered in the production of other biotechnology products. Testing is required according to the FDA's and other applicable regulatory bodies' standards before release for use in humans.

Intellectual Property

We have a patent portfolio and substantial know-how relating to the ELAD System. Our patent portfolio includes patents with claims directed to our ELAD System, specific clonal cells and cell-lines derived from human liver-derived C3A cells, as well as methods of growing such cells. We are currently the owner of record of four issued U.S. patents and over a dozen issued or allowed foreign patents. Additionally, we are the owner of record of two pending Patent Corporation Treaty international applications and three pending U.S. patent applications, as well as numerous corresponding pending foreign applications. One granted U.S. patent claims a method of using C3A cells to treat a patient's blood. The patent has a term that extends to 2027 and may possibly be extended further if the patent is determined to be eligible for patent term extension. Additionally, a second granted U.S. patent includes claims to an extracorporeal device configuration which is cell type independent and which we believe encompasses our ELAD System. The patent has a term that extends to 2025 and may possibly be extended further if the patent is determined to be eligible for patent term extension. Foreign counterparts of these patents have been issued in countries throughout the world, including, for example, in Australia, Canada, Indonesia, Israel, Japan, Mexico, New Zealand, Singapore, South Africa, South Korea, Taiwan and the Philippines. Furthermore, related applications remain pending in certain other jurisdictions including, for example, Europe, Brazil, Hong Kong and India.

We strove to protect the proprietary technology that underlies the ELAD System. We sought patent protection in the U.S. and internationally for the ELAD System, its methods of use and processes of manufacture, and any other technology to which we have rights, where available and when appropriate. We also relied on trade secrets that may be important to the development of our business.

A predecessor company initially developed the ELAD System after the technology was spun out of Baylor College of Medicine in 1990. In 2003, we acquired substantially all of the assets of the predecessor, including trade secrets, know how, clinical experience and key employees and facilities.

Should we determine to pursue any further applications of the ELAD or any other technology, our success may depend on our ability to obtain and maintain patent and other proprietary rights in commercially important technology, inventions and know-how related to our business, the validity and enforceability of our patents, and the continued confidentiality of our trade secrets as well as on our ability to operate without infringing the valid and enforceable patents and proprietary rights of third parties. We would also expect to rely on continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors — Risks Related to Intellectual Property.”

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional priority application. In the U.S., a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or PTO, in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

The term of a U.S. patent that covers an FDA-approved biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the biologic is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved biologic may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors, we would expect to apply for patent term extensions.

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of our proprietary technology are based on unpatented trade secrets and know-how. This includes our methods of expanding, culturing and optimizing the performance of the human VTL C3A cell line. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We seek trademark protection in the U.S. and outside of the U.S. where available and when appropriate. We have registered trademark rights for Vital Therapies in the U.S. and Australia and for ELAD in the U.S., Europe and Australia.

Competitive Environment

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

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

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

In addition, there are several drugs available to treat symptoms associated with liver failure, including steroids, pentoxifylline and N-acetylcysteine. These three drugs, alone or in combination, are used frequently in patients with liver failure resulting from acute hepatocellular insult. Gilead Sciences has conducted a phase 2 trial to evaluate the safety of a non-cellular, drug therapy known as GS-4997 in combination with a steroid named prednisolone, compared with prednisolone alone, in subjects with severe alcoholic hepatitis. Results were presented in 2018 and did not suggest that there was a significant difference in outcome between the treatment groups. An academic collaboration supported by the U.S. NIH also reported data on the use of interleukin-1 receptor antagonist (Anakinra) in combination with pentoxifylline and zinc in subjects with sAH. There was no significant difference in short or long-term outcomes between the treatment groups.

Government Regulation

We operate in a highly-regulated industry that is subject to significant federal, state, local and foreign regulation. Our present and future business has been, and will continue to be, subject to a variety of laws including, the Federal Food, Drug, and Cosmetic Act, or FDC Act, and the Public Health Service Act, or PHS Act, among others. Biologics and medical devices are subject to regulation under the PHS Act and FDC Act.

Regulation of Combination Products

The FDA has specified a definition for the term “combination product,” which includes: (1) a product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity; (2) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; (3) a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or (4) any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

The FDA is divided into various “Centers” by product type. Different Centers typically review drug, biologic, or device applications. In order to review an application for a combination product, the FDA must decide which Center should be responsible for the review. FDA regulations require that the FDA determine the combination product’s primary mode of action, or PMOA, which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The Center that regulates that portion of the product that generates the PMOA becomes the lead evaluator. If there are two independent modes of action, neither of which is subordinate to the other, the FDA makes a determination as to which Center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions or to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product.

When evaluating an application, a lead Center may consult other Centers but still retain complete reviewing authority, or it may collaborate with another Center, by which the Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, the FDA requires a single marketing application submitted to the Center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one Center. One reason to submit multiple evaluations is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product exclusivity. If multiple applications are submitted, each may be evaluated by a different lead Center.

The ELAD System is regulated as a combination biologic/device in the U.S. Based upon the proposed mechanism of action, the primary Center within the FDA responsible for its regulation is the Center for Biologics Evaluation and Research, or CBER. The CBER office responsible for review is the Office of Tissues and Advanced Therapies, and the marketing application would be a biologics license application, or BLA. CBER would consult with the Center for Devices and Radiological Health, or CDRH, in reviewing the device components of the ELAD System.

FDA Approval Process

In the U.S., pharmaceutical and biological products and medical devices are subject to extensive regulation by the FDA. The FDC Act, PHS Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of these products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending license applications, warning and other letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Preclinical Studies

Biological product development in the U.S. typically involves preclinical laboratory and animal tests. Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an investigational new drug application, or IND, along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not objected to the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical Studies

Clinical trials involve the administration of the investigational biologic to healthy volunteers or subjects with the targeted indication, or disease, under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and good clinical practices, or GCP, an international standard meant to protect the rights and health of subjects and to define the roles of clinical trial sponsors, administrators, and monitors, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. subjects and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The clinical trial protocol, protocol amendments and informed consent information for subjects in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of investigational products are required to register on clinicaltrials.gov, a National Institute of Health website registry database, and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Marketing Approval

Clinical trials to support BLAs, which are applications for marketing approval, are typically conducted in three sequential phases, but the phases may overlap. In phase 1, the initial introduction of the investigational biologic candidate into healthy human subjects, the investigational biologic is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited subject population, to determine the effectiveness of the

investigational biologic for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks. In the case of product candidates for severe or life-threatening diseases such as cancer, the initial human testing is often conducted in patients rather than in healthy volunteers.

If an investigational biologic demonstrates evidence of effectiveness and an acceptable safety profile in phase 2 evaluations, phase 3 clinical trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of subjects, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the investigational drug and to provide adequate information for its labeling. In most cases, the FDA requires two adequate and well-controlled phase 3 clinical trials to demonstrate the efficacy and safety of the biologic for use in a specific indication or population. A single phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multi-center trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing of the product may begin in the U.S. The BLA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's manufacture and controls. The cost of preparing and submitting a BLA is substantial. The submission of most BLAs is subject to a substantial application fee and the manufacturer or sponsor of an approved BLA is also subject to annual product and establishment user fees.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. Most such applications for standard review biologics products are reviewed within twelve months of submission; most applications for priority review biologics are reviewed within eight months of submission. Priority review for biologics is limited to those products intended to treat a serious or life-threatening disease with unmet medical need relative to the currently approved products. The review process may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel biologics products or biologics products that present difficult questions of safety or efficacy, to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic product is manufactured. The FDA will not approve the BLA unless compliance with current good manufacturing practice, or cGMP, is satisfactory, including compliance with applicable parts of the medical device Quality System Regulation, or QSR, as defined for combination products, and the BLA contains data that provide substantial evidence that the biologic is safe, pure and potent in the indication studied. Manufacturers of biologics also must comply with the FDA's general biological product standards.

After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter outlines the deficiencies in the submission and may require substantial additional testing, including additional large-scale clinical testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing and distribution of the biologic with specific prescribing information for specific indications. As a condition of BLA approval, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy and may impose other conditions, including labeling restrictions, which can materially affect the product's potential market and profitability. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems or safety issues are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, device components or manufacturing processes or facilities, require submission and FDA approval of a new BLA or

BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Post-Approval Requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as phase 4 testing, Risk Evaluation and Mitigation Strategies, or REMS, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as product manufacturing, packaging and labeling procedures must continue to conform to cGMP's after approval. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to assess compliance with applicable regulations such as cGMPs and the QSR. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP's. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Exclusivity and Approval of Competing Products

Biosimilar Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical study, absent a waiver. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) eighteen months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) eighteen months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug or biologic for this type of disease or condition will be recovered from sales in the U.S. for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of

orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

21st Century Cures Act

In December 2016, President Obama signed the 21st Century Cures Act, or Cures Act, into law. The Cures Act seeks to accelerate the discovery, development, and delivery of new medicines and medical technologies. To that end, and among other provisions, the Cures Act revises the United States Federal Food, Drug, and Cosmetic Act to streamline review of combination

product applications and authorizes the FDA to designate a drug as a “regenerative advanced therapy,” thereby making it eligible for certain expedited review and approval designations.

Federal and State Fraud and Abuse, Privacy and Transparency Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of federal and state laws in the U.S. have been applied to restrict certain business operations and activities in the biopharmaceutical and medical device industries in recent years. These laws that may affect our ability to operate include, but are not limited to:

The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving 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 health care program. The federal healthcare program anti-kickback statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for a statutory exception or a regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal healthcare program anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, or knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government. Recently, the civil False Claims Act has been used to assert liability on the basis of kickbacks and improper referrals, improperly reported government pricing metrics such as Medicaid Best Price or Average Manufacturer Price, improper promotion of drugs or off-label uses not expressly approved by the FDA in a drug’s label, and misrepresentations with respect to the services rendered or items provided. The federal criminal false claims law prohibits, among other things, at any time knowingly and willingly making, or causing to be made, any false statement or representation of a material fact for use in determining rights to a benefit or payment under a federal healthcare program.

Many states also have statutes or regulations similar to the federal fraud and abuse laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor (e.g. private payors). Sanctions under federal, and state healthcare fraud and abuse laws may include, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, 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 operations.

Additionally, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud 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, including private third party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. Many states have similar fraud and abuse statutes and regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, private payors. In addition, we could be subject to, or our marketing activities could be limited by, data privacy and security regulation by both the federal government and the states in which we could eventually conduct our business. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent healthcare reform legislation has strengthened many of these laws. For example, the Patient

Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), among other things, amends the intent requirement of the federal healthcare program anti-kickback statute to a stricter standard such that a person or entity does not need to have actual knowledge of the federal healthcare program anti-kickback statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors, it is possible that some of our business activities may not satisfy the statutory exceptions or regulatory safe harbors and we could be subject to challenge under one or more of such laws. State law equivalents to these federal laws may also apply. Such a challenge could have a material adverse effect on our business, financial condition and results of operations.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report to the Centers for Medicare & Medicaid Services, or CMS, information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals. The Physician Payments Sunshine Act provisions implemented in final regulation requires applicable manufacturers to report annually to CMS certain ownership and investment interests held by physicians and their immediate family members. Manufacturers are required to report such data to CMS by the 90th day of each subsequent calendar year. Other state laws require pharmaceutical companies to adopt and or disclose specific compliance policies to regulate the Company's interactions with healthcare professionals. Moreover, some states, such as Minnesota and Vermont, also impose an outright ban on certain gifts to physicians.

Violations of some of these laws may result in substantial fines. These laws affect promotional activities by limiting the kinds of interactions we may have with hospitals, physicians or other potential purchasers or users of our products. Both the disclosure laws and gift bans will impose additional administrative and compliance burdens on us once and if we receive marketing approval of any product. Although we seek to structure our interactions in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how a law will be applied in specific circumstances. If an employee were to offer an inappropriate gift to a customer, we could be subject to a claim under an applicable state law. Similarly, if we fail to comply with a reporting requirement, we could be subject to penalties under applicable federal or state laws 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. In addition to the federal and state disclosure and gift ban laws, certain countries outside of the U.S. have similarly enacted disclosure laws for which the company in its activities may be subjected to from time to time.

Regulation in the European Union

Biologics and medical devices are subject to extensive regulation outside of the U.S. In the European Union, for instance, a centralized approval procedure, or Centralized Procedures, may be used to authorize the marketing of a product in all countries of the European Union, which includes most major European markets. However, for certain products, if this procedure is not used, approval in one country of the European Union can be used to obtain approval in a second country of the European Union under two simplified application processes, either the mutual recognition procedure or the decentralized procedure. Both of these procedures rely on the principle of mutual recognition. In addition to regulatory approval, pricing and reimbursement approvals are also required in most countries.

In Europe, the ELAD System is regulated as a Combination Somatic Cell Advanced Therapy Medicinal Product, or ATMP. The primary regulatory license application in Europe (a Marketing Authorization Application, or MAA), if any, would be made to The Committee for Advanced Therapies, or CAT, and the Committee for Human Medicinal Products, or CHMP, which are the committees at the European Medicines Agency, or EMA, that are responsible for assessing the quality, safety and efficacy of ATMPs. Marketing Authorization Applications for ATMPs can only be filed using the Centralized Procedure. The CHMP and the CAT liaise closely together so the CHMP is able to make a scientific opinion relating to the authorization to place an ATMP on the market in accordance with Regulation (EC) No 1394/2007 and pharmacovigilance. The CAT has also established collaborations with Notified Bodies, or NBs, in Europe in order to review the device components of combination device products, and we anticipate that the device components of any submission would be reviewed by one of those NBs. During the clinical trial phase in Europe, we were granted authorization to conduct clinical studies at the national level through the health authority agencies in each country, each of which has its own format and regulation for the issuance of clinical trial authorizations, or CTAs. For some countries, it is necessary to obtain separate authorizations in each country for each clinical trial protocol from the medicines and device agencies as there is yet to be developed a procedure for dealing with combination products like the ELAD System. The EMA has provisions for providing companies with advice on topics related to marketing authorization in Europe through the Scientific Advice Working Party, or SAWP. Previously, we sought and obtained advice on the ELAD development program through the SAWP process.

In other jurisdictions we anticipate that there will be different requirements for authorization for clinical trials and ultimately marketing of the ELAD System due to the complex nature of the combination of biological and device components of our ELAD System.

Other Regulations

We are also subject to numerous, federal, state, local and foreign laws and regulations relating to such matters as safe working conditions, manufacturing practices, fire hazard control, environmental protection and the disposal of hazardous and potentially hazardous substances and biological materials. We may incur significant costs to comply with such laws and their related regulations now or in the future. In addition, we would also be subject to laws and regulations in foreign countries outside of the U.S. and Europe where we may seek to commercialize any products. In certain cases, these foreign laws and regulations may change at inopportune times and prevent timely commercialization. For example, several years after we submitted our 2007 regulatory package in China, we were notified of a then newly-enacted 2009 regulation which prohibited the ELAD System's approval in China unless first approved in the U.S.

Research and Development

We recognized $24.8 million, $39.3 million and $30.0 million in research and development expenses in the years ended December 31, 2018, 2017 and 2016, respectively.

Geographic Information

During 2018, 2017 and 2016, substantially all of our long-lived assets were located within the U.S.

Financial Information about Segments

We manage our operations as a single reportable segment for the purposes of assessing performance and making operating decisions. Please see Note 1, "Description of Business and Basis of Financial Statements" in the notes to the consolidated financial statements.

Employees

As of January 31, 2018, we had 10 employees, 2 of whom held M.D. degrees. Of our employees, 2 were engaged in research and development, 1 in manufacturing and 7 in administration. None of our employees is represented by a labor organization or under any collective bargaining arrangement, and we have never had a work stoppage. We consider our employee relations to be good.

Corporate Information and Website

We were incorporated in California in May 2003 as Vitagen Acquisition Corp., changed our name to Vital Therapies, Inc. in June 2003, and reincorporated in Delaware in January 2004. Our principal executive offices are located at 15222-B Avenue of Science, San Diego, CA 92128. Our telephone number is (858) 673-6840. Our website address is http://www.vitaltherapies.com. This Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available (free of charge) on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. The public may read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 100F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. Information contained on, or that can be accessed through, our website, or from the SEC does not constitute part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

"Vital Therapies" and "ELAD" are registered trademarks of Vital Therapies, and the Vital Therapies logo is a trademark of Vital Therapies. Other service marks, trademarks, and tradenames referred to in this Annual Report are the property of their respective owners. Except as set forth above and solely for convenience, the trademarks and tradenames in this Annual Report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We may remain an "emerging growth company" until as late as December 31, 2019 (the fiscal year-end following the fifth anniversary of the completion of our initial public offering), although we may cease to be an "emerging growth company" earlier under certain circumstances, including (i) if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30, in which case we would cease to be an "emerging growth company" as of the following December 31, or (ii) if our gross revenue exceeds $1.07 billion in any fiscal year. We

refer to the Jumpstart Our Business Startups Act of 2012 herein as the "JOBS Act," and references herein to "emerging growth company" are intended to have the meaning associated with it in the JOBS Act.

Item 1A. Risk Factors.

Investing in shares of our common stock involves a high degree of risk. Before deciding to invest in our company or deciding to maintain or increase or decrease your investment, you should consider carefully the risks and uncertainties described below. The risks and uncertainties described below and in our other filings with the Securities and Exchange Commission, or SEC, are not the only ones we face. If one or more of the following risks are realized, our business, financial condition and results of operations and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you may lose all or part of your investment. In January, 2019, we entered into an Exchange Agreement with Immunic AG, or Immunic, pursuant to which, subject to the approval of our stockholders and the satisfaction or waiver of the conditions set forth in the Exchange Agreement, Immunic would become a wholly-owned subsidiary of Vital Therapies, or the Company, referred to herein as the Transaction. If the Transaction is completed, which could be as early as the first half of April, the business of Immunic will become the business of the Company. Additional information regarding the Transaction including risk factors related to Immunic can be found in our registration statement on Form S-4 filed with the Securities and Exchange Commission in February 2019.

Risks Related to the Transaction

The Exchange Ratio is not adjustable based on the market price of our common stock so the Transaction consideration at the closing may have a greater or lesser value than at the time the Exchange Agreement was signed.

The relative proportion of the Company that the our existing stockholders will own when the Transaction closes will be based on the relative valuations of the Company and Immunic as negotiated by the parties and as specified in the Exchange Agreement. Following the completion of the Transaction, (a) our existing stockholders are expected to own approximately 11% of the common stock of the Company and (b) Immunic shareholders are expected to own approximately 89% of the common stock of the Company, on a fully-diluted basis (including shares issued in a concurrent financing by Immunic), assuming that Immunic closes its concurrent financing immediately prior to the effective time of the Transaction. These estimates are based on the anticipated exchange ratio, or the Exchange Ratio, and are subject to adjustment as provided in the Exchange Agreement. Fluctuations in our stock price will not affect our valuation under the Exchange Agreement or the portion of the company to be retained by our existing stockholders. The terms of the Exchange Agreement provide for adjustments to the relative valuations of both Vital Therapies and Immunic in certain events. For example, prior to the consummation of the Transaction, the Exchange Ratio at the closing of the Transaction may be subject to either (i) an upward adjustment to the extent that our net cash at the effective time of the Transaction is less than $4,200,000 (and as a result, our existing securityholders could own less, and Immunic securityholders could own more, of the Company) or (ii) a downward adjustment to the extent that our net cash at the effective time of the Transaction is greater than $5,200,000 (and as a result, our existing securityholders could own more, and Immunic securityholders could own less, of the Company). In addition, if our net cash at the effective time of the Transaction is less than a specified minimum amount of approximately $1,500,000, the Exchange Ratio at the closing of the Transaction may be subject to an additional upward adjustment (and as a result, our existing securityholders could own less, and Immunic securityholders could own more, of the Company). The minimum specified amount will be $1,500,000 if the Transaction closes on or before March 31, 2019, and the minimum cash will be reduced by $5,000 for each day (including any partial day) after March 31, 2019 until the Transaction closes.

Failure to complete the Transaction may result in the Company paying a termination fee to Immunic and could harm the our common stock price and our future business and operations.

If the Transaction is not completed, we are subject to the following risks:

- we may be required to pay Immunic a termination fee of $500,000 and/or up to $275,000 in expense reimbursements;
- the price of our common stock may decline and remain volatile;
- we will have incurred significant expenses related to the Transaction, such as legal and accounting fees, which we estimate will total approximately $1.4 million, many of which must be paid even if the Transaction is not completed; and
- we may be forced to cease its operations, dissolve and liquidate its assets.

In addition, if the Exchange Agreement is terminated and our the board of directors determines to seek another business combination, there can be no assurance that we will be able to find a partner willing to provide equivalent or more attractive consideration than the consideration to be provided in the Transaction or any partner at all.

If the conditions to the closing of the Transaction are not met, the Transaction may not occur.

Even if the change of control and related share issuance are approved by our stockholders, specified conditions must be

satisfied or waived to complete the Transaction. These conditions are set forth in the Exchange Agreement, including Immunic's concurrent financing. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Transaction may not occur or will be delayed, and we would lose the intended benefits of the Transaction.

The Transaction may be completed even though material adverse changes may result from the announcement of the Transaction, industry-wide changes and other causes.

