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

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2019

OR

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: **001-38325**

Hancock Jaffe Laboratories, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**33-0936180**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

70 Doppler
Irvine, California 92618
(Address of principal executive offices)

(949) 261-2900
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading Symbol(s):	Name of Each Exchange on Which Registered:
Common Stock, $0.00001 par value	HJLI	The NASDAQ Stock Market LLC
Warrant to Purchase Common Stock	HJLIW	The NASDAQ Stock Market LLC

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 [x]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [_] No [x]

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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).
Yes [ ] No [X]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
		Emerging growth company	[X]

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. [X]

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2019 (the last business date of the registrant's most recently completed second fiscal quarter), based on the last sale price of the registrant's common stock on such date was $18,639,014.

As of March 16, 2020, there were 19,231,857 shares of common stock outstanding.

HANCOCK JAFFE LABORATORIES, INC.
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PART I

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains, or may contain, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission (or the SEC). Actual results (including, without limitation, the actual timing for and results of the clinical trials described herein, and FDA review of the Company's products in development) may differ significantly from those set forth in the forward-looking statements. These forward-looking statements involve risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

The following discussion should be read in conjunction with our financial statements and the related notes contained elsewhere in this Annual Report on Form 10-K and in our other Securities and Exchange Commission filings.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "we," "us," "our," "our company," "HJLI", or similar terminology refer to Hancock Jaffe Laboratories, Inc.

We use our registered trademarks and trade names, such as VenoValve® and CoreoGraft™, in this Annual Report on Form 10-K. This report also includes trademarks, trade names and service marks that are the property of other organizations, such as ProCol Vascular Bioprosthesis®. Solely for convenience, trademarks and trade names referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

ITEM 1. Business

Overview

Hancock Jaffe Laboratories, Inc. is a medical device company developing tissue based solutions that are designed to be life sustaining or life enhancing for patients with cardiovascular disease, and peripheral arterial and venous disease. The Company's products are being developed to address large unmet medical needs by either offering treatments where none currently exist or by substantially increasing the current standards of care. Our two lead products which we are developing are: the VenoValve®, a porcine based device to be surgically implanted in the deep venous system of the leg to treat a debilitating condition called chronic venous insufficiency ("CVI"); and the CoreoGraft®, a bovine based conduit to be used to revascularize the heart during coronary artery bypass graft ("CABG") surgeries. Both of our current products are being developed for approval by the U.S. Food and Drug Administration ("FDA"). We currently receive tissue for development of our products from one domestic supplier and one international supplier. Our current business model is to license, sell, or enter into strategic alliances with large medical device companies with respect to our products, either prior to or after FDA approval. Our current senior management team has been affiliated with more than 50 products that have received FDA approval or CE marking. We currently lease a 14,507 sq. ft. manufacturing facility in Irvine, California, where we manufacture products for our clinical trials and which has previously been FDA certified for commercial manufacturing of product.

Each of our product candidates will be required to successfully complete clinical trials and other testing to demonstrate the safety and efficacy of the product candidate before it will be approved by the FDA. The completion of these clinical trials and testing will require a significant amount of capital and the hiring of additional personnel.

Products

VenoValve

Background

Chronic venous disease ("CVD") is the world's most prevalent chronic disease. CVD is generally classified using a standardized system known as CEAP (clinical, etiological, anatomical, and pathophysiological). The CEAP system consists of seven clinical classifications (C0 to C6) with C5 to C6 being the