In general, either the Company or Immunic can refuse to complete the Transaction if there is a material adverse change affecting the other party between January 6, 2019, the date of the Exchange Agreement, and the closing of the Transaction. However, certain types of changes do not permit either party to refuse to complete the Transaction, even if such change could be said to have a material adverse effect on the Company or Immunic, including:

- any rejection by a governmental body of a registration or filing by the Company or Immunic relating to their respective intellectual property rights;
- any change in the cash position of the Company or Immunic that results from operations in the ordinary course of business;
- conditions generally affecting the industries in which the Company or Immunic participates or the U.S. or global economy or capital markets as a whole, to the extent that such conditions do not have a disproportionate impact on the Company or Immunic and their respective subsidiaries, taken as a whole;
- any failure by Immunic to meet internal projections or forecasts on or after the date of the Exchange Agreement, provided that any such effect, change, event, circumstance or development causing or contributing to any such failure to meet projections or forecasts may constitute a material adverse effect of the Company or Immunic and may be taken into account in determining whether a material adverse effect has occurred;
- our failure to meet internal projections or forecasts or third-party predictions for any period ending (or for which results are released) on or after the date of the Exchange Agreement or any change in the price or trading volume of the our common stock, provided that any such effect, change, event, circumstance or development causing or contributing to any such failure to meet projections or forecasts may constitute a material adverse effect and may be taken into account in determining whether a material adverse effect has occurred;
- the execution, delivery, announcement or performance of obligations under the Exchange Agreement or the announcement, pendency or anticipated consummation of the Transaction or Immunic's concurrent financing;
- a transfer, sale, lease, disposition or license of our assets that is permitted under the Exchange Agreement;
- any natural disaster or any acts of terrorism, sabotage, military action or war or any escalation or worsening thereof; or
- any changes after the date of the Exchange Agreement in U.S. GAAP or applicable laws.

If adverse changes occur and we still complete the Transaction, our stock price following the closing of the Transaction may suffer. This in turn may reduce the value of the Transaction to our stockholders.

Some of our executive officers and directors have interests in the Transaction that are different from yours and that may influence them to support or approve the Transaction without regard to your interests.

Some of our officers and directors are parties to arrangements that provide them with interests in the Transaction that are different from yours, including, among others, service as an officer or director of the company following the closing of the Transaction, severance and retention benefits, the acceleration of equity award vesting, and continued indemnification.

The market price of our common stock following the Transaction may decline as a result of the Transaction.

The market price of our common stock may decline as a result of the Transaction for a number of reasons, including if:

- investors react negatively to the prospects of our business and prospects following the closing of the Transaction;
- the effect of the Transaction on our business and prospects following the closing of the Transaction is not consistent with the expectations of financial or industry analysts; or
- we do not achieve the perceived benefits of the Transaction as rapidly or to the extent anticipated by stockholders or financial or industry analysts.

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Our stockholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the Company following the closing of the Transaction as compared to their current ownership and voting interest.

After the completion of the Transaction, our stockholders will own a smaller percentage of the Company than their ownership prior to the Transaction. Immediately after the Transaction, it is currently estimated that Immunic securityholders will own approximately 89% of the common stock of the Company, with our current stockholders, whose shares of our common stock will remain outstanding after the Transaction, will own approximately 11% of the common stock of the Company on a fully-diluted basis, calculated on a pro forma basis including after giving effect to (i) the issuance of common shares by Immunic immediately prior to the effective time of the Transaction pursuant to a concurrent investment, and (ii) the Transaction. These estimates are based on the anticipated Exchange Ratio and are subject to adjustment as provided in the Exchange Agreement.

In addition, the five member board of directors of the Company will initially consist of four individuals with prior affiliations with Immunic and Dr. Duane D. Nash, currently Chief Executive Officer, President and a director of the Company. Consequently, our current stockholders will exercise substantially less influence over the management and policies of the Company following the closing of the Transaction.

During the pendency of the Transaction, we may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Exchange Agreement, which could adversely affect our businesses.

Covenants in the Exchange Agreement impede our ability to make acquisitions, subject to specified exceptions relating to fiduciary duties or complete other transactions that are not in the ordinary course of business pending completion of the Transaction. As a result, if the Transaction is not completed, we may be at a disadvantage to their competitors during that period. In addition, while the Exchange Agreement is in effect, we are generally prohibited from soliciting, initiating, encouraging or entering into specified extraordinary transactions, such as a merger, sale of assets or other business combination, with any third party, subject to specified exceptions, even if any such transactions could be favorable to us.

Certain provisions of the Exchange Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the arrangements contemplated by the Exchange Agreement.

The terms of the Exchange Agreement prohibit us from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when our board of directors determines in good faith, after consultation with its independent financial advisor, if any, and outside counsel, that an unsolicited competing proposal constitutes, or would reasonably be expected to result in, a superior competing proposal and that failure to take such action would be reasonably likely to result in a breach of the fiduciary duties of the board of directors. In addition, if we terminate the Exchange Agreement under specified circumstances, including terminating because of a decision of a board of directors to recommend a superior competing proposal, we may be required to pay Immunic a termination fee of $500,000 and/or up to $275,000 in expense reimbursements. This termination fee may discourage third parties from submitting competing proposals to our stockholders, and may cause our board of directors to be less inclined to recommend a competing proposal.

Because the lack of a public market for Immunic’s capital stock makes it difficult to evaluate the fairness of the Transaction, we may pay more than the fair market value of Immunic’s capital stock.

The outstanding capital stock of Immunic is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Immunic’s capital stock. Because the percentage of the Company’s equity to be issued to Immunic shareholders was determined based on negotiations between the parties, it is possible that we may pay more than the aggregate fair market value for Immunic’s capital stock.

Risks Related to Our Evaluation of Strategic Alternatives

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

In September 2018, we voluntarily discontinued our development of our product candidate, the ELAD® System, or ELAD, in view of the results of our VTL-308 phase 3 clinical trial in the U.S. and Europe. We have engaged Ladenburg Thalmann & Co. Inc., as a financial advisor to assist us in pursuing strategic alternatives, and on January 7, 2019, we announced that we had entered in to the Exchange Agreement. We continue to evaluate additional strategic alternatives in order to enhance stockholder value, including the possibility of a sale of our assets related to the ELAD System, and we have suspended many of our research and development activities to reduce operating expenses while we evaluate and pursue these opportunities. We have and expect to continue to devote significant time and resources to identifying and evaluating strategic alternatives, including the Transaction; however, there can be no assurance that the Transaction or other such activities will enhance stockholder value. In addition, potential strategic transactions that require stockholder approval, such as the

Transaction and the related matters stockholders are being asked to approve, may not be approved by our stockholders. Further, any strategic transaction that is completed ultimately may not deliver the anticipated benefits or enhance stockholder value.

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

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

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

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

There can be no assurance that the Transaction or any other strategic transactions we may identify or undertake, including the possible sale of our assets, will result in one or more successfully consummated transactions. If the Transaction is not completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we continue to pursue our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations; (ii) obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our company; (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business; and (iv) non-cancelable facility lease obligations. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company.

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

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

We are evaluating and pursuing strategic alternatives with a goal to enhance stockholder value , including the Transaction and the potential sale of assets, and have suspended most of our research and development activities, other than our early stage normothermic liver perfusion program, to reduce operating expenses while we focus on closing the Transaction and pursuing other strategic alternatives with respect to the sale of assets.

There can be no assurance that our efforts to sell certain of our assets will result in any definitive agreement to buy such assets or if made, what the terms thereof will be or that the Transaction or any asset sale will be approved or consummated. In addition, there can be no assurance that any transactions, involving our company and/or assets, that is consummated would enhance stockholder value. There also can be no assurance that we will conduct additional research or development activities in the future.

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

In September 2018, we instituted across the board expense reductions to conserve capital, including a workforce reduction of approximately 85%. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction, including the Transaction, depends in large part on our ability to retain certain of our remaining personnel, particularly Duane D. Nash M.D., our Chief Executive Officer and President, Robert A. Ashley, our Executive Vice President and Chief Scientific Officer, Michael V. Swanson, our Executive Vice President and Chief Financial Officer, and John M. Dunn, our General Counsel and Secretary. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to evaluate and pursue strategic alternatives, as well as fulfill our reporting obligations as a public company. Competition among biotechnology companies for qualified employees is intense, and the ability to retain our key employees is critical to our ability to effectively manage our resources and to consummate a strategic transaction. Although we have suspended most of our research and development activities, if we resume the development of ELAD outside the U.S. or of new therapeutic products, such development requires expertise from a number of different disciplines, some of which are not widely available. The failure of the VTL-308 clinical trial will likely make it more challenging to retain qualified personnel and difficult to recruit personnel in the future, if necessary. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede our ability to identify and execute on a strategic path forward.

Our key employees have a significant amount of know-how and experience in our company, and the loss of one or more of them could have a material and adverse effect on our operations or ability to consummate a strategic transaction. While we have taken steps to retain our employees, including the granting of equity awards, paying competitive salaries and implementing appropriate bonus programs, these factors may not be enough to retain the employees that we need, particularly in light of the recent failure of our VTL-308 clinical trial and the scaling back of our operations.

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

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

advisor may impede our ability to identify and execute on our strategy.

Risks Related to Our Business

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

We are subject to all of the uncertainties and complexities affecting a clinical-stage, combination product, biologic and medical device company. We have not successfully completed clinical development for any of the ELAD System's potential indications in the U.S. or Europe where the ELAD System is regulated as a combination biologic and medical device, and as a combined somatic cell Advanced Therapy Medicinal Product, respectively. In September 2018, we announced that our VTL-308 clinical trial failed to meet both its primary and secondary endpoints. In light of these results, we do not believe that the ELAD System can be approved in the U.S. or Europe, if ever, without additional clinical trials that would require substantial capital and time to complete. Consequently, we have ceased any further development of the ELAD System and are exploring strategic options including the potential sale of these assets. We do not have any other product candidates in our near-term product pipeline, other than our normothermic liver perfusion program which is early in development.

Our VTL-308 clinical trial was performed in certain subjects with severe alcoholic hepatitis, or sAH. Any additional indications we elect to pursue in future trials will require the initiation and completion of additional phase 3 clinical trials demonstrating safety and efficacy for each such indication. For example, even prior to our VTI-208 clinical trial, the Food and Drug Administration, or FDA, had noted its view that preliminary clinical evidence did not indicate that the ELAD System may demonstrate a substantial improvement over standard of care. Since then, our VTI-208 and VTL-308 clinical trials failed to meet both their primary and secondary endpoints. There is no guarantee that any potential future clinical trials would be completed in a timely fashion or would succeed. Further, there can be no assurance that any potential future clinical trials will be timely, successful, or that regulators will approve the ELAD System in a timely manner, or at all. Finally, even if clinical testing of the ELAD System is resumed in the future and the ELAD System is subsequently proven to be safe and effective and ultimately receives regulatory approval, there is no guarantee that its commercialization would be successful.

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

We are a clinical-stage company, and we have no approved products or revenues from the sale of products. Our operations to date have been limited to organizing, staffing and financing our company, applying for patent rights, manufacturing on a clinical scale, undertaking clinical trials, and engaging in research and development. Our VTL-308, VTI-208, VTI-210 and VTI-212 trials failed to reach both their primary and secondary endpoints or were terminated. We have not yet demonstrated an ability to obtain regulatory approval, manufacture products on a commercial scale, or conduct the sales and marketing activities necessary for successful product commercialization. As a result, there is limited information about us for investors to use when assessing our future viability and our potential to successfully develop product candidates, conduct clinical trials, manufacture our products on a commercial scale, obtain regulatory approval or profitably commercialize any approved products.

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

We must obtain regulatory approval for each indication we seek before we can market and sell the ELAD System in a particular jurisdiction for such indication. To date, we have not applied for or received the regulatory approvals required for the commercial sale of the ELAD System for any indication in the United States or Europe. In light of the clinical results from our VTL-308 clinical trial, we do not believe that the ELAD System can be approved in the U.S. or Europe, if ever, without additional clinical trials that would require substantial capital and time to complete.

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

Although we have suspended our research and development activities related to the ELAD System, if we resume the development of the ELAD System, therapies such as the ELAD System are paid for primarily by private and government insurance, although in some markets payment may be made by private individuals and their families. Reimbursement policies and decisions for medical products is a highly bureaucratic, politicized and regulated process

that includes consideration of factors such as cost effectiveness and meaningful patient benefit. Government and third-party payors are under great pressure to reduce costs. Furthermore, there are no therapies approved to restore liver function and the lack of an established reimbursement structure introduces additional uncertainty with regard to reimbursement for the ELAD System. Although we do not expect to pursue regulatory approval of the ELAD System at this time, we believe it may be difficult to sustain a commercial price outside of the U.S. at or above the commercial price within the U.S. In addition, we will have no control over the reimbursement or conditions that may be set by the government or private insurers, if any, assuming we were able to secure marketing approval for the ELAD System. In markets where payment would be made by private individuals and their families, such private payors may not be prepared to pay an acceptable price.

Although we have suspended our research and development activities related to the ELAD System, if we resume development, and if we are unable to implement our sales, marketing, distribution, training and support strategies in the U.S. and Europe or enter into agreements with third parties to perform these functions in markets outside of the U.S. and Europe, we would not be able to effectively commercialize the ELAD System or any other product candidates and may not reach profitability.

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

Further, we do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of biologic products and medical devices. To achieve commercial success of any product candidates, assuming we were to obtain marketing approval, we would need to establish a sales and marketing organization, and we are unable to currently predict how we would market any such product candidates.

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

We are a clinical-stage company, and clinical development of a novel therapy is a highly speculative undertaking. We have incurred significant losses in each fiscal year since our inception, including net losses of $41.5 million for the twelve months ended December 31, 2018 and $52.1 million, $41.0 million and $52.0 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2018, we had an accumulated deficit of $337.4 million Even though we discontinued most of our research efforts in September 2018, we expect to continue to spend a considerable amount of our resources on strategic opportunities. We continue to incur expenses related to the pursuit of strategic alternatives, including the Transaction, and we expect these expenses will increase as we work towards obtaining stockholder approval and closing of the Transaction, and as we continue to evaluate opportunities to sell assets. We also may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on our decisions on strategic alternatives. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

We have suspended most of our research and development activities to reduce operating expenses while we continue to pursue closing of the Transaction and efforts to sell assets. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we evaluate these strategic alternatives and continue our efforts to close the Transaction.

As a result of these factors, we expect to continue to incur significant operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have a material adverse effect on our stockholders' equity, financial position, cash flows and working capital. We are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to produce revenue and achieve profitability is dependent on our ability to complete the development of product candidates, obtain necessary regulatory approvals, and to successfully manufacture and market products. We cannot assure you that we will ever be profitable even if we successfully enter into strategic transactions or commercialize products. Failure to become and remain profitable or the perception that we may never become profitable would adversely affect the market price of our common stock and our ability to raise capital and continue operations.

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

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $337.4 million through December 31, 2018. Based on our current employees, our known commitments, and our ongoing administrative costs to explore and pursue strategic options, we believe that our existing cash and cash equivalents of $13.3 million as of December 31, 2018 should be sufficient to meet our known liabilities and commitments as of December 31, 2018; however, we expect our resource requirements to change materially to the extent we enter into the Transaction or any other strategic alternatives. To advance the development of product candidates, we would need to obtain additional financing and increase our expenditures.

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

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

- the timing and structure of any strategic options that are being considered by us, including the Transaction and any potential asset sales;
- our ability to establish new collaborations, licensing or other arrangements and the financial terms of such agreements;
- the number and characteristics of any future product candidates we pursue (if any);
- the timing and progress in the development of our normothermic liver perfusion program;
- the scope, progress, results and costs of research and development and future clinical trials, if any, related to the ELAD System or other product candidates;
- the cost and timing of any regulatory submissions;
- the cost and timing of scaling up and validating the manufacturing process for the ELAD System or any other potential product candidates for commercialization;
- the cost and timing of commercialization activities, including reimbursement, marketing, sales and distribution costs, both before and after product approval (if any);
- the costs involved with being a public company;
- the cost, timing and outcome of any future litigation;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties, if any, on the ELAD System and any future product candidates.

We may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances, marketing or distribution arrangements or a combination thereof. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. General market conditions or the market price of our common stock may not support capital raising transactions such as an additional public or private offering of our common stock or other securities. In addition, our ability to raise additional capital may be dependent upon our stock being quoted on The Nasdaq Stock Market, or Nasdaq, or upon obtaining stockholder approval. On October 25, 2018, we received a letter from the staff of Nasdaq providing notification that, for the previous 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement, or the Bid Price Requirement, for continued listing on Nasdaq. The notification had no immediate effect on the listing of our common stock. In accordance with Nasdaq listing rules, we were afforded 180 calendar days, or

until April 23, 2019, to regain compliance with the Bid Price Requirement. There can be no assurance that we will be able to satisfy the criteria for continued listing on Nasdaq or that we will be able to obtain

stockholder approval, if it is necessary, to take the steps needed to remedy the Bid Price Requirement. If our common stock is delisted, this would, among other things, substantially impair our ability to close the Transaction and limit our strategic alternatives, and result in fewer development opportunities. If adequate funds are not available, we may be required to close our operations.

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

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

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

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

As of December 31, 2018, we had net operating loss, or NOL, carryforwards of approximately $208.6 million and $203.0 million (prior to our adjustments for uncertain tax positions), net of estimated limitations caused by certain ownership changes under Section 382 of the Internal Revenue Code, for federal and state income tax purposes, respectively. In general, under Section 382, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOL and tax credit carryforwards. We believe our existing NOL and tax credit carryforwards are subject to limitations arising from previous ownership changes, and if we undergo any further ownership changes, such as in connection with the Transaction, our ability to utilize NOL and tax credit carryforwards could be further limited. Future changes in our stock ownership, some of which are outside of our control, could also result in additional ownership changes under Section 382. The strategic options that we are pursuing, including the Transaction, will create an ownership change under Section 382 of the Internal Revenue Code, which would limit all or substantially all of our NOL and tax credit carryforwards. Furthermore, our ability to utilize NOLs and tax credit carryforwards of companies that we may acquire in the future, if any, may be subject to limitations.

Furthermore, in 2013, California adopted a single factor, sales, for apportioning income and losses to the state. Although completely offset by our valuation allowance, we had recognized NOL and tax credit carryforwards from 2013 through 2017 based on a multiple factor apportionment based on salaries, property and sales in the state. This position was based on prior court rulings supporting the use of the multiple factor apportionment. This ruling was overturned by the California Supreme Court in December 2015, and, in October 2016, the U.S. Supreme Court declined to hear the case. California has no regulations or guidance nor have there been any rulings addressing how a company with no sales should apportion losses to California. As most of our operations are in California, we have filed our tax returns using a multiple factor apportionment. For these reasons and due to the limitations discussed above, we likely will not be able to utilize all or substantially all of such NOL and tax credit carryforwards, even if we attain profitability.

We conduct business and file income tax returns in various tax jurisdictions. Our tax position could be adversely affected by several factors, many of which are outside of our control. For example, in the U.S., recently enacted U.S. tax reform in December 2017 commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act, may have a negative impact on our business. In addition, it is possible that further changes to the U.S. tax code and the tax rules in the other jurisdictions could occur in the near future. Although we monitor these developments, it is not possible to

assess to what extent changes may be implemented in the U.S. and other jurisdictions in which we conduct our business, what impact they may have on the way in which we conduct our business, or how they may impact our effective tax rate due to the unpredictability and interdependency of these potential changes. Even though we maintain a full valuation allowance to offset our NOL and tax credit carryforwards, changes in tax laws and related regulations and practices could have a material adverse effect on our business operations, cash flows, effective tax rate, financial position and results of operations and likelihood of consummating a strategic transaction.

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

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

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

Our industry is characterized by frequent claims and litigation, including claims regarding patent or other intellectual property rights, as well as product liability. Additionally, in the past, companies that experience volatility in the market price of their stock have been subject to securities class action litigation. For example, following our announcement that the ELAD System, our sole product candidate, failed to meet its primary and secondary endpoints in our VTI-208 phase 3 clinical trial, we became the subject of a lawsuit alleging securities law violations. Although this litigation was dismissed, this type of litigation can be expensive and disruptive to normal business operations and divert management's attention, and the outcome can be difficult to predict regardless of the facts involved. We are at a heightened risk of, and could be subject to, additional litigation following our announcement in September 2018 that the ELAD System failed to meet its primary and secondary endpoints in our VTL-308 phase 3 clinical trial. An unfavorable outcome with respect to a lawsuit could have a material adverse effect on our business, financial condition, results of operations or cash flows and ability to consummate strategic transactions.

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

If we resume the clinical development of any product candidates, we have limited experience in conducting pivotal clinical trials used to support regulatory approval, and our prior clinical trials of the ELAD System did not demonstrate a statistically significant improvement in survival, the primary endpoint that was needed to support regulatory approval.

Our VTI-208 phase 3 randomized, controlled, open-label trial evaluating the ELAD System in subjects primarily with severe alcoholic hepatitis, or sAH, failed to meet the primary endpoint of overall survival through at least 91 days assessed using the Kaplan Meier statistical method. Our protocol for our subsequent clinical trial of the ELAD system in sAH, VTL-308, incorporated limits on subjects' age, model for end-stage liver disease score, or MELD score, and its three components. While the endpoints and populations for VTL-308 were derived from results of our prior studies, including the results of VTI-208, and based on medical literature, in none of those prior studies had we demonstrated a statistically significant effect on the population based on the endpoints prospectively described in the study plan. Our prior clinical trials of the ELAD System in sAH did not demonstrate statistically significant improvement over standard of care in the primary endpoint of survival through at least study day ninety-one. Similarly, our prior clinical trials of the ELAD System in fulminant hepatic failure, or FHF, did not demonstrate statistically significant improvement in the primary endpoint of 28-day survival. In September 2018, we announced that the VTL-308 clinical

trial failed to meet both its primary and secondary endpoints. The lack of statistical significance from these previous trials could be attributed to various factors, including the lack of power to demonstrate significance, the design of the studies and the lack of an ELAD System treatment benefit.

If we resume the clinical development of the ELAD System or any other product candidate, any positive results from previous clinical trials may not be predictive of future results.

Any positive results from our prior clinical trials, including either statistical significance in some endpoints or trends towards statistical significance in other endpoints, should not be relied upon as evidence that our potential future clinical trials will necessarily succeed. For example, our primary endpoint in VTL-308 was based on the results of a subset of subjects in our VTI-208 clinical trial. Additionally, our primary endpoint in VTI-208 was based on the results of a subset of subjects in our VTI-206 clinical trial. Although these subsets showed a trend toward increased survival up to at least study day ninety-one, the subsequent trials still failed to meet their primary and secondary endpoints. The FDA has noted its belief that this preliminary clinical evidence did not indicate that our product may demonstrate a substantial improvement over standard of care. We cannot provide any guarantee that any potential future clinical trials of any product candidates will provide statistically significant data sufficient to support regulatory approval.

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

Regulatory authorities worldwide have adopted the standard that, to gain marketing approval, clinical trials should produce a result that has less than a 5% probability of being due to random variation. There is no assurance that any of our potential future clinical trials will meet that standard. In addition, we have designed all of our past clinical trials to be judged by a survival primary endpoint, which may have been difficult to achieve for many reasons, including unanticipated survival rates of control subjects due to random variations, deficiencies in our exclusion and inclusion criteria, and the standard of care of the subjects, which may vary from site to site and country to country and is continuously evolving. Such difficulties may continue in any potential future clinical trials.

Any of these factors, which are beyond our control, could materially and adversely affect the results of any potential future trials and prevent us from gaining regulatory approval of any product candidates. In addition, even if the results of any potential future clinical programs are positive, our inability to control or adequately account for these factors between treatment arms could cause the FDA or other regulatory authorities to determine that the results are not adequate, or must be reproduced in a confirmatory study, to support marketing approval.

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

The ELAD System therapy was targeted toward very sick patients who were likely to die if left untreated. Patients with liver failure resulting from acute hepatocellular insult quickly develop failure of other organs including lungs, kidney, brain, and blood coagulation systems. Patients who received the ELAD System therapy were at risk of dying due to other serious health problems even if the ELAD System was demonstrated to be effective.

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

Data from our prior clinical trials suggest that ELAD treatment should not be used in subjects with acute kidney injury (defined as a serum creatinine level of greater than or equal to 1.5 mg/dL). The use of extracorporeal systems such as ELAD may cause harm in patients with pre-existing kidney injury because these subjects are at an increased risk to

develop fluid overload due to the renal impairment. Furthermore, ELAD treatment should be stopped if a patient develops any indication for renal replacement therapy, because patients with renal impairment are less likely to be able to tolerate the increased stresses associated with two extracorporeal devices requiring high venous flow rates.

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

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

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

We did not conduct our VTI-208, VTI-210, VTI-212 or VTL-308 clinical trials with a sham control extracorporeal circuit that includes empty cartridges. This is due to the potential harm that the extracorporeal circuit can cause to control subjects without the potential for any benefit, which makes it unethical to subject the controls to a sham. Although regulatory agencies agree that, due to the nature of the ELAD System therapy, it is not possible to conduct a blinded study, they have expressed concern that the open-label nature of the study design may introduce significant bias in the treatment of the ELAD System or control subjects, since the study subject, physicians and caregivers know who has and has not received the ELAD System therapy. We had developed a protocol that attempted to minimize this bias to the extent possible, including defining a protocol-specific standard of care, specifying steroid treatment, standardizing the discharge criteria for both the ELAD-treated and control subjects, requiring that follow-up visits are conducted by a blinded reviewer, ensuring home healthcare nurses and other clinical personnel are unaware of treatment assignment, educating subjects not to reveal treatment assignment to their caregivers and monitoring concomitant medications, alcohol recidivism and interaction with the healthcare system to provide evidence that there is no meaningful difference between the groups that might have significantly confounded the trial data. However, there is no guarantee that bias will not enter into any potential future clinical trial, affect the results of such trials or cause regulatory agencies to refuse marketing approval of the ELAD System or any other product candidates.

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

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

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

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

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

If we resume the clinical development of any product candidates, we may face delays in completing any potential future clinical trials, and we may be required to suspend, repeat or terminate any potential future clinical trials if they are not conducted in accordance with applicable regulatory requirements, the results are negative or inconclusive, or the clinical trials are not well-designed or executed as expected.

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

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

- delays or failures in designing an appropriate clinical trial protocol with sufficient statistical power and in reaching agreement on trial design with investigators and regulatory authorities;
- delays or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays or failure by CROs, investigators and clinical trial sites in ensuring the proper and timely conduct of any potential future clinical trials;
- delays or failure by us in manufacturing sufficient quantities of product pursuant to required quality standards and by third-party manufacturers in supplying the product or necessary and suitable components;
- delays or failure in transporting products to clinical trial sites with sufficient rapidity to enable treatment to begin early enough to have an opportunity for clinical benefit;
- delays or failure in completing data analysis and achieving primary and secondary endpoints;
- delays in subject enrollment or site initiation, including in light of, among other things, our prior clinical results;
- regulators or clinical site ethics committees or IRBs may not approve or may delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about subject safety;

- we may suspend or terminate any potential future clinical trials if we believe our product is exposing the participating subjects to unacceptable health risks or for other reasons;
- subjects may not complete any potential future clinical trials due to safety issues, adverse events, inconvenience or other reasons;
- subjects in any potential future clinical trials may die or suffer other adverse events for reasons that may be either related or unrelated to our product;
- we may have difficulty in maintaining contact with subjects after treatment, preventing us from collecting the data required by our study protocol; and
- final analysis of the data from any potential future clinical trials may conclude that such product candidate lacks sufficient clinical efficacy or presents unacceptable safety risks, such as occurred with the VTL-308 clinical trial.

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

Risks Related to Regulatory Matters

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

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

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

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

- the FDA may disagree with the design or implementation of the clinical trials or the study endpoints. For example, in our ELAD clinical trials, the FDA had expressed concern about the open-label design and multiplicity of confounding variables, including the need for delineating the standard of care that both the treated and control groups received during our studies;
- we may be unable to demonstrate to the satisfaction of the FDA that our product is safe and effective for its proposed indications or that the product provides significant clinically relevant benefits or that the benefits outweigh the safety risks;
- the results of a clinical trial may not meet the level of statistical significance required by the FDA for approval or may not support approval of a label that could command a price sufficient for us to be profitable;
- the FDA may disagree with our interpretation of data from any preclinical studies or clinical trials;
- the FDA may not accept clinical data from trials which are conducted outside their jurisdiction;
- the opportunity for bias in any potential future clinical trials as a result of the open-label design may not be adequately handled and may cause any potential future trial to fail;
- the product may be subject to an FDA advisory committee review, which is triggered by an FDA request and is solely within the FDA’s discretion, which may result in unexpected delays or additional hurdles to approval;
- the FDA may determine that the manufacturing processes at our facilities or facilities of third party manufacturers with which we contract for clinical and commercial supplies are inadequate;

- even if a future clinical trial is successful in demonstrating a statistically significant improvement over standard of care, in light of the fact that certain confounding factors may be viewed by the FDA as limiting the persuasiveness of the study results, a single successful phase 3 clinical trial may not be sufficient to provide the substantial evidence of effectiveness necessary to support regulatory approval, and therefore we may need more than one additional phase 3 clinical trial to secure regulatory approval;
- the approval policies or regulations of the FDA may significantly change in a manner rendering any future clinical data insufficient for approval; and
- the failure of prior clinical trials could result in more stringent requirements being imposed by regulatory bodies and advisory groups.

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

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

If we begin or resume the clinical development of any biologic product candidates, we do not have, and may never obtain, the regulatory approvals we need to market our product.

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

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

If we resume the development of any product candidates, the FDA may or may not grant an accelerated or “Priority Review” to any potential future BLA, if requested by us, and even if the FDA designates Priority Review for any product candidate, that designation would not assure FDA approval and may not even lead to a faster regulatory review or approval process.

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

Accordingly, we cannot assure you that any future BLA will be approved in a timely manner, or at all.

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

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

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

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

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

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

Risks Related to the Medical Device Components of the ELAD System or Any of Our Products

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

We are required to demonstrate and maintain compliance with applicable regulations for the manufacturing of combination biologic products, including specified parts of the QSR and European Medical Device Directives, or MDD, with

respect to any biological product candidates. Our third-party medical device manufacturers are required to demonstrate and maintain compliance with the QSR and MDD. The QSR and MDD are complex regulatory schemes that cover the methods and documentation of and for the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of the regulated products. Regulatory agencies enforce the QSR and MDD through periodic inspections. Prior to any potential approval of any such product in the U.S. and Europe, our manufacturing facility would be subject to a preapproval inspection to determine compliance with the applicable regulations, including cGMPs, parts of the QSR, the European drug cGMP regulations, and the MDD. In addition, our third-party medical device component manufacturers would be subject to a preapproval inspection to determine compliance with QSR and MDD requirements. Our failure, or the failure of our third-party manufacturers, to pass a preapproval inspection, or to take satisfactory and prompt corrective action in response to an adverse inspection, could prevent or significantly delay approval of any product.

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

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

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

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

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

The device components of the ELAD System must be reviewed as part of any BLA for ELAD. If the manufacturers of those components make modifications, discontinue supplying or are unable to supply sufficient quantities of such components during any potential clinical testing or after any approval, or if we elect to change a component, we would need to perform validation testing and obtain FDA and other regulatory approval prior to using the modified or replacement component. For example, one of our suppliers of a key component in our manufacturing process was having an issue meeting all of their customer orders for the component. If we were unable to obtain sufficient

quantities of the component on a timely basis, there could have been a delay in enrollment in our clinical trial or, following an approval, in the marketing of ELAD until additional supplies became available, or we would be required to validate an alternative component to use, which could delay any clinical trials or the marketing of a product, and increase our costs. If the FDA or any other regulatory body fails to approve use of those modified or replacement devices or if we were unable to validate a replacement component, we would not be able to initiate or complete clinical trials or, in the future, we might not be able to market or could have to suspend marketing in certain jurisdictions.

If we determine to resume the clinical development of ELAD, we may be unable to demonstrate that devices cleared for different uses may be safe and effective for use in the ELAD System.

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

Risks Related to the Cellular Products and Related Components

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

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

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

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

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

guarantee of success.

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

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

We have manufactured our biologic product and assembled the device component at our facility in San Diego, California. No other manufacturing or assembly facilities are currently available to us, and any additional manufacturing or assembly facilities that we might use would need to be qualified and approved by regulatory authorities prior to our use. Our facility and the equipment would be costly to replace and could require substantial lead-time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our research, development and manufacturing for some period of time. The inability to perform our manufacturing activities, combined with our limited inventory of reserve raw materials and manufactured supplies, could result in the delay of any potential future clinical trials.

We often rely on third parties for certain aspects of the manufacture of our clinical products and supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or if they encounter other manufacturing issues.

We would expect to use third parties for certain parts of our production process for any products under development. This would expose us to a number of risks, including the following:

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

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

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

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

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

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

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

Cellular therapy is a complex treatment with multiple variables that are not fully understood. For example, our VTL C3A cells, which were used in the ELAD cartridges produce hundreds of metabolites. Likewise, the plasma ultrafiltrate formed from blood, which has been treated by our VTL C3A cells in our ELAD cartridges, is a similarly complex material. The composition and stability of the treated blood can also be affected by the conditions of its generation in the ELAD System bedside unit, which could affect treatment outcomes. For instance, while most subjects treated with the ELAD System typically only required a single set of cartridges, some subjects required more than one set during their treatment period, which may have implications for efficacy and costs. While we believed that we had identified the key parameters of the ELAD System VTL C3A cartridges and set them in an appropriate range, it was possible that there were other variables that were important to safety and efficacy that were not anticipated. Likewise, the potential mechanism of action for the ELAD System remains unproven and may never be proven. The ELAD System's mechanism of action appears complex, may involve numerous pathways and we may not succeed in ever elucidating the exact role of any given pathway. Moreover, our research on mechanism of action was primarily based on laboratory studies, and needed correlation with in vivo studies and patient outcomes.

Risks Related to Doing Business Internationally

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

If we were to commercialize the ELAD System or any other product in countries where the business, economic and political climates are very different from those of the U.S., we may not be aware of some of these issues, and it may be difficult for a U.S. company to overcome these issues and ultimately become profitable. For instance, we completed our Chinese pivotal clinical trial in 2007 and submitted our data to the China Food and Drug Administration, or CFDA, showing a statistically significant improvement in transplant-free survival among the ELAD System-treated subjects compared with control subjects. However, this application has been neither approved nor rejected and the timing and nature of any potential decision is highly uncertain. 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 were to receive any marketing approval in foreign countries outside of the U.S. and Europe, we could create wholly-owned subsidiaries or work with a partner in those countries or in a region. These subsidiaries will need to build an effective sales, marketing, distribution, training and support staff and system, find an effective marketing partner or both. Any internal sales, marketing, training and support capabilities of the subsidiaries will need to be developed by these subsidiaries and will need to be built from scratch. The culture and accepted practices related to selling medical products in many foreign countries are unique, and it is possible that we will not be able to successfully penetrate these markets. We cannot guarantee that our approach to the U.S., European, Chinese or any other international market would be effective.

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

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

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

If we were to pursue foreign commercialization, these efforts may be through wholly-owned, foreign domiciled subsidiaries. Our efforts to expand internationally pose risks that could adversely affect our business. These risks include, among others, the effects of:

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

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

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

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

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

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

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

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

We have limited business insurance coverage internationally.

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

Ownership of our intellectual property may be claimed by others.

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

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

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

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

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

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

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

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

Risks Related to Our Capital Requirements and Finances

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

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $337.4 million through December 31, 2018. Based on our current employees, our known commitments, and our ongoing administrative costs to explore and pursue strategic options, we believe that our existing cash and cash equivalents of $13.3 million as of December 31, 2018 should be sufficient to meet our known liabilities and commitments as of December 31, 2018. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The timing and amount of our actual expenditures will be based on many factors, including, but not limited to, whether and when the Transaction closes, future research and development efforts if any, other strategic options that we may pursue, and any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned.

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

As a result of our decision to cease development of the ELAD System in the United States and Europe, our history of operating losses and the other factors discussed above, we believe there is substantial doubt about our ability to continue as a going concern for one year from the date of issuance of our consolidated financial statements for the year ended December 31, 2018.

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

In September 2015, and again in September 2018, we instituted across the board expense reductions to conserve capital, and we may, in the future, need to undertake additional workforce reductions or restructuring activities. As a result of the reduction in our workforce, we face an increased risk of employment litigation. We also need to effectively manage our operations and facilities. Following our recent workforce reduction in September 2018, it is possible that our infrastructure may be inadequate to support our future efforts and business strategy or to maintain operational, financial and management controls and reporting systems and procedures. If we cannot successfully manage our operations, we may be unsuccessful in executing our business strategy, including potential strategic options, including the Transaction.

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

We may need to raise substantial additional capital to:

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

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

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

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

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

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

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of those securities could result in substantial dilution for our current stockholders and the terms may include liquidation or other preferences that adversely affect the rights of our current stockholders. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings. The failure of the VTI-208 and VTL-308 clinical trials to meet their primary or secondary endpoints, in addition to general market conditions, may make it very difficult for us to seek and obtain further financing from the capital markets on favorable terms, or at all. There is no assurance that we will be able to obtain additional funding on acceptable terms or at all.

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

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

Risks Related to Being a Public Company

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

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

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

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of The Nasdaq Stock Market LLC and other applicable securities rules and regulations. Compliance with these rules and regulations increases our legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and increases demand on our systems and resources, and even more so after we are no longer an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight are required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. To assist us in complying with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our costs and expenses.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Common Stock

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

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

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

The market price of our common stock has been and is likely to continue to be highly volatile. Since our initial public offering in April 2014 at a price of $12.00 per share, the sale price of stock as reported on the The Nasdaq Global Market has ranged from $0.15 to $35.20, through February 28, 2019. Our announcement in 2015 that the VTI-208 clinical trial failed to meet its primary or secondary endpoints resulted in a significant decline in the market price of our common stock. Then again in September 2018, our announcement that the VTL-308 clinical trial failed to meet its primary or secondary endpoints resulted in a significant decline in the market price of our common stock. Following the announcement on the morning of September 12, 2018 that our VTL-308 clinical trial failed to meet its primary or secondary endpoints, the price of our common stock dropped $5.85 per share, or 93%, from $6.30 per share as of the close of business on September 11, 2018 to $0.45 per share as of the close of business on September 12, 2018. The closing price of our common stock was $0.24 on February 28, 2019. In addition, as with any public company, some investors hold a short position in our common stock. Such investors have published and distributed information about our company including on past and recent clinical trials. Activities by these investors may increase the volatility of the market price of our common stock, and may affect our ability to raise additional funds and to complete any potential future clinical trials or transactions.

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

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

In addition, an active and liquid market may not develop or persist, and you may not be able to sell your shares quickly or at a price that is higher than what you paid for them. These and other factors may make the price of our stock volatile and subject to unexpected fluctuations.

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

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

In May 2018, we filed a shelf registration statement on Form S-3, or the 2018 Shelf Registration Statement, which became effective in June 2018. The 2018 Shelf Registration Statement permits: (i) the offering, issuance and sale by us of up to a maximum aggregate offering price of $200.0 million of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination; (ii) sales of up to 2.5 million shares of common stock by certain selling stockholders; and (iii) the offering, issuance and sale by us of up to a maximum aggregate offering price of $60.0 million of our common stock that may be issued and sold under an “at-the-market” sales agreement, or ATM, with Cantor Fitzgerald & Co. At December 31, 2018, $200.0 million remains available for issuance and sale under the 2018 Shelf Registration Statement, $60.0 million of which may be offered, issued and sold under the ATM. However, we expect the amounts available under the shelf registration statement to be significantly limited to the extent our public float remains below $75.0 million, and our ability to use the ATM will likewise be limited or completely unavailable based on the requirements of the ATM. Additionally, funding is expected to be more difficult to secure due to our VTL-308 clinical trial not meeting its primary or secondary endpoints.

In addition, we have filed registration statements on Form S-8 registering a total of 9,634,695 shares of common stock subject to options or reserved for future issuance under our 2012 Stock Option Plan, 2014 Equity Incentive Plan and 2017 Inducement Equity Incentive Plan. Shares registered under these registration statements are available for sale in the public market subject to vesting arrangements, the exercise of such options and, in the case of our affiliates, the restrictions of Rule 144. As of December 31, 2018, options to purchase 6,183,266 shares of our common stock were exercisable.

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

Anti-takeover provisions in our amended and restated certificate of incorporation and our amended and restated bylaws as well as Delaware law, could discourage a takeover.

Our amended and restated certificate of incorporation, bylaws, 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 amended and restated certificate of

incorporation;

- require the approval of a supermajority (75% and majority of the minority, if applicable) vote of our outstanding shares of capital stock to approve the sale or liquidation of the company;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that directors may be removed only for cause by a supermajority (75%) vote of our outstanding shares of capital stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that in general the number of directors on our board may only be fixed from time to time by a supermajority (75%) vote of our directors then in office; and
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;

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

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

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

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We leased 44,000 square feet in San Diego in four different facilities at December 31, 2018. We have consolidated our operations in a single 19,000 square foot leased facility, the lease on which runs to June 2022. The three other leases for approximately 25,000 square feet expired in January 2019. Our remaining facility is adequate to meet our existing needs.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.
Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is listed in the The Nasdaq Global Market under the symbol "VTL".

Holders

As of February 15, 2019, there were approximately 51 holders of record of our common stock, which excludes stockholders whose shares were held in nominee or street name by brokers. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data.

The following table summarizes our selected consolidated financial data for the periods and as of the dates indicated. We have derived the consolidated statement of operations data for the years ended December 31, 2018, 2017 and 2016 and the consolidated balance sheet data as of December 31, 2018 and 2017 from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statement of operations data for the years ended December 31, 2015 and 2014 and the balance sheet data as of December 31, 2016, 2015 and 2014 are derived from our audited financial statements not included in this Annual Report on Form 10-K. This data should be read in conjunction with the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and with our audited consolidated financial statements and their related notes, which are included elsewhere in this Annual Report.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
Consolidated Statement of Operations Data:	(in thousands, except share and per share amounts)				
Operating expenses:					
Research and development	$24,825	$39,341	$30,046	$39,118	$39,479
General and administrative	13,585	13,314	11,220	12,139	10,863
Severance costs	2,395	—	—	863	—
Impairment loss	1,219	—	—	—	—
Total operating expenses	42,024	52,655	41,266	52,120	50,342
Loss from operations	(42,024)	(52,655)	(41,266)	(52,120)	(50,342)
Net loss	(41,475)	(52,078)	(40,969)	(52,023)	(47,667)
Net loss attributable to common stockholders	$(41,475)	$(52,078)	$(40,969)	$(52,023)	$(56,821)
Net loss per share attributable to common stockholders, basic and diluted	$(0.98)	$(1.31)	$(1.31)	$(2.07)	$(3.54)
Weighted-average common shares outstanding, basic and diluted (1)	42,369,245	39,859,009	31,387,579	25,152,948	16,054,452

(1) Please refer to Note 2, "Summary of Significant Accounting Policies," in the notes to the consolidated financial statements, for an explanation of the method used to calculate basic and diluted net loss per share attributable to common stockholders and the number of shares used in the computation of the per share amounts.

	As of December 31,				
	2018	2017	2016	2015	2014
Consolidated Balance Sheet Data:	(in thousands)				
Cash and cash equivalents	$13,324	$56,901	$59,991	$83,416	$102,238
Working capital	11,722	47,840	55,983	78,433	94,538
Total assets	14,978	60,384	64,026	89,081	108,082
Preferred stock	—	—	—	—	—
Additional paid-in-capital	349,771	345,915	302,185	285,098	248,305
Accumulated deficit	(337,428)	(295,953)	(243,825)	(202,856)	(150,833)
Total stockholders’ equity	12,427	50,044	58,446	82,325	97,563

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in "Risk Factors" included elsewhere in this Annual Report. As used in this report, unless the context suggests otherwise, "we," "us," our" or "the Company" refer to Vital Therapies, Inc. and its subsidiaries.

Overview

We are a biotherapeutic company that has been developing a cell-based therapy targeting the treatment of acute forms of liver failure. Our initial product candidate, the ELAD® System, or ELAD, is a human-cell-based, bio-artificial liver, which was being developed to improve rates of survival among patients with acute forms of liver failure. Since inception, we have devoted essentially all of our efforts to product development, clinical testing and pilot manufacturing and have not recognized revenues from our planned principal operations.

In September 2018, we reported top-line data from a phase 3 clinical trial of ELAD, VTL-308, in 151 subjects with severe alcoholic hepatitis. Although there was a numerical improvement in survival in the ELAD-treated group between three months and one year following randomization, the study failed to meet the primary endpoint of a significant improvement in overall survival through at least ninety-one days. The secondary endpoint of the proportion of survivors at study day ninety-one also showed no statistically significant difference between the groups. Considering these results, we do not believe the ELAD System can be approved in the United States or the European Union without additional clinical trials, if ever, and that such clinical trials would require substantial capital and time to complete. Consequently, we have ceased any further development of the ELAD System for the United States and Europe, substantially reduced our workforce, discontinued most of our supply and service agreements, and shifted our strategic focus to identifying and exploring strategic alternatives including a merger, or an acquisition or sale of assets.

In January 2019, we entered into an exchange agreement with, Immunic AG, or Immunic, and all of the current shareholders of Immunic, or the Exchange Agreement, pursuant to which all of the Immunic shareholders will exchange all of their Immunic shares for shares of our common stock, with the result of Immunic becoming a wholly-owned subsidiary of the Company, which is referred to as the Transaction. In addition, all Immunic shareholders and certain of Immunic's executive officers and directors, entered agreement, with Immunic, pursuant to which they agreed, subject to the terms and conditions of such agreement, to invest prior to the consummation of the Transaction an aggregate amount of approximately €26.7 million, or approximately $30.5 million based on the exchange rate at December 31, 2018 in Immunic. Following the closing of the Transaction, the company will focus on advancing Immunic's pipeline of treatments for chronic inflammatory and autoimmune diseases. The issuance of the company common stock under the Exchange Agreement and certain related transactions must be approved by the company's stockholders. There can be no assurance that such transactions will be approved by the stockholders or that the Transaction will be consummated.

Further, our business, operating results, financial condition and prospects are subject to significant risks and uncertainties. Even if we complete the Transaction, we will have no commercial products or products in later stage development and it may be difficult to secure additional funding in light of the risks and circumstances outlined above. In addition to the Transaction and as noted above, we are exploring selling assets, including those relating to ELAD, and options to reduce the amount of space we lease, in order to increase our cash balance and reduce expenses. If the proposed transaction with Immunic is not completed and we are unable to seek an appropriate alternate use for our remaining assets, we may decide to pursue a dissolution and liquidation of the company. In such event, the amount of cash available for distribution to stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities. There can be no assurance any transaction will result from our evaluation of strategic alternatives.

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $337.4 million through December 31, 2018. In consideration of our decision to cease the further development of ELAD in the United States and Europe, we have made reductions in operating expenses as we pursue strategic

alternatives for the Company. As a result, we believe that our existing cash and cash equivalents of $13.3 million as of December 31, 2018 would be sufficient to meet our known liabilities and commitments at such date; however, we expect our resource requirements to change materially to the extent we enter into and complete any strategic transactions, such as and including the Exchange Agreement with Immunic. We have based our estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The timing and amount of our actual expenditures will be based on many factors, including, but not limited to, the strategic options that we pursue, any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned, or any future research and development efforts we decide to pursue.

Financial Operations Overview

Research and Development Expenses

Research and development expenses have principally related to the development of the ELAD System and are expensed as incurred. Our research and development expenses consisted primarily of:

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

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

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

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

A change in any of these variables can result in a significant change in the costs and timing associated with clinical development. For example, if we were to conduct an additional clinical trial, we would be required to expend significant additional financial resources and time on the completion of the clinical development of the ELAD System. However, based on our current plan, and in light of our VTL-308 clinical trial results, we expect significantly reduced research and development costs over at least the next several quarters.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, information technology, marketing and legal functions. Other general and administrative expenses include but are not limited to related facility costs, stock-based compensation, professional fees for legal, consulting, accounting and tax services and insurance costs. Based on our current plans and the recent reduction in our workforce, we expect significantly reduced general and administrative costs at least over the next several quarters.

Severance Costs

As a result of the failure of the Company’s clinical trial, the Company completed a staff reduction plan in order to reduce operating expenses and to conserve cash. The plan reduced our workforce by approximately 85%. The staff reduction was completed in September 2018. We also expect to incur costs related to the termination of the executive officers, pursuant to severance and change of control agreements previously entered into with such officers.

Impairment Loss

We evaluate long-lived assets, such as property and equipment, for impairment whenever events or changes in

circumstances indicate that the carrying amount of the assets may not be recoverable. If a long-lived asset is considered to be impaired, the impairment to be recognized is the amount by which the carrying amount of the asset exceeds the fair value of the asset or asset group. The resulting impairment charge is included as a loss from operations in the condensed consolidated statements of operations. We recorded such an impairment loss in conjunction with the termination of our VTL-308 clinical trial in the third quarter of 2018.

Other Income

Interest Income

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

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the U.S., or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an on-going basis, management makes its best estimate of the ultimate outcome for these items based on historical trends and other information available when the financial statements are prepared. Changes in estimates are typically recognized in the period when new information regarding estimates becomes available to management. Actual results could differ from those estimates.

Our significant accounting policies are described in more detail in Note 2, "Summary of Significant Accounting Policies," in the notes to the consolidated financial statements. However, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Clinical Trial Accruals

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

Stock-Based Compensation

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

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

The fair value of options granted to consultants is estimated using the BSM option pricing model and is re-measured at each reporting date with changes in fair value prior to vesting recognized as expense in the consolidated statements of operations across the applicable vesting period. Beginning in 2019, we will measure and recognize compensation expense for consultants based on the estimated fair value at the grant date. For performance-based stock options to consultants, we record

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stock-based compensation expense only when the performance-based milestones are achieved unless there is a performance commitment.

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

Income Taxes

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

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

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

Results of Operations

Comparison of Fiscal Years Ended December 31, 2018 and 2017

The following table summarizes our operating expenses for the years ended December 31, 2018 and 2017 (dollars in thousands):

	Year Ended December 31,		Change	
	2018	2017	$	%
Operating expenses:				
Research and development	$24,825	$39,341	$(14,516)	(37)%
General and administrative	13,585	13,314	271	2 %
Severance Costs	2,395	—	2,395	100 %
Impairment Loss	1,219	—	1,219	100 %
Total operating expenses	$42,024	$52,655	$(10,631)	(20)%

The $14.5 million decrease in research and development expense during the year ended December 31, 2018 as compared to the year ended December 31, 2017 principally reflects a $7.2 million decrease in costs related to the VTL-308 clinical trial due to completion of enrollment in the first quarter of 2018. There were 97 subjects enrolled in the VTL-308 clinical trial in the twelve months ended December 31, 2017, while there were 19 subjects enrolled in the twelve months ended December 31, 2018 due to the completion of enrollment. In addition, upon the release of results from the VTL-308 clinical trial in September 2018, we ceased substantially all development efforts related to the ELAD System. As a result, research and development expense also reflects a $1.7 million reduction in salaries and wages, $1.4 million reduction in estimated incentive compensation costs and a $1.3 million net reversal of stock-based compensation in the 2018 period, all reflecting that our VTL-308 clinical trial did not successfully reach its primary or secondary survival endpoints and a related reduction in staff. Manufacturing supplies, travel and entertainment, outside marketing efforts and consulting also all decreased primarily as a result of the completion of the VTL-308 clinical trial by $918,000, $697,000, $498,000 and $225,000, respectively. Depreciation expense also decreased by $279,000 in 2018 as compared to 2017, in part due to the impairment loss recorded in 2018.

The $0.3 million increase in general and administrative expense during the year ended December 31, 2018 as compared to the year ended December 31, 2017 reflects an increase of $786,000 in outside services, primarily due to strategic marketing efforts in anticipation of the potential commercialization of ELAD, and increases in patent and other legal and securities-related costs of $882,000 including costs for the filing of a shelf registration statement on Form S-3 in the second quarter of 2018 and the subsequent write-off of deferred offering costs as a result of our inability to complete a follow-on offering considering the VTL-308 clinical trial results. These increased costs were largely offset by a $1.5 million decrease in compensation-related costs driven by a $862,000 reduction in stock-based compensation for the reversal of previously recognized expense related to performance-based stock options and a $502,000 reduction in estimated incentive compensation costs both reflecting that our VTL-308 clinical trial did not successfully reach its primary or secondary survival endpoints.

As previously reported, we ceased substantially all of our development efforts related to the ELAD System in September 2018. This resulted in a substantial change in the expected use of our long-lived assets and a significant decrease in the benefits expected to be realized from these assets. Accordingly, we recognized an impairment charge of $1.2 million on our property and equipment reflecting the difference in the carrying value of such property and equipment and its estimated fair value, and severance costs of $2.4 million for the related reduction in staff, in the consolidated statement of operations for the year ended December 31, 2018.

In conjunction with our review of strategic alternatives and our decision to cease the further development of ELAD, we have significantly reduced our projected monthly cash usage entering into 2019. In addition, we are exploring options to reduce the amount of space we lease to further reduce expenses. The reduction in staff in September 2018 and the cancellation of stock options in January 2019 has also reduced and should reduce reported stock-based compensation in 2019. However, we expect our expenditures will change materially to the extent we enter into any strategic transactions, such as the Transaction with Immunic. For example, the Transaction would be expected to trigger the accelerated vesting of restricted stock unit awards and payments to our officers under severance and control agreements increasing costs. The timing and amount of our actual expenditures will be based on many factors, including, but not limited to, future research and development efforts including such costs incurred by Immunic assuming completion of the Transaction, and any other strategic options that we pursue.

Comparison of Fiscal Years Ended December 31, 2017 and 2016

The following table summarizes our operating expenses for the years ended December 31, 2017 and 2016 (dollars in thousands):

	Year Ended December 31,		Change	
	2017	2016	$	%
Operating expenses:				
Research and development	$39,341	$30,046	$9,295	31%
General and administrative	13,314	11,220	2,094	19%
Total operating expenses	$52,655	$41,266	$11,389	28%

The $9.3 million increase in research and development expense during the year ended December 31, 2017 as compared to the year ended December 31, 2016 principally reflects an $8.0 million increase in costs related to the VTL-308 and prior clinical trials, primarily in higher costs for subjects, sites, manufacturing, enrollment support activities and consulting. As enrollment started in the second quarter of 2016, 35 subjects were enrolled in the VTI-308 clinical trial in the year ended December 31, 2016, while 97 subjects were enrolled during the year ended December 31, 2017. Costs also increased by $1.2

million for activities to support a potential biologics license application, or BLA, submission in the future.

The $2.1 million increase in general and administrative expense during the year ended December 31, 2017 as compared to the year ended December 31, 2016 was largely the result of a $1.9 million increase in compensation-related costs. In December 2017, our chief executive officer transitioned from being an employee to a consultant. As a result of the related transition and consulting agreements, we recorded $525,000 in severance costs and $674,000 in stock-based compensation related to stock option modifications. In total, stock-based compensation increased by $1.2 million in 2017 as compared to 2016 principally due to the stock option modifications and an increase in the number of options outstanding.

Liquidity and Capital Resources

Overview

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $337.4 million through December 31, 2018. In consideration of our decision to cease the further development of ELAD in the United States and Europe, we have made reductions in operating expenses as we pursue strategic alternatives for the Company. As a result, we believe that our existing cash and cash equivalents of $13.3 million as of December 31, 2018 would be sufficient to meet our known liabilities and commitments at such date; however, we expect our resource requirements to change materially to the extent we enter into and complete any strategic transactions. The timing and amount of our actual expenditures will be based on many factors, including, but not limited to, the strategic options that we pursue, any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned, or any future research and development efforts we decide to pursue.

We currently have an effective shelf registration statement on Form S-3 on file with the Securities and Exchange Commission, or SEC, which expires June 2021. The shelf registration statement currently permits the offering, issuance and sale by us of up to an aggregate offering price of $200.0 million of common stock, preferred stock, warrants, debt securities or units in one or more offerings and in any combination, of which $60.0 million may be offered, issued and sold under an "at-the-market" sales agreement with Cantor Fitzgerald & Co. However, amounts available under the shelf registration statement are significantly limited as our public float was below $75.0 million as measured on December 31, 2018. Additional funding is not likely at this time due to our past clinical trials not meeting their primary or secondary survival endpoints.

Should the Transaction with Immunic be completed, as a condition to closing, the Immunic shareholders and certain executive officers and directors are expected to invest an aggregate amount of approximately €26.7 million, or approximately $30.5 million based on the exchange rate at December 31, 2018, in Immunic prior to the consummation of the Transaction. Following the closing of the Transaction, such funds would be available to support the development of Immunic’s current pipeline of treatments for chronic inflammatory and autoimmune diseases; however, there can be no assurance that such transactions will receive the necessary approvals from our stockholders or that the Transaction will be consummated.

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

We believe that due to the factors described above, there is substantial doubt about our ability to continue as a going concern for one year from the date of the issuance of our consolidated financial statements for the twelve months ended December 31, 2018.

Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with an intent to maximize liquidity and preserve capital. As of December 31, 2018, such funds were held in cash and money market funds.

Cash Flows

The following table shows a summary of our cash flows for each of the years ended December 31, 2018, 2017, and 2016 (in thousands):

	2018	2017	2016
Cash (used in) provided by:			
Operating activities	$(43,165)	$(40,397)	$(35,774)
Investing activities	(415)	(678)	(21)
Financing activities	4	37,984	12,374

Net cash used in operating activities

During the year ended December 31, 2018, operating activities used $43.2 million of cash. The use of cash primarily related to our net loss of $41.5 million adjusted for non-cash charges of $3.7 million related to stock-based compensation, $1.2 million in impairment losses, and $727,000 related to depreciation and amortization; and by a $7.6 million change in our operating assets and liabilities. Changes in our operating assets and liabilities during the year ended December 31, 2018 consisted primarily of a decrease of $7.7 million in accrued expenses and accounts payable slightly offset by a decrease of $165,000 in prepaid expenses and other current assets. The decrease in accrued expenses and accounts payable was primarily attributable to the decrease in amounts due for our VTL-308 clinical trial, and for accrued compensation due to the reduction in staff and no incentive compensation being accrued for 2018.

During the year ended December 31, 2017, operating activities used $40.4 million of cash. The use of cash primarily related to our net loss of $52.1 million adjusted for non-cash charges of $5.5 million related to stock-based compensation and $998,000 related to depreciation and amortization, partially offset by a $4.9 million change in our operating assets and liabilities. Changes in our operating assets and liabilities during the year ended December 31, 2017 consisted primarily of an increase of $4.8 million in accrued expenses and accounts payable and a decrease of $165,000 in prepaid expenses and other current assets. The increase in accrued expenses and accounts payable was primarily attributable to the increase in amounts due for our VTL-308 clinical trial.

During the year ended December 31, 2016, operating activities used $35.8 million of cash. The use of cash primarily related to our net loss of $41.0 million adjusted for non-cash charges of $4.7 million related to stock-based compensation and $1.8 million related to depreciation and amortization, partially offset by a $1.4 million change in our operating assets and liabilities. Changes in our operating assets and liabilities during the year ended December 31, 2016 consisted primarily of a decrease of $1.0 million in accrued expenses and accounts payable and an increase of $232,000 in prepaid expenses and other current assets. The decrease in accrued expenses and accounts payable was primarily attributable to the reduction in amounts due to clinical sites for our VTI-208, VTI-210 and VTI-212 clinical trials, partially offset by increases in amounts due for our VTL-308 clinical trial.

Net cash used in investing activities

During the year ended December 31, 2018, net investing activities used $415,000 of cash, primarily due to capital expenditures of $597,000 for purchases of equipment for manufacturing and research and development offset by proceeds of $182,000 received for the sale of research and development equipment due to the VTL-308 clinical trial.

During the year ended December 31, 2017, net investing activities used $678,000 of cash, primarily due to capital expenditures of $685,000 for facility improvements and purchases of equipment for manufacturing and research and development.

During the year ended December 31, 2016, net investing activities used $21,000 of cash, including capital expenditures of $556,000 principally for purchases of equipment for manufacturing and clinical operations, partially offset by $533,000 from a decrease in restricted cash requirements relating to our clinical trials and lease commitments.

Net cash provided by financing activities

During the year ended December 31, 2018, financing activities provided $4,000 of cash related to net cash proceeds from the exercise and sale of stock options.

During the year ended December 31, 2017, financing activities provided $38.0 million of cash related to net cash proceeds after underwriters' commissions and cash payments for offering costs from a follow-on offering completed in March 2017 and ATM offerings completed in 2017.

During the year ended December 31, 2016, financing activities provided $12.4 million of cash, which included net proceeds of $12.4 million after underwriters' commissions and offering costs from ATM offerings and a private placement completed in the year ended December 31, 2016.

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

- the timing and structure of any strategic options and transactions, if any;
- the cost, timing and outcome of any future litigation costs;
- personnel-related expenses, including salaries, benefits, stock-based compensation expense and other compensation expenses related to retention and termination of personnel;
- the scope, progress, results and costs of research and development and any future clinical trials;
- the cost and timing of future regulatory submissions;
- the cost and timing of developing and validating the manufacturing processes for any potential product candidates;
- the cost and timing of any commercialization activities, including reimbursement, marketing, sales and distribution costs;
- our ability to establish new collaborations, licensing or other arrangements and the financial terms of such agreements;
- the number and characteristics of any future product candidates we pursue (if any);
- the costs involved with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount from the sales of, or royalties on any future product candidates, if any.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of stock offerings, debt financings, strategic alliances, collaborations and licensing arrangements. We do not expect to achieve revenue from product sales prior to the use of the net proceeds from our public and private offerings to date. We do not have any committed external source of funds. Additional funds may not be available on acceptable terms, if at all. To the extent that we raise additional capital through the sale of equity securities or complete the Transaction with Immunic, the ownership interest of our stockholders will be diluted and it may be on terms that are not favorable to us or our stockholders. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt or other terms that are not favorable to us or our stockholders. If we raise additional funds through collaborations and licensing arrangements with third parties, we would expect to relinquish substantial rights to our technologies or our future products, or grant licenses on terms that may not be favorable to us. If we were to complete a merger, we may relinquish all control over the organization and could experience detrimental tax effects. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets. Any of these factors could harm our operating results.

Off-Balance Sheet Arrangements

Through December 31, 2018, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

Contractual Obligations

Some of our most significant clinical trial expenditures have been to investigative sites and to CROs. These agreements are cancellable by either party at any time upon written notice and do not have any cancellation penalties, but do obligate us to reimburse the providers for any time or costs incurred through the date of termination and to close out clinical sites. These items are not included in the table below. We lease office and manufacturing space in San Diego, California. The following table summarizes our contractual obligations at December 31, 2018 and the effect such obligations are expected to have on our cash flow in future periods:

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	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
	(In thousands)				
Operating lease obligations	$1,511	$ 469	$ 821	$ 221	$ —

As of December 31, 2018, we had no material purchase commitments. During the years ended December 31, 2018, 2017 and 2016, we purchased $659,000, $1.1 million and $943,000, respectively, of cell culture media from a supplier. During the years ended December 31, 2018, 2017 and 2016, we purchased $143,000, $228,000 and $139,000, respectively, of cartridges used in our clinical trial and our manufacturing process from another supplier. In the course of normal business operations, we may also enter into agreements with contract service providers and others. We can elect to discontinue the work under these contracts and purchase orders with notice.

Recent Accounting Pronouncements

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

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

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

In June 2018, the FASB issued ASU No. 2018-07, "Improvements to Non-Employee Share-Based Payment Accounting," or ASU 2018-07. ASU 2018-07, which simplifies the accounting for non-employee share-based payment transactions, specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, and early adoption is permitted. We currently expect to adopt ASU 2018-07 in the first quarter of 2019. We do not expect the adoption of this standard to have a material impact on our consolidated financial statements.

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

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other companies.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Sensitivity

We had cash and cash equivalents of $13.3 million at December 31, 2018, which was held for working capital purposes. We do not enter into investments for trading or speculative purposes. We do not believe that we have any material exposure to changes in the fair value of these investments as a result of changes in interest rates due to their short-term nature. Declines or increases in interest rates, however, will reduce or increase future investment income, respectively, to the extent we have funds available for investment.

Foreign Currency Exchange Risk

We have entered and may continue to enter into international agreements, primarily related to our clinical studies. Accordingly, we have an exposure to foreign currency exchange rates. To date, we have not entered into, and do not have any current plans to enter into, any foreign currency hedging transactions or derivative financial transactions. We expect our transactions outside of the U.S. in the near-term will primarily entail payments for clinical trials, and for vendors and consultants supporting those trials within Europe. Our exposure to foreign currency risk will fluctuate in future periods as our clinical trial activity in Europe changes. We do not currently maintain any significant amount of assets outside of the U.S.

The functional currencies of our foreign subsidiaries are the local currencies. Accordingly, the effects of exchange rate fluctuations on the net assets of these operations are accounted for as translation gains or losses in accumulated other comprehensive income within stockholders' equity. Our foreign subsidiaries are currently inactive and, accordingly, a change of 10% in such foreign currency exchange rates would not have a material impact on their financial position or results of operations.

Effects of Inflation

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements required pursuant to this item are included in Part IV, Item 15 of this Annual Report, and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Management, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. The term “disclosure controls and procedures,” as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance (a) transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, (b) our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (c) regarding the prevention or timely detection of the unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2018, our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). Based on this evaluation, our management concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management’s report in this annual report.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth the names, ages and positions of our executive officers and directors as of February 28, 2019:

Name	Age	Position
Executive Officers:		
Duane D. Nash, M.D., J.D.	48	Director, Chief Executive Officer and President
Robert A. Ashley, M.A.	61	Executive Vice President and Chief Scientific Officer
Michael V. Swanson, M.B.A.	64	Executive Vice President and Chief Financial Officer
John M. Dunn, J.D.	67	General Counsel and Secretary
Non-Employee Directors:		
Faheem Hasnain [(1)(2)(3)]	60	Chairman
Cheryl L. Cohen[(1)(2)(3)]	53	Director
Lowell E. Sears, M.B.A.[(1)(2)(3)]	68	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of Nominating and Governance Committee.

Executive Officers

Duane D. Nash, M.D., J.D. has served as a director and our chief executive officer since January 2019 and as our President since March 2016. Dr. Nash joined Vital Therapies, Inc. in 2012, where he has held various leadership roles, including Medical Director, Executive Vice President, Chief Business Officer and President. Prior to joining Vital Therapies, Dr. Nash held various positions at Wedbush PacGrow Life Sciences, an investment bank, where he was employed from March 2009 to March 2012, serving most recently as Senior Vice President in Equity Research. Before that, he was a research analyst at Pacific Growth Equities, an investment bank, from April 2008 through March 2009, which was subsequently acquired by Wedbush Securities, Inc. Dr. Nash also practiced as an attorney from November 2002 to February 2008, most recently at the law firm of Davis Polk, where he focused on intellectual property litigation and corporate matters. Dr. Nash served on the board of directors of Aerpio Pharmaceuticals, Inc. (Nasdaq: ARPO), from 2012 to 2017, and Akebia Therapeutics (Nasdaq: AKBA) from 2013 to 2018. Dr. Nash earned a B.A. in biology from Williams College, an M.D. from Dartmouth Medical School, a J.D. from the University of California, Berkeley, and a M.B.A. from the University of Oxford. Dr. Nash completed his internship in general surgery at the University of California at San Francisco.

Robert A. Ashley, M.A. has served as our Executive Vice President and Chief Scientific Officer since November 2018, having previously served as our Executive Vice President and Chief Technical Officer since September 2013. Between May 2008 and September 2013 he served as our Vice President and Chief Operating Officer. Mr. Ashley's career in the pharmaceutical industry extends more than 30 years. He was formerly Chairman, President and Chief Executive Officer of AmpliMed Corporation, a privately-held cancer drug development company, from January 2004 to March 2007, and Senior Vice President of Commercial Development at CollaGenex Pharmaceuticals, Inc., a publicly-held pharmaceutical company, from September 1994 to December 2003. Prior to that he held positions of increasing responsibility at Bristol-Myers Squibb from January 1989 to September 1994, and with Amersham International from 1979 to 1989. He earned a Master's Degree in Biochemistry from Oxford University. Mr. Ashley is the inventor of several issued and pending patents, as well as the author of several scientific papers. He serves on the Board of Directors of Rowpar Pharmaceuticals, a privately-held manufacturer of proprietary dental pharmaceuticals.

Michael V. Swanson, M.B.A. joined us in August 2013 as our Chief Financial Officer and has also served as our Executive Vice President since March 2016. Mr. Swanson has over 25 years of experience in senior financial positions in both public and private life sciences companies. Mr. Swanson was Chief Financial Officer of Amira Pharmaceuticals, Inc., a pharmaceutical company focused on the discovery and early development of drugs to treat inflammatory and fibrotic diseases, from May 2008 until the company was acquired in September 2011, and of Panmira Pharmaceuticals, LLC, a spin out from Amira from September to December 2011. From January 2012 to October 2015, Mr. Swanson provided financial consulting services to development stage companies. From July 2000 to April 2008, Mr. Swanson served in senior finance positions including Senior Vice President, Finance and Chief Financial Officer at Prometheus Laboratories Inc., a specialty pharmaceutical company marketing and selling pharmaceutical products and diagnostic testing services for gastrointestinal diseases and disorders. Previously, Mr. Swanson was Senior Vice President and Chief Financial Officer of Advanced Tissue Sciences, Inc., a publicly-traded biomedical company, where he served in senior financial positions for over ten years. Mr. Swanson also served as Director of Finance of the Fisher Scientific Group, Inc., a health and scientific technology company, and its parent, The Henley Group, Inc., a widely diversified holding company. Mr. Swanson began his career working approximately nine years with the public accounting firm of Deloitte Haskins & Sells, now Deloitte LLP.
Mr. Swanson earned a B.S. in business administration from the California Polytechnic State University at San Luis Obispo and an M.B.A. from the University of Southern California. He is also a Certified Public Accountant (inactive).
John M. Dunn, J.D. has served as our General Counsel since November 2014 and as our Secretary since February 2015. Mr. Dunn has over 25 years of national law firm and in-house general counsel experience. Mr. Dunn was Senior Vice President Legal and Compliance, General Counsel and Secretary of IDEC Pharmaceuticals from 2002 until its merger with Biogen in late 2003. From 2004 to 2012, Mr. Dunn served as an Executive Vice President at Biogen Idec where he was in charge of Biogen Idec’s internal corporate venture fund and Innovation Incubator. More recently, Mr. Dunn was providing legal and corporate development advisory services to emerging life science companies. Previously, Mr. Dunn was a partner for 16 years in the Corporate, Securities and Technology Group at the Pillsbury Winthrop law firm where his practice focused on the healthcare industry. Mr. Dunn earned a B.S. in finance and his J.D. from the University of Wyoming. He serves as an advisor to TVM Capital, a life science venture capital firm, and is a member of the board of directors of Acer Therapeutics, Inc., a publicly-traded specialty orphan pharmaceutical company.

Board of Directors

Duane D. Nash. Please see biographical information above in the section entitled "Executive Officers."
Faheem Hasnain has served on our board of directors since August 2016. Mr. Hasnain is currently Executive Chairman since August 2018 and served as Chairman and Chief Executive Officer from October 2015 through July 2018 at Gossamer Bio, Inc. Gossamer Bio is a publicly-traded company focused on the discovery and development of novel and differentiated therapeutic products to address unmet need amongst various targeted patient populations. Previously, Mr. Hasnain served as the Chief Executive Officer, President, and a director at Receptos, Inc. from November 2010 to August 2015. Prior to joining Receptos, Inc., Mr. Hasnain was the President and Chief Executive Officer and a director of Facet Biotech Corporation, a biology-driven antibody company with a focus in multiple sclerosis and oncology. He held that position from December 2008 until the company’s acquisition by Abbott Laboratories in April 2010. Previously, Mr. Hasnain was President, Chief Executive Officer and a director of PDL BioPharma, Inc. from October 2008 until Facet Biotech was spun off from PDL BioPharma in December 2008. From October 2004 to September 2008, Mr. Hasnain was at Biogen Inc., most recently as Executive Vice President in charge of the oncology/rheumatology strategic business unit. Prior to Biogen, Mr. Hasnain held roles with Bristol Myers Squibb, where he was President of the Oncology Therapeutics Network, and for 14 years at GlaxoSmithKline and its predecessor organizations. He serves as Chairman of the board of directors of Sente, Inc. and Tocagen Inc., and has served as a member of the board of directors of Kura Oncology, Inc. He previously served as a member of the board of directors of Ambit Biosciences Corporation, Aragon Pharmaceuticals, Pernix Sleep, Inc., Seragon Pharmaceuticals, Somaxon Pharmaceuticals, Inc. and Tercica, Inc. Mr. Hasnain received a B.H.K. and B.Ed. from the University of Windsor Ontario in Canada.

We believe that Mr. Hasnain is qualified to serve on our board of directors based on his extensive operational and leadership experience in biotechnology and pharmaceutical companies and as a director of publicly-traded companies. Cheryl L. Cohen has served on our board of directors since July 2015. Ms. Cohen served as chief commercial officer of Medivation, Inc., a publicly-traded bio-pharmaceutical company, from September 2011 until July 2014. Ms. Cohen currently serves as president of CLC Consulting, a pharmaceutical and biotechnology consulting firm specializing in new product start-up and commercialization, where she also served as president from September 2008 until September 2011. From November 2007 to September 2008, she served as the vice president, strategic commercial group, of Health Care Systems, Inc., a Johnson & Johnson company, and from October 1998 to November 2007, she worked at Janssen Biotech, Inc. (formerly Centocor

Biotech, Inc.), a Johnson & Johnson company, in a variety of senior sales roles including vice president, rheumatology franchise. Ms. Cohen currently serves on the board of Novus Therapeutics, Inc. (reverse merger of Tokai Pharmaceuticals, Inc.,) a publicly-traded pharmaceutical company focused on the acquisition, development, and commercialization of ear, nose, and throat products. In addition, she currently serves on the board of Aerpio Pharmaceuticals, which is a biopharmaceutical company focused on advancing first-in class treatments for ocular disease. Ms. Cohen served on the board of Protein Sciences Corporation, a privately held bio-pharmaceutical company specializing in vaccine development from October 2014 to August 2017, and she served on the board of Cytrx Corporation, a publicly traded bio-pharmaceutical company specializing in oncology, from June 2015 through October 2016. Ms. Cohen began her career at Solvay Pharmaceuticals in a variety of sales positions. Ms. Cohen received her B.A. from Saint Joseph College.

We believe that Ms. Cohen is qualified to serve on our board of directors based on her experience as an executive officer and director of private and publicly-traded companies, including companies in the pharmaceutical and bio-pharmaceutical industries.

Lowell E. Sears, M.B.A. has served on our board of directors since May 2013. Mr. Sears is the Chairman and Chief Executive Officer of Sears Capital Management, a venture investment and portfolio management firm specializing in life sciences. From February 2012 to January 2017, he served on the board of directors of Cellerant Therapeutics, Inc., a clinical stage biotechnology company focused on the regulation of the hematopoietic, or blood-forming, system. From September 2005 to March 2017, Mr. Sears has also served on the board of directors of SymBio Pharmaceuticals, KK, Ltd., a biotechnology company that is engaged in identifying and developing therapeutics for the treatment of leukemia, multiple myeloma and lymphoma. He has served on the board of directors of SiteOne Therapeutics, Inc., a privately-held company developing small molecular pain therapies, and has been Chairman of the Board since September 2014. He has also served on the board of directors of Halcyon Medical, a cardiovascular device company, since April 2014. From 1986 until 1994, Mr. Sears was a part of the senior management team of Amgen, Inc., a developer and manufacturer of therapeutics targeting cancers, kidney ailments, inflammatory disorders, and metabolic diseases, where he was Chief Financial Officer as well as the Senior Vice President responsible for the Asia Pacific Region. Prior to joining Amgen, Mr. Sears held senior planning and financial positions with Atlantic Richfield Company, an oil company from 1976 until 1986, including Chief Financial Officer for its Ventures Division. He earned a B.A. in economics from Claremont McKenna College and an M.B.A. from the Stanford University Graduate School of Business.

We believe that Mr. Sears is qualified to serve on our board of directors based on his experience as a senior manager and director of private and publicly-traded companies, including several in the life sciences industry.

Family Relationships

There are no family relationships among any of our directors and executive officers.

Board Composition

Our board of directors is currently composed of four members. Three of the four directors that comprise our board of directors are independent within the meaning of the independent director guidelines of the Nasdaq Stock Market. Please see the section entitled “Director Independence” in Item 13 below for further information. Our certificate of incorporation and bylaws currently in effect provide that the number of directors shall be at least one and will be fixed from time to time by resolution of our board of directors.

Our board of directors is divided into three classes of directors. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2021 for the Class I directors, 2019 for the Class II directors and 2020 for the Class III directors.

The Class I director is Dr. Nash.

The Class II director is Mr. Hasnain.

The Class III directors are Ms. Cohen and Mr. Sears.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our board of directors or a change in control.

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Board Leadership Structure and Lead Director

Our board of directors is currently chaired by Mr. Hasnain.

Our board of directors believes that the Company and its stockholders are currently best served by having Mr. Hasnain serve as Chairman of the Board. As Chairman, Mr. Hasnain promotes unified leadership and direction for our board and management and provides the critical leadership necessary for carrying out our strategic initiatives. Mr. Hasnain, together with our board's committee system and substantial majority of independent directors, allows our board to maintain effective oversight of our business operations, including independent oversight of our financial statements, executive compensation, selection of director candidates, and corporate governance programs. We believe our current board leadership structure enhances the board's ability to effectively carry out its roles and responsibilities on behalf of our stockholders.

Audit Committee

Our board of directors has a separately-designated standing audit committee, which operates pursuant to a charter. Our audit committee members currently consist of Messrs. Sears and Hasnain and Mrs. Cohen. Mr. Sears serves as the chairman. Our board of directors has determined that Mr. Sears qualifies as an audit committee financial expert within the meaning of the rules and regulations of the Securities and Exchange Commission, or SEC, and is independent under Rule 10A-3 of the Exchange Act and the current rules of the Nasdaq Stock Market and financially literate under the rules of the SEC and Nasdaq Stock Market.

The audit committee has (1) reviewed and discussed the audited financial statements with management; (2) discussed with the independent auditors the matters required by Public Company Accounting Oversight Board, or PCAOB, Auditing Standard No. 16, Communications with Audit Committees; (3) received written disclosures and the letter from the independent accountants required by applicable requirements of the PCAOB regarding the independent accountant's communications with the audit committee concerning independence and has discussed their independence with the independent accountants; and (4) recommended to the board of directors that the audited financial statements be included in the annual report on Form 10-K for the last fiscal year.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership and changes of ownership on Forms 3, 4 and 5 with the SEC. Such directors, executive officers and 10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of the copies of such forms we have received and written representations from certain reporting persons that they filed all required reports, we believe that all of our officers, directors and greater than 10% stockholders complied with all Section 16(a) filing requirements applicable to them with respect to transactions during 2018.

Code of Business Conduct and Ethics

Our board of directors has adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code of business conduct and ethics is available on the corporate governance section of our website, which is located at http://ir.vitaltherapies.com/corporate-governance.cfm. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website.

Item 11. Executive Compensation.

Our named executive officers for the year ended December 31, 2018, which consist of our principal executive officer and our two other most highly compensated executive officers, are Russel J. Cox, our Chief Executive Officer from January 3, 2018 until January 25, 2019, Duane D. Nash, M.D., J.D., our Chief Executive Officer since January 26, 2019 and our President, and Robert A. Ashley, our Executive Vice President and Chief Scientific Officer.

Name and Principal Position	Year	Salary ($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)[3]	Total ($)
Russell J. Cox	2018	572,626	7,080,630	330,000	73,433	8,056,689
Chief Executive Officer	2017	—	—	—	—	—
Duane D. Nash, M.D., J.D.	2018	414,800	294,737	—	43,615	753,152
Chief Executive Officer and President	2017	400,000	193,647	177,496	—	771,143
Robert A. Ashley, M.A.	2018	396,344	260,062	—	47,769	704,175
Executive Vice President and Chief Scientific Officer	2017	381,000	170,865	158,200	—	710,065

(1) The amounts in the “Option Awards” column reflect the aggregate grant date fair value of stock options granted during the calendar year computed in accordance with the provisions of Accounting Standards Codification, or ASC, 718, Compensation - Stock Compensation. The assumptions that we used to calculate these amounts are discussed in Note 7 to our financial statements appearing at the end of this Annual Report. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(2) Includes a cash signing bonus in 2018 for Mr. Cox, and 2017 bonuses approved by our board of directors on January 30, 2018 for Dr. Nash and Mr. Ashley.

(3) "All Other Compensation" includes reimbursement for temporary housing, commuting expenses and legal fees for Mr. Cox, and the payment of accrued vacation for Dr. Nash and Mr. Ashley.

Non-Equity Incentive Plan Compensation and Bonus

Executive Incentive Compensation Plan

Our Executive Incentive Compensation Plan, or Incentive Plan, was adopted by our board of directors on July 8, 2013. Our Incentive Plan is administered by our compensation committee; provided, however, that our board of directors must approve any award or any amendment to any award made thereunder. Our compensation committee determines the performance goals applicable to any award, which goals may include, without limitation, the attainment of research and development milestones, sales bookings, business divestitures and acquisitions, cash flow, cash position, earnings (which may include earnings before interest and taxes, earnings before taxes and net earnings), earnings per share, net income, net profit, net sales, operating cash flow, operating expenses, operating income, operating margin, overhead or other expense reduction, product defect measures, product release timelines, productivity, profit, return on assets, return on capital, return on equity, return on investment, return on sales, revenue, revenue growth, sales results, sales growth, stock price, time to market, total shareholder return, working capital, and individual objectives or other subjective or objective criteria. Performance goals that include the Company’s financial results may be determined in accordance with United States generally accepted accounting principles, or GAAP, or such financial results may consist of non-GAAP financial measures. The performance goals may be on an individual, divisional, business unit, functional or company-wide basis. The performance goals may differ from participant to participant and from award to award.

Pursuant to the employment letter agreements entered into between us and our named executive officers, our named executive officers are each eligible to receive annual bonuses as a percentage of their annual base salary based upon achievement of the performance goals determined by our compensation committee. For additional information regarding the terms of these employment letter agreements, see below under “Agreements With Our Named Executive Officers.”

Notwithstanding the eligibility for bonus awards, our board of directors may, in its sole discretion and at any time, increase, reduce or eliminate a participant’s actual award, or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant’s target award, in the discretion of our board. Our board may determine the amount of any reduction on the basis of such

factors as it deems relevant, and it is not required to establish any allocation or weighting with respect to the factors it considers.

Actual awards are paid in cash only after they are earned, which usually requires continued employment through the date of payment of the award. Payment of bonuses occurs as soon as administratively practicable after they are earned, but no later than the dates set forth in the Incentive Plan.

Our board of directors has the authority to amend, alter, suspend or terminate the Incentive Plan provided such action does not impair the existing rights of any participant with respect to any earned bonus.

Considering the results of our phase 3 clinical trial of our ELAD System, our board of directors did not make any bonus awards to any named executive officer or any other officer of the company pursuant to the Incentive Plan for 2018.

Agreements With Our Named Executive Officers

Russell J. Cox

We entered into an employment letter agreement, dated November 30, 2017, with Mr. Cox, which set forth the terms and conditions of his employment with us. The employment letter agreement had no specific term and provides for at-will employment. Mr. Cox's current annual base salary was $540,000 and he was awarded a signing bonus of $330,000 payable within 30 days of his start date of January 3, 2018, and he was eligible for an annual bonus equal to 50% of his base salary.

Duane D. Nash

We entered into an employment letter agreement, dated October 30, 2013, with Dr. Nash, which sets forth the terms and conditions of his employment with us. The employment letter agreement has no specific term and provides for at-will employment. This agreement supersedes all existing agreements he may have with us concerning his employment relationship. Dr. Nash’s current annual base salary is $414,800, and he is eligible for an annual bonus equal to 40% (increased to 50% for 2017) of his annual base salary.

Robert A. Ashley

We entered into an employment letter agreement, dated October 30, 2013, with Mr. Ashley, which sets forth the terms and conditions of his employment with us. The employment letter agreement has no specific term and provides for at-will employment. Mr. Ashley’s current annual base salary is $396,344, and he is eligible for an annual bonus equal to 35% (increased to 45% for 2017) of his annual base salary.

Executive Change of Control and Severance Agreements

We have entered into a change of control and severance agreement, with each of our executive officers, which requires us to make payments if the executive officer’s employment with us is terminated in certain circumstances. In January 2019, the compensation committee of the board of directors restructured the severance arrangements with our executive officers, including our chief executive officer, in an effort to advance and support our pursuit of strategic alternatives considering the results of our phase 3 clinical trial of the ELAD System.

In connection with the restructuring, the compensation committee approved (i) the cancellation of options held by our executive officers; (ii) amendments to the existing change of control and severance agreements with each of our executive officers; and (iii) grants of restricted stock units to such officers, contingent upon each officer agreeing and entering into all agreements necessary to effectuate these transactions. Under such agreements, Mr. Cox, Dr. Nash and Mr. Ashley cancelled outstanding options for 1,588,832 shares, 613,391 shares and 583,391 shares, respectively, and were granted 1,854,376, 886,316 and 816,634 restricted stock units, respectively. The restricted stock units can be settled in cash or shares of common stock at the discretion of the company and vest 25% annually.

Under the amended change of control and severance agreements, if prior to the six-month period before or after the twelve-month period following a change of control (such period, the Change of Control Period), an executive officer’s employment is terminated without “cause” or an executive officer resigns for “good reason” (as such terms are defined in the change of control and severance agreement), such officer will be eligible to receive the following benefits if such officer timely signs and does not revoke a release of claims:

- a lump sum payment equal to his base salary for a period of six months (12 months in the case of Mr. Cox);

reimbursement by us for up to six months (12 months in the case of Mr. Cox) of COBRA premiums to continue health insurance coverage for such officer and such officer's eligible dependents, or taxable monthly payments for the equivalent period in the event payment for COBRA premiums would violate applicable law; and

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- 100% accelerated vesting of all outstanding equity awards.

If, within the Change of Control Period, such officer's employment is terminated without cause or such officer resigns for good reason, such officer will be entitled to the following benefits if such officer timely signs a release of claims:

- a lump sum payment equal to (x) 12 months (18 months in the case of Mr. Cox) his annual base salary (for the year of the change of control or such officer's termination, whichever is greater), plus (y) 1.0x (1.5x in the case of Mr. Cox) the greater of: (A) such officer's target annual bonus (for the year of the change of control or such officer's termination, whichever is greater) or (B) such officer's actual bonus for performance relating to the calendar year immediately prior to the calendar year of such officer's termination, less (z) an amount equal to the grant date fair value of the January 2019 restricted stock unit award; and

- reimbursement by us for up to 12 months (18 months in the case of Mr. Cox) of COBRA premiums to continue health insurance coverage for such officer and such officer's eligible dependents, or taxable monthly payments for the equivalent period in the event payment for COBRA premiums would violate applicable law; and

- 100% accelerated vesting of all outstanding equity awards.

In addition, in the event any of the amounts provided for under these agreements or otherwise payable to our executive officers would constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code and could be subject to the related excise tax, the executive officer would be entitled to receive either full payment of benefits under this agreement or such lesser amount which would result in no portion of the benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to the executive officer. The agreements do not require us to provide any tax gross-up payments.

Further to the above, the stock awards granted to Mr. Cox, Dr. Nash and Mr. Ashley made pursuant to our 2014 Plan, provide for accelerated vesting in connection with a change in control in limited circumstances, as described below.

2014 Equity Incentive Plan

Our 2014 Plan provides that in the event of a merger or change in control, as defined in the 2014 Plan, each outstanding award will be treated as the administrator determines, including, without limitation, that awards may be assumed or substituted for by the acquiring or succeeding corporation, awards may be terminated immediately prior to the consummation of the merger or change in control, awards may vest in whole or in part prior to or upon consummation of the merger or change in control and, to the extent the administrator determines, terminate on or immediately prior to the effectiveness of the merger or change in control, or awards may be terminated in exchange for cash or property or replaced with other rights or property. If a successor corporation does not assume or substitute an equivalent award for any outstanding award, then such award will fully vest, all restrictions on such award will lapse and all performance goals or other vesting criteria applicable to such award will be deemed achieved at one hundred percent (100%) of target levels. Additionally, if a successor corporation does not assume or substitute an option or stock appreciation right, the administrator will notify the participant in writing or electronically that such award will be exercisable for a specified period of time determined by the administrator prior to the transaction, and such award will then terminate upon the expiration of such period.

In addition, pursuant to their stock option agreements, certain optionees, including our named executive officers who have awards under the 2014 Plan, are eligible for full vesting acceleration of their outstanding options in the event their service is terminated other than for cause.

2012 Stock Option Plan and Option Agreements

Our 2012 Plan provides that in the event of a change in control, as defined in the 2012 Plan, the surviving, continuing, successor, or purchasing corporation or other business entity or parent thereof may assume or substitute an equivalent award for each outstanding option under the 2012 Plan. If there is no assumption or substitution of outstanding options, such options will terminate upon the expiration of a stated notice period unless otherwise specified in the applicable stock option agreement.

In addition, pursuant to their stock option agreements, certain optionees are eligible for full vesting acceleration of their outstanding options in the event their service is terminated other than for cause or they resign from their service

for good reason. Furthermore, if there is no assumption or substitution of outstanding options following a change in control and, provided further that, such optionee's service has not terminated prior to such change in control, such outstanding options are

eligible for full vesting acceleration as of the date ten days prior to the date of a change in control and will terminate upon the expiration of the stated notice period unless exercised or terminated in exchange for cash or property.

Outstanding Equity Awards at Fiscal Year-End for Fiscal 2018

The following table sets forth certain information concerning outstanding equity for our named executive officers awards at fiscal year-end December 31, 2018:

Name	Vesting Commencement Date		Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
Russell J. Cox	1/3/2018	(1)	—	1,588,832	$ 6.30	1/2/2028
Chief Executive Officer						
Duane D. Nash, M.D., J.D.	2/8/2012		93,377	—	$ 0.43	3/31/2022
Chief Executive Officer and	4/25/2012		23,344	—	$ 0.43	4/24/2022
President	9/13/2012		241,670	—	$ 8.00	9/25/2022
	4/16/2016	(2)	56,666	28,334	$ 8.28	5/12/2026
	6/10/2017	(2)	31,875	53,125	$ 3.20	6/9/2027
	6/9/2018	(2)	10,625	74,375	$ 5.00	6/8/2028
Robert A. Ashley, M.A.	2/8/2012		93,377	—	$ 0.43	3/31/2022
Executive Vice President and	4/25/2012		23,344	—	$ 0.43	4/24/2022
Chief Scientific Officer	9/13/2012		241,670	—	$ 8.00	9/25/2022
	4/16/2016	(2)	50,000	25,000	$ 8.28	5/12/2026
	6/10/2017	(2)	28,125	46,875	$ 3.20	6/9/2027
	6/9/2018	(2)	9,375	65,625	$ 5.00	6/8/2028

(1) These options vest 25% on the first anniversary of the vesting commencement date and then in equal monthly installments over the following 36 months.

(2) These options vest in equal monthly installments over the four-year period following the vesting commencement date.

Perquisites, Health, Welfare and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We provide a 401(k) savings plan to our employees, including our current named executive officers, as discussed in the section below entitled “401(k) Savings Plan.”

We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances and as noted in the Summary Compensation Table above. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible employees, including named executive officers, with an opportunity to save for retirement on a tax advantaged basis. All participants’ interests in their deferrals are 100% vested when contributed. Pre-tax and after-tax contributions are allocated to each participant’s individual account and are then invested in selected investment alternatives according to the participant’s directions. Currently, we do not make matching contributions into the plan. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Internal Revenue Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan, and all matching contributions, if any, are deductible by us when made.

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Director Compensation

Our compensation committee has retained Aon Hewitt to, among other things, provide recommendations on non-employee director compensation based on an analysis of market data compiled from comparable companies in the biotechnology industry. The following table summarizes compensation paid to our non-employee directors during or with respect to the fiscal year ended December 31, 2018.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1]	All Other Compensation ($)[2]	Total ($)
Jean-Jacques Bienaimé	30,000	124,958 (3)	—	154,958
Cheryl L. Cohen	48,951	124,958 (4)	—	173,909
Philip M. Croxford, M.B.A.	15,699	— (5)	—	15,699
Douglas E. Godshall, M.B.A.	33,663	124,958 (6)	—	158,621
Errol R. Halperin, J.D., L.L.M.	39,375	124,958 (7)	—	164,333
Faheem Hasnain	60,375	174,940 (8)	—	235,315
J. Michael Millis, M.D.	37,500	124,958 (9)	31,000	193,458
Muneer A. Satter, J.D., M.B.A.	33,750	124,958 (10)	—	158,708
Lowell E. Sears, M.B.A.	57,250	124,958 (11)	—	182,208
Randolph C. Steer, M.D., Ph.D.	19,623	— (12)	—	19,623

(1) The amounts in the “Option Awards” column reflect the aggregate grant date fair value of stock options granted during the calendar year computed in accordance with the provisions of ASC 718. The assumptions that we used to calculate these amounts are discussed in Note 7 to our financial statements appearing at the end of this Annual Report. These amounts do not reflect the actual economic value that will be realized by the director upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options. As of December 31, 2018, Mr. Cox, our Chief Executive Officer had outstanding and unexercised option awards for 1,588,832 shares.

(2) Dr. Millis’ was paid an aggregate of $31,000 in consideration for services as a consultant and for services rendered as chair of our Clinical Advisory Board in 2018.

(3) Mr. Bienaimé had a total of 147,225 stock options outstanding as of December 31, 2018.

(4) Ms. Cohen had a total of 108,740 stock options outstanding as of December 31, 2018.

(5) Mr. Croxford had a total of 111,416 stock options outstanding as of December 31, 2018.

(6) Mr. Godshall had a total of 167,043 stock options outstanding as of December 31, 2018.

(7) Mr. Halperin has a total of 111,924 stock options outstanding as of December 31, 2018.

(8) Mr. Hasnain has a total of 160,171 stock options outstanding as of December 31, 2018.

(9) Dr. Millis had a total of 106,059 stock options outstanding as of December 31, 2018.

(10) Mr. Satter has a total of 93,270 stock options outstanding as of December 31, 2018.

(11) Mr. Sears has a total of 196,581 stock options outstanding as of December 31, 2018.

(12) Dr. Steer had a total of 122,400 stock options outstanding as of December 31, 2018.

Mr. Cox was not eligible to receive board compensation because he was an employee. We reimburse our directors for their reasonable expenses incurred in connection with attending board and committee meetings.

Director Compensation Policy

In May 2013, our board of directors adopted and approved a compensation policy for our non-employee directors, which was subsequently amended on March 2015, December 2015 and May 2016, which provides for the following compensation to our non-employee directors:

- each non-employee director receives an annual base retainer of $35,000 except that the Non-Executive Chairman of the Board receives an annual base retainer of $50,000;
- in addition to the annual base retainer, the chairman of our audit committee receives an annual fee of $15,000 and other members of our audit committee receive an annual fee of $7,500;
- in addition to the annual base retainer, the chairmen of our other committees receive an annual fee of $10,000 and other members of our other committees receive an annual fee of $5,000;
- in addition to the fees listed above, each non-employee director shall receive a per-meeting attendance fee of $500 for attending telephonic meetings of the Board. In addition, each Outside Director will be paid a per-meeting attendance fee of $2,500 for attending in-person meetings of the Board in excess of four during each calendar year.

Pursuant to this policy, except as approved by our board of directors, each new director will receive an initial grant of non-qualified common stock options with a Black-Scholes value of approximately $250,000 on the date of grant with vesting monthly over forty-eight months, subject to the director's continued service with us. In addition, on the date of each annual meeting of the Company's stockholders, each Outside Director who was a Director for the entire 6-month period preceding each such meeting automatically will be granted a non-statutory stock option with a Black-Scholes value of approximately $125,000, or $175,000 in the case of the Non-Executive Chairman of the Board. Each annual award will fully vest on the earlier of (i) the one-year anniversary of its grant date or (ii) the day prior to the next annual meeting, subject to the director's continued service with us.

Compensation Committee Interlocks and Insider Participation

As of December 31, 2018, the members of our compensation committee currently are Ms. Cohen and Messrs. Hasnain and Sears. None of the current or past members of our compensation committee is or has been an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) or director of any entity that has one or more executive officers serving on our compensation committee or our board of directors.

Compensation Committee Report

The compensation committee has reviewed and discussed the foregoing "Executive Compensation" section of this Annual Report on Form 10-K with management. Based on this review and discussion, the compensation committee recommended to our board of directors that such information be included in this Annual Report on Form 10-K.

The Compensation Committee
Cheryl L. Cohen (Chair)
Faheem Hasnain
Lowell E. Sears

The information contained in the Compensation Committee Report shall not be deemed to be soliciting material or to be filed with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that Vital Therapies specifically incorporates it by reference in such filing.

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Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes information about our equity compensation plans as of December 31, 2018. All outstanding option awards relate to our common stock.

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excl securities reflected in column (a)) (c)
Equity compensation plans approved by security holders:			
2012 Stock Option Plan	2,266,206	$6.76	—
2014 Equity Incentive Plan (1)	2,328,228	$6.40	2,813,218
Equity compensation plans not approved by security holders:			
Amended & Restated 2017 Inducement Equity Incentive Plan	1,588,832	$6.30	261,168
Total	6,183,266	$6.51	3,074,386

(1) Our 2014 Equity Incentive Plan provides for an annual increase in the number of shares available for issuance thereunder on each anniversary date of our initial public offering, equal to the lower of: (i) 1,200,000 shares of our common stock; (ii) 3% of the outstanding shares of our common stock on the second-to-last day prior to each anniversary date; (iii) an amount as our board of directors may determine.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth the beneficial ownership of our common stock as of February 15, 2019 by:

- each person, or group of affiliated persons, who we know to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage ownership information shown in the table is based on an aggregate of 42,369,694 shares of our common stock outstanding as of February 15, 2019.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable on or before April 29, 2018, which is 60 days after February 28, 2018. These shares are deemed to be outstanding and beneficially owned by the person holding those options and warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Unless otherwise noted below, the address of each of the individuals and entities named in the table below is c/o Vital Therapies, Inc., 15222-B Avenue of Science, San Diego, California 92128. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

	Number of Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned	
5% Stockholders:			
KCK Ltd. [1]	2,788,181	6.6	%
Named Executive Officers and Directors:			
Russell J. Cox[2]	1,854,376	4.2	%
Duane D. Nash, M.D., J.D. [3]	8,224	*	
Robert A. Ashley, M.A. [4]	2,000	*	
Faheem Hasnain [5]	107,293	*	
Cheryl L. Cohen [6]	78,415	*	
Lowell E. Sears, M.B.A. [7]	225,615	*	
All directors and executive officers as a group and certain former named executive officers [8]	2,287,808	5.1	%

(1) The address of KCK Ltd. is KCK Ltd. A/C KCK Ltd OMC Chambers, Wickhams Cay 1, Road Town, Tortola VG1110 British Virgin Islands. KCK Ltd., through a board of directors consisting of three or more persons, has sole voting and investment power with respect to 2,788,181 shares of common stock held by KCK Ltd. This information is based solely upon a Schedule 13G filed by KCK Ltd. on February 13, 2017 for beneficial ownership as of December 31, 2016.

(2) Consists of vested stock unit awards as of February 15, 2019.

(3) Consists of 8,224 shares held at February 15, 2019.

(4) Consists of 2,000 shares held at February 15, 2019.

(5) Consists of 4,500 shares held by Faheem Hasnain, 3,500 shares held by Faheem Hasnain Trust and options to purchase 99,293 shares of common stock that are exercisable or becoming exercisable within 60 days of February 15, 2019.

(6) Consists of options to purchase 78,415 shares of common stock that are exercisable or becoming exercisable within 60 days of February 15, 2019.

(7) Consists of 58,572 shares held and options to purchase 167,043 shares of common stock.

(8) Consists of 88,681 shares held or beneficially owned, 2,199,127 shares that may be acquired pursuant to restricted stock unit awards and the exercise of options to purchase shares of common stock that are exercisable or becoming exercisable within 60 days of February 15, 2019.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Since January 1, 2018, we have not been a party to any transactions in which the amount involved exceeded $120,000 and in which any of our executive officers, directors, promoters or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements described under the section of this proxy statement titled “Executive Compensation.”

Senior Preferred Investors’ Rights Agreement

We and certain of our former directors, former executive officers and stockholders, are parties to the Senior Preferred IRA. The Senior Preferred IRA contains customary registration rights and related provisions, including customary market standoff provisions.

Series D Investors' Rights Agreement

We and certain of our former directors, former executive officers and stockholders, are or were parties to an investors' rights agreement, dated June 7, 2011, or the Series D IRA. The Series D IRA contains restrictions on transfer (for compliance with applicable securities laws) and customary registration rights. Upon the closing of our initial public offering in April 2014, all covenants in this agreement, except for the rights relating to the registration of shares under the Securities Act, terminated. The rights of any of our directors, officers or stockholders under the Series D IRA, who became parties to the Senior Preferred IRA, were superseded by the Senior Preferred IRA.

Indemnification of Officers and Directors

We have entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements and our amended and restated certificate of incorporation and amended and restated bylaws require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law.

Related-Person Transactions Policy

We adopted a written Related Person Transactions Policy that sets forth our policies and procedures regarding the identification, review, consideration, approval and oversight of "related person transactions."

For purposes of our policy only, a "related-person transaction" is a past, present or future transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants, the amount involved exceeds $120,000 and a related person has a direct or indirect material interest. Various transactions are not covered by this policy, including transactions involving compensation for services provided to us as an employee, director, consultant or similar capacity by a related person, equity and debt financing transactions with a related person that are approved by the Board, and other transactions not otherwise required to be disclosed under Item 404 of Regulation S-K. A "related person," as determined since the beginning of our last fiscal year, is any executive officer, director or nominee to become director, a holder of more than 5% of our common stock, including any immediate family members of such persons. Any related-person transaction may only be consummated if approved or ratified by the affirmative vote of seventy-five percent (75%) of our dis-interested directors then in office in accordance with the policy guidelines set forth below.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee for review and recommendation for approval to our board of directors. In considering related-person transactions, our audit committee and board of directors take into account the relevant available facts and circumstances including, but not limited to whether the terms of such transaction are no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related person's interest in the transaction. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval process.

Director Independence

As a company listed on the Nasdaq Global Market we are required under the listing rules of Nasdaq, or the Nasdaq listing rules, to maintain a board comprised of a majority of independent directors as determined affirmatively by our board. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of our audit, compensation and nominating and governance committees must be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Exchange Act. Under the Nasdaq listing rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, the director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has undertaken a review of the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that none of Ms. Cohen and Messrs. Hasnain and Sears, representing three of our four directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is an "independent director" as that term is defined under the Nasdaq listing rules. Mr. Cox was not considered an independent director, and Dr. Nash is currently not considered an independent director because of their respective positions as our chief executive officer.

In making these determinations, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence, including consulting relationships, family relationships and the beneficial ownership of our capital stock by each non-employee director.

Item 14. Principal Accounting Fees and Services.

The audit committee of our board of directors selected PricewaterhouseCoopers LLP to be our independent registered public accounting firm for the year ended December 31, 2018.

The following table represents aggregate fees for services provided to us in the fiscal years ended December 31, 2018 and 2017 by PricewaterhouseCoopers LLP, our principal accountant. All fees below were pre-approved by the audit committee:

	Fiscal Year Ended	
	2018	2017
Audit Fees [1]	$525,175	$547,621
Audit-related Fees [2]	—	—
Tax Fees [3]	—	—
All Other Fees [4]	2,700	1,800
Total Fees	$527,875	$549,421

(1) Audit fees consist of fees incurred for professional services by PricewaterhouseCoopers LLP for audit and quarterly reviews of our financial statements, reviews of our registration statements on Form S-3 and Form S-8 and related services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) We did not engage PricewaterhouseCoopers LLP to perform audit-related services.

(3) We did not engage PricewaterhouseCoopers LLP to perform tax advisory services.

(4) Represents annual licensing fees for an accounting database subscription and, in 2018, to a disclosure checklist.

In connection with the audit of the 2018 financial statements, we entered into an engagement agreement with PricewaterhouseCoopers LLP that sets forth the terms by which PricewaterhouseCoopers LLP will perform audit services for us. Such engagement was approved in advance by our audit committee.

Auditor Independence

In 2018, there were no other professional services provided by PricewaterhouseCoopers LLP that would have required our audit committee to consider their compatibility with maintaining the independence of PricewaterhouseCoopers LLP.

Pre-Approval Policy

Our audit committee's policy is to pre-approve all audit and permissible non-audit services provided by the independent accountants. These services may include audit services, audit-related services, tax services and other services. Our audit committee generally pre-approves particular services or categories of services on a case-by-case basis. The independent registered public accounting firm and management are required to periodically report to our audit committee regarding the extent of services provided by the independent registered public accounting firm in accordance with these pre-approvals, and the fees for the services performed to date. All of the services of PricewaterhouseCoopers LLP for 2018 and 2017 described above were pre-approved by our audit committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Notes to Consolidated Financial Statements

2. Financial Statement Schedules. None.

3. Exhibits. The following exhibits are filed herewith or are incorporated by reference to exhibits previously filed with the U.S. Securities and Exchange Commission.

EXHIBITS

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1	Exchange Agreement, dated as of January 6, 2019 by and among Vital Therapies, Inc., Immunic AG, and the Shareholders of Immunic AG.	8-K	001-36201	2.1	January 7, 2019
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	S-1/A	333-191711	3.2	November 6, 2013
3.2	Second Amended and Restated Bylaws of the Registrant.	S-1/A	333-191711	3.4	November 6, 2013
4.1	Specimen Common Stock Certificate of the Registrant.	S-1/A	333-191711	4.1	November 6, 2013
4.2	Fourth Amended and Restated Investors' Rights Agreement, dated August 28, 2013.	S-1	333-191711	4.2	October 11, 2013
4.3	Investors' Rights Agreement, dated February 23, 2012.	S-1	333-191711	4.3	October 11, 2013
4.4	Amended and Restated Investors' Rights Agreement, dated June 7, 2011.	S-1	333-191711	4.4	October 11, 2013
10.1	Investment and Subscription Agreement, dated as of January 6, 2019, among Immunic AG and its Shareholders.	8-K	001-36201	10.1	January 7, 2019
10.2	Investment Banking Agreement between Ladenburg Thalmann & Co. Inc. and Vital Therapies, Inc., dated October 11, 2018.	8-K	001-36201	10.1	October 12, 2018
10.3+	Form of Indemnification Agreement between the Registrant and its directors and officers.	S-1/A	333-191711	10.1	November 6, 2013
10.4+	Employment Letter Agreement between the Registrant and Duane Nash, dated October 30, 2013.	S-1/A	333-191711	10.2	November 6, 2013
10.5+	Employment Letter Agreement between the Registrant and Robert A. Ashley, dated October 30, 2013.	S-1/A	333-191711	10.3	November 6, 2013
10.6+	Transition Agreement and Release between the Registrant and Terence E. Winters, dated December 4, 2017.	10-K	001-36201	10.4	March 13, 2018
10.7+	Employment Letter Agreement between the Registrant and Michael V. Swanson, dated August 30, 2013.	S-1/A	333-191711	10.5	November 6, 2013
10.8+	Employment Letter Agreement between the Registrant and Andrew Henry, dated October 30, 2013.	S-1/A	333-191711	10.6	April 3, 2014
10.9+	Employment Letter Agreement between the Registrant and Aron P. Stern, dated October 30, 2013.	S-1/A	333-191711	10.7	March 11, 2014
10.10+	Employment Letter Agreement between the Registrant and Richard Murawski, dated October 30, 2013.	S-1/A	333-191711	10.9	March 11, 2014
10.11+	Employment Letter Agreement between the Registrant and John Dunn, dated March 5, 2015.	10-K	001-36201	10.10	March 20, 2015
10.12+	Employment Letter Agreement between the Registrant and Russel J. Cox, dated November 30, 2017.	10-K	001-36201	10.10	March 13, 2018
10.13+	2012 Stock Option Plan and form of agreements.	S-1	333-191711	10.6	October 11, 2013
10.14+	2014 Equity Incentive Plan and form of agreements.	S-1/A	333-191711	10.11	March 11, 2014
10.15+	Amended Global Stock Option Agreement under 2014 Equity Incentive Plan.	10-K	001-36201	10.13	March 13, 2018

10.16+	Form of RSU Award Agreement under 2014 Equity Incentive Plan	8-K	001-36201	10.1	January 14, 2019
10.17+	Vital Therapies, Inc. Amended & Restated 2017 Inducement Equity Incentive Plan.	S-8	333-222886	4.2	February 6, 2018
10.18+	Amended & Restated 2017 Inducement Equity Incentive Plan - Form of U.S. Stock Option Agreement.	S-8	333-222886	4.3	February 6, 2018
10.19+	Executive Incentive Compensation Plan.	S-1	333-191711	10.8	October 11, 2013
10.20+	Form Change of Control and Severance Agreement.	S-1	333-191711	10.9	October 11, 2013
10.21+	Form of Amendment No. 1 to Change of Control and Severance Agreement	8-K	001-36201	10.2	January 14, 2019
10.22+	Non-Employee Director Compensation Policy.	S-1/A	333-191711	10.10	November 15, 2013
10.23+	Amended Outside Director Compensation Policy.	8-K	001-36201	10.1	May 27, 2016
10.24	Standard Industrial/Commercial Multi-Tenant Lease between R.E. Hazard Contracting Company and the Registrant, dated May 5, 2017.	10-Q	001-36201	10.18	May 9, 2017
10.25	Standard Office Lease between Arden Realty Limited Partnership and the Registrant, dated May 7, 2013.	S-1	333-191711	10.12	October 11, 2013
10.26	Amended Lease between BRA CA Office Owner LLC and the Company, dated August 23, 2016.	8-K	001-36201	10.1	August 29, 2016
21.1*	List of subsidiaries of the Registrant.				
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (included on the signature page).				
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.				

+ Indicates a management contract or compensatory plan or arrangement.

* Filed herewith.

** 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-K 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.

VITAL THERAPIES, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Board of Directors and Stockholders of
Vital Therapies, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Vital Therapies, Inc. and its subsidiaries ("the Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern
The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations, cash outflows from operating activities, and its VTL-308 clinical trial failed to meet its primary or secondary endpoints that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.
/s/ PricewaterhouseCoopers LLP
San Diego, California
March 4, 2019

We have served as the Company's auditor since 2010.

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

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$13,324	$56,901
Other current assets and prepaid expenses	908	1,220
Total current assets	14,232	58,121
Property and equipment, net	709	2,155
Other assets	37	108
Total assets	$14,978	$60,384
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$268	$1,049
Accrued expenses	2,221	9,141
Other current liabilities	21	91
Total current liabilities	2,510	10,281
Long-term liabilities	41	59
Commitments and contingencies (note 4)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at December 31, 2018 and 2017	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized at December 31, 2018 and 2017; 42,369,694 and 42,368,864 shares issued and outstanding at December 31, 2018 and 2017, respectively	4	4
Additional paid-in capital	349,771	345,915
Accumulated other comprehensive income	80	78
Accumulated deficit	(337,428)	(295,953)
Total stockholders' equity	12,427	50,044
Total liabilities and stockholders' equity	$14,978	$60,384

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

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

	Years Ended December 31,		
	2018	2017	2016
Operating expenses:			
Research and development	$24,825	$39,341	$30,046
General and administrative	13,585	13,314	11,220
Severance costs	2,395	—	—
Impairment loss	1,219	—	—
Total operating expenses	42,024	52,655	41,266
Loss from operations	(42,024)	(52,655)	(41,266)
Other income:			
Interest income	521	650	284
Other income (expense), net	28	(73)	13
Total other income	549	577	297
Net loss	$(41,475)	$(52,078)	$(40,969)
Net loss per share, basic and diluted	$(0.98)	$(1.31)	$(1.31)
Weighted-average common shares outstanding, basic and diluted	42,369,245	39,859,009	31,387,579

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

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

	Years Ended December 31,		
	2018	2017	2016
Net loss	$(41,475)	$(52,078)	$(40,969)
Other comprehensive income (loss):			
Unrealized gains (losses) on cash equivalents	(2)	(6)	4
Foreign currency translation	—	1	(1)
Total comprehensive loss	$(41,477)	$(52,083)	$(40,966)

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

VITAL THERAPIES, INC.
Consolidated Statements of Stockholders' Equity
(In thousands, except shares)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2016	30,473,083	$ 3	$ 285,098	$ 80	$ (202,856)	$ 82,325
Net loss	—	—	—	—	(40,969)	(40,969)
Other comprehensive loss	—	—	—	3	—	3
Exercise of stock options and change in stock option early exercise repurchase liability	8,098	—	54	—	—	54
Stock-based compensation	—	—	4,678	—	—	4,678
Issuance of common stock, net of issuance costs	1,662,294	—	12,355	—	—	12,355
Balance at December 31, 2016	32,143,475	3	302,185	83	(243,825)	58,446
Net loss	—	—	—	—	(52,078)	(52,078)
Other comprehensive income	—	—	—	(5)	—	(5)
Exercise of stock options	2,889	—	5	—	—	5
Stock-based compensation	—	—	5,480	—	—	5,480
Common stock issued for services	60,000	—	256	—	—	256
Issuance of common stock, net of issuance costs	10,162,500	1	37,939	—	—	37,940
Other	—	—	50	—	(50)	—
Balance at December 31, 2017	42,368,864	4	345,915	78	(295,953)	50,044
Net loss	—	—	—	—	(41,475)	(41,475)
Other comprehensive income	—	—	—	2	—	2
Exercise of stock options	830	—	5	—	—	5
Stock-based compensation	—	—	3,736	—	—	3,736
Common stock issued for services	—	—	115	—	—	115
Balance at December 31, 2018	42,369,694	$ 4	$ 349,771	$ 80	$ (337,428)	$ 12,427

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

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

	Years Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	$(41,475)	$(52,078)	$(40,969)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	727	998	1,808
Fixed Asset Impairment	1,219	—	—
Stock-based compensation	3,736	5,480	4,678
Common stock issued for services	115	256	—
Other	119	(1)	85
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	165	165	(232)
Accounts payable	(770)	287	(459)
Accrued expenses	(6,914)	4,490	(587)
Other liabilities	(87)	6	(98)
Net cash used in operating activities	(43,165)	(40,397)	(35,774)
Cash flows from investing activities:			
Purchases of property and equipment	(597)	(685)	(556)
Change in restricted cash	—	—	533
Proceeds from sale of equipment	182	7	2
Net cash used in investing activities	(415)	(678)	(21)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net of issuance costs	—	37,998	12,355
Proceeds from exercise of stock options	4	5	32
Deferred financing costs	—	(19)	(13)
Net cash provided by financing activities	4	37,984	12,374
Effect of exchange rate changes on cash and cash equivalents	(1)	1	(4)
Net change in cash and cash equivalents	(43,577)	(3,090)	(23,425)
Cash and cash equivalents, beginning of period	56,901	59,991	83,416
Cash and cash equivalents, end of period	$13,324	$56,901	$59,991
Supplemental disclosure of non-cash investing and financing activities:			
Purchase of property and equipment included in liabilities	$—	$16	$41
Stock issuance costs included in liabilities	$—	$1	$—
Change in stock option early exercise repurchase liability	$—	$—	$23

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

Notes to Consolidated Financial Statements

1. Description of Business and Basis of Financial Statements

Description of Business

We are a biotherapeutic company that has been developing a cell-based therapy targeting the treatment of acute forms of liver failure. Our initial product candidate, the ELAD® System, or ELAD, is a human-cell-based, bio-artificial liver, which was being developed to improve rates of survival among patients with acute forms of liver failure. Since inception, we have devoted essentially all of our efforts to product development, clinical testing and pilot manufacturing and have not recognized revenues from our planned principal operations.

In September 2018, we reported top-line data from our phase 3 clinical trial of ELAD, VTL-308, in 151 subjects with severe alcoholic hepatitis. Although there was a numerical improvement in survival in the ELAD-treated group between three months and one year following randomization, the study failed to meet the primary endpoint of a significant improvement in overall survival through at least ninety-one days. The secondary endpoint of the proportion of survivors at study day ninety-one also showed no statistically significant difference between the groups. Considering these results, we do not believe the ELAD System can be approved in the United States or the European Union without additional clinical trials, if ever, and that such clinical trials would require substantial capital and time to complete. Consequently, we have ceased any further development of the ELAD System for the United States and Europe, substantially reduced our workforce, discontinued most of our supply and service agreements, and have shifted our strategic focus to identifying and exploring strategic alternatives including a merger, an acquisition or sale of assets or even a dissolution and liquidation of the company. See Note 11 for events subsequent to the reporting period.

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

Going Concern

We have a history of incurring losses and negative cash flows from operations and have an accumulated deficit of $337.4 million through December 31, 2018. In consideration of the results of the VTL-308 clinical trial and our decision to cease the further development of ELAD in the United States and Europe, we have made reductions in operating expenses as we pursue strategic alternatives for the company. As a result, we believe that our existing cash and cash equivalents of $13.3 million as of December 31, 2018 would be sufficient to meet our known liabilities and commitments at such date based on our current operations; however, we expect our resource requirements to change materially to the extent we enter into and complete any strategic transactions. The timing and amount of our actual expenditures will be based on many factors, including, but not limited to, the strategic options that we pursue, any unforeseen cash needs which may deplete current cash and cash equivalents sooner than planned, or any future research and development efforts we decide to pursue.

We currently have an effective shelf registration statement on Form S-3 on file with the Securities and Exchange Commission, or SEC, which expires June 2021. The shelf registration statement permits the offering, issuance and sale by us of up to an aggregate offering price of $200.0 million of common stock, preferred stock, warrants, debt securities or units in one or more offerings and in any combination, of which $60.0 million may be offered, issued and sold under an “at-the-market” sales agreement with Cantor Fitzgerald & Co. However, amounts available under the shelf registration statement are significantly limited as our public float was below $75.0 million as measured on December 31, 2018. Additional funding is not likely at this time due to our past clinical trials not meeting their primary or secondary survival endpoints.

In addition, in October 2018, we received a letter from the staff of Nasdaq providing notification that, for the previous 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement, or the Bid Price Requirement, for continued listing on the Nasdaq Global Market. The notification had no immediate effect on the listing of our common stock. In accordance with Nasdaq listing rules, we are afforded 180

calendar days, or until April 23, 2019, to regain compliance with the Bid Price Requirement. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds to sustain our operations and our ability to successfully enter into strategic transactions, and could result in the loss of investor interest.

We believe that due to the factors described above, there is substantial doubt about our ability to continue as a going concern for one year from the date of the issuance of our consolidated financial statements for the twelve months ended December 31, 2018.

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in conformity with United States generally accepted accounting principles, or GAAP, and include the accounts of Vital Therapies, Inc. and its wholly-owned subsidiaries located in the United Kingdom and China, both of which are currently inactive. All intercompany accounts and transactions have been eliminated in consolidation. We manage our operations as a single reportable segment for the purposes of assessing performance and making operating decisions.

2. Summary of Significant Accounting Policies

Use of Estimates

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

Cash and Cash Equivalents

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

Fair Value of Financial Instruments

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

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

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

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

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

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

Property and Equipment

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

Impairment of Long-Lived Assets

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

We recognized an impairment charge of $1.2 million on our property and equipment in the consolidated statements of operations for the twelve months ended December 31, 2018. We did not recognize any impairment losses in the years ended December 31, 2017 or 2016.

Clinical Trial Accruals

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

As a result of the completion of our VTL-308 clinical trial in September 2018, we gained access to subject-specific and clinical site information used for estimating our clinical trial accruals. This enabled us to further analyze our clinical trial accrual against the actual services performed and to adjust our clinical trial accrual based on such information. As a result of this analysis and our ongoing review with the clinical sites, we reduced our clinical trial accrual and reduced research and development expense for the year ended December 31, 2018 by $670,000.

Research and Development

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

Stock-Based Compensation

We measure and recognize compensation expense for all stock-based compensation for employees and directors based on the estimated fair value at the date of grant, and to consultants based on the ongoing estimated fair value. Currently, our stock-based awards consist only of stock options; however, future grants under our equity compensation plan may also consist of shares of restricted stock, restricted stock units, stock appreciation rights, performance awards and performance units (see Note 11 to the consolidated financial statements). We estimate the fair value of stock options using the Black-Scholes-Merton, or BSM, option pricing model, which requires the use of estimates.

We recognize stock-based compensation cost for employees and directors for ratably vesting stock options on a straight-line basis over the requisite service period of the award. For performance-based stock options to employees and directors, we record stock-based compensation expense only when the performance-based milestone is deemed probable of achievement. We utilize both quantitative and qualitative criteria to judge whether milestones are probable of achievement. If performance-based milestones are later determined not to be probable of achievement, then all

previously recorded stock-based compensation expense associated with such options is reversed in the period that we make this determination.

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

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

Risk-free Interest Rate

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

Expected Dividend Yield

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

Expected Volatility

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

Expected Term

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

Leases

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

Comprehensive Income (Loss)

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

Foreign Currency Translation and Transactions

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

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the 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 December 31, 2018 and 2017, we maintained a full valuation allowance against our entire balance of deferred tax assets.

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

Net Loss Per Share

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

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

	As of December 31,		
	2018	2017	2016
Options to purchase common stock	6,183,266	6,083,482	4,841,274
Warrants to purchase common stock	240,620	240,620	240,620

Recently Issued and/or Adopted Accounting Pronouncements

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

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

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

In June 2018, the FASB issued ASU No. 2018-07, "Improvements to Non-employee Share-Based Payment Accounting," or ASU 2018-07. ASU 2018-07, which simplifies the accounting for non-employee share-based payment transactions, specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, and early adoption is permitted. We currently expect to adopt ASU 2018-07 in the first quarter of 2019. We do not expect the adoption of this standard to have a material impact on our consolidated financial statements.

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

3. Other Financial Information

Property and Equipment

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

	December 31,	
	2018	2017
Manufacturing, clinical and laboratory equipment	$6,480	$7,500
Leasehold improvements	4,627	4,727
Office furniture and equipment	105	234
Construction in progress	—	17
	11,212	12,478
Less: accumulated depreciation and amortization	(10,503)	(10,323)
Total	$709	$2,155

Depreciation and amortization expense was $727,000, $998,000 and $1.8 million for the years ended December 31, 2018, 2017 and 2016, respectively.

In September 2018, we ceased substantially all of our development efforts related to ELAD. This resulted in a substantial change in the expected use of our long-lived assets and a significant decrease in the benefits expected to be realized from these assets. Accordingly, we recognized an impairment charge of $1.2 million on our property and equipment in the consolidated statements of operations for the year ended December 31, 2018 reflecting the difference in the carrying value of such property and equipment and its estimated fair value. The impairment charge is reflected as a reduction in the cost of the related assets.

Accrued Expenses

Accrued expenses consist of (in thousands):

	December 31,	
	2018	2017
Accrued clinical and related costs	$1,336	$5,377
Accrued compensation and related taxes	543	3,591
Accrued other	342	173
Total	$2,221	$9,141

4. Commitments and Contingencies

Operating Leases

We lease office, manufacturing and research and development facilities, and equipment under various non-cancellable operating lease agreements with expiration dates into 2022. In August 2016, we entered into amendments to extend certain leases for office and research and development space to January 2019. These amended leases are being allowed to expire. In May 2017, we entered into a new lease, or the Lease, extending the term of our existing manufacturing and research and development facility lease from June 2017 to June 2022. The Lease includes a renewal option, provides for periodic rent increases and requires the payment of our proportionate share of the facility's operating expenses. Future minimum annual obligations under non-cancellable operating lease commitments at December 31, 2018 are as follows (in thousands):

	Total	2019	2020	2021	2022	2023	Thereafter
Operating lease obligations	$1,511	$469	$387	$434	$221	$—	$—

We recognize rent expense for our facility operating leases on a straight-line basis. We account for the difference between the minimum lease payments and the straight-line amount as deferred rent. Total rent, property taxes and routine maintenance expense under our operating leases was $1,120,000, $999,000 and $993,000 during the years ended December 31, 2018, 2017 and 2016, respectively. Current and long-term deferred rent totaled $22,000 and $41,000 at December 31, 2018 and $91,000 and $59,000 at December 31, 2017, respectively.

Contractual Commitments

In October 2018, we entered into an investment banking agreement, or the Engagement Agreement, with Ladenburg Thalmann & Co. Inc., or Ladenburg, pursuant to which Ladenburg is acting as our strategic financial advisor to assist in the review of our business and assets and exploration of strategic opportunities for enhancing stockholder value, including the potential sale or merger of the company. Under the Engagement Agreement, as compensation for the services provided by Landenburg, we shall pay, or cause to be paid, to Ladenburg, the following nonrefundable fees: (i) if we consummate a transaction, we shall pay Ladenburg a transaction fee of $1,000,000 (the “Transaction Fee”) at the closing of the transaction, (ii) a retainer fee of $75,000, which was paid in 2018 and is creditable against the Transaction Fee, and (iii) an opinion fee of $250,000 paid in 2019. In January 2019, we entered into an exchange agreement Immunic AG which, if completed, would result in the payment of the Transaction Fee to Ladenburg.

Purchase Commitments

We have no significant purchase commitments as of December 31, 2018.

Legal Proceedings

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

5. Fair Value

The following fair value hierarchy 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 December 31, 2018			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$12,940	$12,940	$—	$—

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

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

For our money market funds, unrealized gains and losses are reported as accumulated other comprehensive income (loss), and realized gains and losses are included in interest income on the consolidated statements of operations. We estimated the fair value of certain property and equipment based on third-party market value appraisals, and classified the fair value of such property and equipment as a Level 3 measurement due to the significance of the unobservable inputs. There were no transfers between Level 1, Level 2 or Level 3 for our assets or liabilities during the periods presented.

6. Common Stock and Stock Warrants

Certificate of Incorporation

The material terms of our amended restated certificate of incorporation, which became effective as of the closing of our IPO, are as follows:

Authorized Shares

Our amended and restated certificate of incorporation authorizes us to issue 150,000,000 shares of stock consisting of 130,000,000 shares of common stock, par value of $0.0001 per share, and 20,000,000 shares of preferred stock, par value $0.0001 per share.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preferences that may be granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock, which we may designate and issue in the future.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Because of this absence of cumulative voting, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. In addition, our amended and restated certificate of incorporation also provides that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the combined voting power of all our stockholders entitled to vote on the election of directors, voting together as a single class.

Subject to supermajority votes for some matters, matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter, provided that the holders of our common stock are not allowed to vote on any amendment to our certificate of incorporation that relates solely to the terms of one or more series of preferred stock if the holders of such affected series are entitled, either separately or together with the holders or one or more such series, to approve such amendment. The affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in any annual election of directors and, in some cases, the affirmative vote of a majority of minority stockholders entitled to vote in any annual election of directors, are required to amend or repeal our bylaws, amend or repeal certain provisions of our certificate of incorporation, approve certain transactions with certain affiliates, or approve the sale or liquidation of the company. The vote of a majority of minority stockholders applies when an individual or entity and its affiliates or associates together own more than 50% of the voting power of our then outstanding capital stock, excluding any such person that owned 15% or more of our outstanding voting stock immediately prior to our IPO, and such a vote would require the approval of the majority of our voting stock, excluding the voting stock held by such a majority holder.

Public Offerings of Common Stock

In May 2018 we filed a shelf registration statement on Form S-3, or the 2018 Shelf Registration Statement, which became effective in June 2018. The 2018 Shelf Registration Statement permits: (i) the offering, issuance and sale by us of up to a maximum aggregate offering price of $200.0 million of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination; (ii) sales of up to 2.5 million shares of common stock by certain selling stockholders; and (iii) the offering, issuance and sale by us of up to a maximum aggregate offering price of $60.0 million of our common stock that may be issued and sold under an “at-the-market” sales agreement, or ATM, with Cantor Fitzgerald & Co. However, amounts available under the shelf registration statement are significantly limited as long as our our public float remains below $75.0 million.

Under our prior registration statement filed on Form S-3 in May 2015, or the 2015 Shelf Registration Statement, we completed follow-on public offerings in March 2017 and October 2015, and under the ATM in 2017 and 2016. We did not sell any shares under the 2018 or 2015 Shelf Registration Statements during the year ended December 31, 2018. The 2015 Shelf Registration Statement was replaced by the 2018 Shelf Registration Statement in June 2018.

In March 2017, we completed follow-on public offering under the 2015 Shelf Registration statement raising gross proceeds of $40.3 million. Under this follow-on public offering, we sold 10.1 million shares of our common stock at a price of $4.00 per share. The net proceeds to us from the March 2017 follow-on offering were $37.5 million, after deducting underwriting discounts and commissions of $2.4 million and offering expenses of approximately $362,000.

During the year ended December 31, 2017, we also raised gross proceeds of $600,000 pursuant to the ATM selling 100,000 shares of our common stock at a price of $6.00 per share. The net proceeds to us from the ATM were $468,000 after deducting underwriter commissions of $18,000 and estimated offering expenses of $114,000.

During the year ended December 31, 2016, we raised gross proceeds of $12.2 million pursuant to the ATM selling 1.5 million shares of our common stock at a weighted average price of $7.90 per share. The net proceeds to us from the ATM were $11.7 million after deducting underwriter commissions of $366,000 and estimated offering expenses of $173,000.

Private Placement of Common Stock

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

Common Stock Issued for Services

In October 2017, we entered into an independent consulting agreement, or the Consulting Agreement, with two consulting groups, or the Consultants, pursuant to which we issued 60,000 restricted shares of our common stock to the Consultants as partial consideration for investor relations services to be rendered. The restricted shares were not registered based on a specific exemption from the registration requirements of the Securities Act. We had the right to terminate this agreement for any reason within 180 days following the effective date, whereby each of the Consultants would have been required to promptly surrender to us 40% of the number of restricted shares issued to it. In connection with this transaction, we valued 36,000 shares, or 60% of the shares, at the quoted market price of $207,000, or $5.75, per share, on the date of the agreement. The remaining 24,000 shares were adjusted to fair value based on the closing price at the end of each reporting period with the expense being recorded ratably over the 180-day period. We recognized expense in connection with these consulting shares of $115,000 and $256,000 during the year ended December 31, 2018 and 2017, respectively, in general and administrative expenses.

Warrants

We issued warrants in connection with financing activities and for consulting services in years prior to our initial public offering. As of December 31, 2018 and 2017, warrants for 240,620 shares of common stock were outstanding and exercisable at an exercise price of $92.99 and expire in September 2019.

Stock Reserved for Future Issuance

Shares reserved for future issuance at December 31, 2018 are as follows:

	Number of Shares
Common stock options outstanding	6,183,266
Common stock options available for future grant:	
2014 Equity Incentive Plan	2,813,218
2017 Inducement Equity Incentive Plan	261,168
Common stock reserved for issuance for outstanding warrants	240,620
Total common shares reserved for future issuance	9,498,272

7. Stock Compensation Plans

Equity Incentive Plans

Our 2014 Equity Incentive Plan, or the 2014 Plan, became effective in April 2014 and replaced our 2012 Stock Option Plan, or the 2012 Plan, with respect to future awards. The 2014 Plan provides for the grant of stock options, restricted stock, restricted stock units, stock appreciation rights, performance awards and performance units to employees, directors, and consultants. The 2012 Plan provided for the grant of stock options, restricted stock, restricted stock units, stock purchase rights, and performance awards to employees, directors, and consultants.

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

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

Pursuant to such provisions, the number of shares available for issuance under the 2014 Plan was increased by 1,200,000 shares effective April 16, 2018. Shares available for grant under the 2014 Plan totaled 2,813,218 shares as of December 31, 2018.

In September 2017, our board of directors approved the 2017 Inducement Equity Incentive Plan and amended and restated the plan in November 2017, or the Inducement Plan, which has terms and conditions substantially similar to our 2014 Plan. Under the Inducement Plan, 1,850,000 shares of our common stock were reserved to be used exclusively for non-qualified grants to individuals who were not previously our employees or directors as an inducement material to the individual's entry into employment with us within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. During the twelve months ended December 31, 2018, we granted options to purchase 1,699,636 shares of our common stock under the Inducement Plan and 110,804 shares were forfeited or cancelled, leaving 261,168 shares available for grant under the Inducement Plan.

Option grants made under the 2014 Plan and the 2012 Plan generally vest over one year or ratably over four years, except for performance-based stock options. Our performance-based stock options were set to become fully vested and exercisable only on achievement of the performance conditions while the participant was a continuing service provider. Options currently outstanding under the Inducement Plan become 25% vested on the one year anniversary of the grant date and then vest ratably over an additional three years or ratably over four years. Options generally expire ten years from the grant date or earlier in accordance with the terms of the plans and the related stock option agreement.

In 2015, the Board approved grants for performance-based stock options to certain employees and consultants under the 2014 Plan. Performance-based stock options that had not been forfeited would have fully vested on the third anniversary of the grant date if (i) our VTL-308 clinical trial had achieved statistical significance in its primary efficacy endpoint and (ii) the participant was a continuing service provider through the third anniversary of the grant date (as such terms are defined in the 2014 Plan). Prior to the announcement of the VTL-308 clinical trial results, we deemed the performance conditions as being probable and recorded stock-based compensation expense over the requisite service period for all performance-based stock options held by employees of $357,000 for the twelve months ended December 31, 2018. In September 2018, we announced that the VTL-308 clinical trial failed to achieve its primary efficacy endpoint. Accordingly, the performance conditions of the performance-based stock options were not met. In connection with this determination, we recorded a reversal of stock-based compensation expense of $1.7 million, including $873,000 to research and development expense and $862,000 to general and administrative expense in the consolidated statements of operations for the year ended December 31, 2018.

The following table summarizes stock option activity under the 2012 and 2014 Plans and the 2017 Inducement Plan:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding as of January 1, 2018	6,083,482	$ 6.76		
Granted	2,815,900	$ 6.05		
Exercised	(830)	$ 5.35		
Forfeited and expired	(2,715,286)	$ 6.60		
Outstanding as of December 31, 2018	6,183,266	$ 6.51	5.6	$ —
Options vested and expected to vest as of December 31, 2018	5,599,448	$ 6.57	5.2	$ —
Options exercisable as of December 31, 2018	3,908,151	$ 6.80	3.6	$ —

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of our common stock for those shares that had exercise prices lower than the fair value of our common stock as of December 31, 2018. The number of options vested and expected to vest is calculated as the total number of options vested plus the number of unvested options remaining after applying our estimated forfeiture rate.

The following table summarizes information about stock options (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Aggregate intrinsic value of options exercised	$ 2	$ 10	$ 39

We have not capitalized any stock based-compensation into the cost of inventory nor have we recognized an income tax benefit from the exercise of any stock options as we continue to record a full valuation allowance on our deferred tax assets.

Stock-based Compensation Expense

The weighted-average grant date fair value of stock options granted to employees and directors during the years ended December 31, 2018, 2017 and 2016 was $4.26, $2.34 and $5.70, respectively. The following are the ranges of underlying assumptions used to determine the fair value of stock options granted to employees and non-employees:

	Years Ended December 31,		
	2018	2017	2016
Employees and Directors:			
Risk-free interest rate	2.0% - 2.5%	1.5% - 2.0%	1.5% - 1.7%
Expected dividend yield	— %	— %	— %
Expected volatility	80% - 82%	82% - 85%	77% - 86%
Expected term of options (years)	5.9 - 6.2	5.9 - 6.1	5.9 - 6.0
Range of common stock value	$0.45 - $8.00	$2.75 - $5.80	$5.90 - $8.97
Non-Employees:			
Risk-free interest rate	2.1% - 3.0%	1.0% - 2.1%	0.5% - 1.9%
Expected dividend yield	— %	— %	— %
Expected volatility	71% - 82%	66% - 84%	77% - 97%
Expected term of options (years)	0.1 - 9.3	0.5 - 4.5	0.2 - 5.5
Range of common stock value	$0.19 - $6.85	$2.90 - $5.95	$4.35 - $9.07

The following tables summarize the allocation of stock-based compensation expense to employees and non-employees (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Employees and Directors:			
Research and development	$364	$1,645	$1,758
General and administrative	3,160	3,742	2,751
Total	$3,524	$5,387	$4,509
Non-Employees:			
Research and development	$81	$93	$153
General and administrative	131	—	16
Total	$212	$93	$169

As of December 31, 2018, there was $7.5 million of total compensation cost related to unvested employee stock option awards not yet recognized. Stock-based compensation expense for employee stock option awards is expected to be recognized over a remaining weighted-average vesting period of 2.7 years, respectively.

8. Income Taxes

Our net loss before income tax was subject to tax in the following jurisdictions for the following periods (in thousands):

	Year Ended December 31,		
	2018	2017	2016
United States	$(41,467)	$(52,066)	$(40,929)
Foreign	(8)	(12)	(40)
	$(41,475)	$(52,078)	$(40,969)

Our rate reconciliation consists of the following:

	Year Ended December 31,		
	2018	2017	2016
Federal statutory rate	21.0 %	35.0 %	35.0 %
State tax (net of federal benefit)	0.0 %	0.0 %	0.1 %
Effects of U.S. tax rate change	0.0 %	(47.6)%	0.0 %
Federal and state tax credits	0.2 %	46.8 %	2.9 %
Uncertain tax positions	0.0 %	(5.3)%	(16.0)%
Stock options	(1.6)%	(1.4)%	(1.5)%
Other	(0.3)%	(0.2)%	(2.5)%
Change in valuation allowance	(19.3)%	(27.3)%	(18.0)%
Effective tax rate	0.0 %	0.0 %	0.0 %

Deferred income taxes result from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements that will result in taxable or deductible amounts in future years. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in years in which those temporary differences are expected to be recovered or settled. As tax laws and rates change, deferred tax assets and liabilities are adjusted through income tax expense.

On December 22, 2017, H.R. 1/Public Law No. 115-97 known as the Tax Cuts and Jobs Act, or the Tax Act, was signed into law. The effects of this new federal legislation are recognized upon enactment, which is the date a bill is signed into law. The Act included numerous changes in existing tax law, including a permanent reduction in the federal corporate income tax rate from 35% to 21% effective on January 1, 2018. As a result of the Tax Act, we revalued our net deferred tax assets as of December 31, 2017 to reflect the rate reduction and recorded a reduction in our net deferred tax assets of $24.8 million. However, the revaluation did not result in any change to net income tax expense as our net deferred tax assets are fully offset by a valuation allowance. As of December 22, 2018, the Company’s accounting for the remeasurement of its deferred tax assets and liabilities was complete and there were no changes to the amount previously recorded.

Significant components of our net deferred tax assets are shown below. A valuation allowance has been established as realization of such net deferred tax assets has not met the more likely-than-not threshold requirement. If our judgment changes and it is determined that we will be able to realize these net deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on the net deferred tax assets will be accounted for as a reduction to income tax expense.

	December 31,	
	2018	2017
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$44,540	$43,600
Federal and state tax credits	43,701	35,903
Stock-based compensation	2,538	2,371
Foreign net operating loss carryforwards	122	169
Other, net	955	1,809
Total deferred tax assets	91,856	83,852
Less valuation allowance	(91,856)	(83,852)
	$—	$—

We have incurred net operating losses each year since inception due to our history as a development stage company with no realized revenues from our planned principal operations. These cumulative operating losses provide significant negative evidence in the determination of whether or not we will be able to realize our deferred tax assets such as our net operating losses and other favorable temporary differences. There can be no assurance that we will ever generate taxable income. As a result, we have maintained a full valuation allowance against the entire balance of our net deferred tax assets since the date of inception. The valuation allowance increased by $8.0 million and $14.2 million for the years ended December 31, 2018 and 2017, respectively.

In 2017, we made the decision to amend our federal tax returns to claim an orphan drug credit for the tax periods from 2013 through 2016. As a result, before consideration of any uncertain tax positions, we recorded orphan drug credit carryforwards of $34.2 million and reductions to our federal research and development credit and NOL carryforwards of $4.5 million and $7.3 million, respectively, in 2017.

As of December 31, 2018, we had available net operating loss, or NOL, carryforwards of approximately $208.6 million and $203.0 million for federal and state income tax purposes, respectively. These state NOL carryforwards include $191.1 million in California NOL carryforwards generated in 2013 through 2017, which have been determined to be uncertain tax positions and, accordingly, are not included in our deferred tax assets. The federal NOL carryforwards generated prior to 2018 and unexpired state NOL carryforwards begin to expire in 2032. The 2018 federal NOL carryforwards do not expire. In addition, as of December 31, 2018, before consideration of any uncertain tax positions, we had federal orphan drug, federal research and development, and state research and development tax credit carryforwards of $43.8 million, $0.9 million and $3.6 million, respectively. Certain federal orphan drug tax credits and federal research and development credits begin to expire in 2033 and 2032, respectively, and the state research and development tax credits do not expire. These carryforwards and tax credits are net of the Section 382 and 383 limitations discussed below.

During the year ended December 31, 2018, $194,000 of NOL carryforwards from our Chinese subsidiary expired leaving $490,000 of NOL carryforwards from our Chinese subsidiary as of December 31, 2018. There will be further expirations of this NOL carryforward in 2019 and beyond.

Sections 382 and 383 of the Internal Revenue Code, or the IRC, limit a company’s ability to utilize certain net operating losses and tax credit carryforwards in the event of a cumulative change in ownership in excess of 50%, as defined. We experienced changes in ownership, as defined in Section 382, in February 2012 and in December 2013. As a result, the deferred tax asset associated with our federal and state net operating loss carryforwards and federal and state tax credits have been reduced based on the Section 382 limitations. The amount of the reduction in our deferred tax assets is based on the estimated amount of the NOL carryforwards and federal and state research credits we believe cannot be used based on the estimated amount of our Section 382 annual limitation. We have reduced our deferred tax assets by $15.0 million and have estimated that approximately $58.7 million and $37.8 million, respectively, of our federal and state NOL carryforwards for tax purposes cannot be used in future years as a result of this change in ownership. Additionally, we have estimated that approximately $2.2 million and $1.6 million of our federal and state research and development tax credits, respectively, cannot be used in future years due to the Section 382 limitation. If additional Section 382 changes occur, such as due to a merger or a similar transaction, limitations

against the utilization of net operating losses and tax credits could further reduce up to substantially all of our NOL and credit carryforwards and impact our future cash flows, but would not impact our 2018 consolidated financial statements, due to the existence of a full valuation allowance against our deferred tax assets.

The following table summarizes the activity related to our uncertain tax positions (in thousands):

	Year Ended December 31,	
	2018	2017
Balance at beginning of year	$23,270	$16,095
Additions based on tax positions related to the current year	—	5,134
Changes for prior period tax positions	108	2,041
Balance at end of year	$23,378	$23,270

Our uncertain tax positions relate to the apportionment of losses to California and to expenses qualifying for federal and state tax credits. In 2013, California adopted a single factor, sales, for apportioning income and losses to the state. However, we have filed our 2013 through 2017 California state tax returns utilizing a multiple factor apportionment based on salaries, property and sales in the state as most of our operations are in California. This position is based on a prior court ruling supporting the use of the multiple factor apportionment; however, this ruling was overturned by the California Supreme Court in December 2015. The ruling was filed with the U.S. Supreme Court, and in October 2016, the U.S. Supreme Court declined to hear the case. California has no regulations or guidance nor have there been any rulings addressing how a company with no sales should apportion losses to California.

We do not anticipate any significant changes in the amount of uncertain tax positions as of December 31, 2018 over the next twelve months; however, should California rule or provide guidance on apportionment to companies operating in the state, we would again recognize deferred tax assets for NOL carryforwards for losses apportioned to California based on such rule or guidance. Due to the full valuation allowance that we have on our net deferred tax asset balance, there are no uncertain tax positions that would impact the effective tax rate if recognized.

We are subject to U.S. federal, California and various other states and Chinese income taxes. We are no longer subject to U.S. federal or state income tax examination by tax authorities for tax returns filed for the years ended on or before December 31, 2014 and 2013, respectively. However, to the extent allowed by law, the taxing authorities may have the right to examine the period from 2003 through 2018 where NOL carryforwards or tax credits were generated and carried forward, and make adjustments to the amount of the NOL or tax credit carryforwards. We are not currently under examination by any federal or state jurisdictions.

9. Selected Quarterly Data (unaudited)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for 2018 and 2017 are as follows (in thousands, except per share data):

	For the Quarters Ended				
	March 31	June 30	September 30	December 31	Total Year
2018:					
Operating expenses	$14,492	$12,917	$ 12,064	$ 2,551	$42,024
Net loss	$(14,388)	$(12,682)	$ (11,941)	$ (2,464)	$(41,475)
Basic and diluted net loss per share (1)	$(0.34)	$(0.30)	$ (0.28)	$ (0.06)	$(0.98)
2017:					
Operating expenses	$12,687	$12,549	$ 12,639	$ 14,780	$52,655
Net loss	$(12,602)	$(12,407)	$ (12,481)	$ (14,588)	$(52,078)
Basic and diluted net loss per share (1)	$(0.39)	$(0.29)	$ (0.30)	$ (0.35)	$(1.31)

(1) Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per share calculations will not necessarily equal the annual per share calculation.

10. Severance Costs

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

During the twelve months ended December 31, 2018, we paid $2.1 million in severance benefits to separating employees related to the staff reduction plan. At December 31, 2018, unpaid severance costs of $254,000 are included in current liabilities in the condensed consolidated balance sheet and are expected to be paid by the end of the first quarter of 2019.

11. Subsequent Events

Exchange Agreement with Immunic AG

In January 2019, we entered into an exchange agreement with, Immunic AG, or Immunic, and all of the current shareholders of Immunic, or the Exchange Agreement, pursuant to which all of the Immunic shareholders will exchange all of their Immunic shares for shares of our common stock, with the result of Immunic becoming a wholly-owned subsidiary of the Company, which is referred to as the Transaction. Following the closing of the Transaction, the company, which will be renamed “Immunic, Inc.” and will focus on advancing Immunic’s pipeline of treatments for chronic inflammatory and autoimmune diseases. As a result of the exchange, Immunic shareholders are expected to own approximately 89% of the company subject to adjustment as provided in the Exchange Agreement.

Prior to entry into the Exchange Agreement, all current Immunic shareholders as well as certain of Immunic’s executive officers and directors entered into an Investment and Subscription Agreement, or the Subscription Agreement, with Immunic, pursuant to which certain Immunic shareholders have agreed, subject to the terms and conditions of such agreement, to invest, prior to the consummation of the Transaction, an aggregate amount of approximately €26.7 million, or approximately $30.5 million based on the exchange rate at December 31, 2018.

The issuance of the company common stock to be issued under the Exchange Agreement and certain related transactions must be approved by the company’s stockholders. There can be no assurance that such transactions will be approved by the stockholders or that the Transaction will be consummated.

Cancellation of Stock Options and Issuance of Stock Equity Awards

In an effort to maximize the cash on our balance sheet in the share exchange transaction with Immunic, in January 2019, the compensation committee of the board of directors, or the Committee, agreed and approved the restructuring of our executive officers' existing severance and change of control agreements. Among other things, the Committee approved (i) the cancellation of options for 3,100,614 shares having a weighted average exercise price of $6.53 and representing all the stock options held by such executive officers; (ii) grants of 5,100,000 restricted stock units, or RSUs, under the 2014 Plan to such executive officers; and (iii) amended the existing change of control and severance agreements with each of the executive officers to include a total reduction of $1.3 million in cash severance payments the executive officers would otherwise receive on a termination as a result of a change of control such as pursuant to the Transaction; all conditioned upon the executive officers agreeing to and entering into each of the agreements necessary to effectuate these transactions. Following Committee approval, each of the executive officers executed the respective amendments to their change of control and severance agreements, executed an option cancellation agreement, and received the RSU grants.

The RSU grants vest 25% annually over four years, however, the vesting accelerates and the grants fully vest on termination by the company without cause or the executive officer's resignation for good reason pursuant to the amended change of control and severance agreements. The RSUs can be settled in cash or shares of common stock solely at the company's discretion and the RSU's have a ten-year term.

CEO Termination

In January 2019, in an effort to further reduce operating costs, our board of directors notified Mr. Russell J. Cox, our chief executive officer at the time, that his employment with us would be terminated without cause and Mr. Cox submitted his resignation as a director to coincide with his termination date. Pursuant to his amended change of control and severance agreement, Mr. Cox will receive a lump sum cash payment equivalent to twelve months salary and the 1,854,376 restricted stock units held by Mr. Cox on his termination date vested.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Vital Therapies, Inc.

Date: March 4, 2019 By: /s/ Duane D. Nash
Duane D. Nash, M.D.
Chief Executive Officer and President

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Duane D. Nash and Michael V. Swanson, and each of them, his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ DUANE D. NASH Duane D. Nash, M.D.	Director, Chief Executive Officer and President (Principal Executive Officer)	March 4, 2019
/s/ MICHAEL V. SWANSON Michael V. Swanson	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 4, 2019
/s/ FAHEEM HASNAIN Faheem Hasnain	Chairman	March 4, 2019
/s/ CHERYL L. COHEN Cheryl L. Cohen	Director	March 4, 2019
/s/ LOWELL E. SEARS Lowell E. Sears	Director	March 4, 2019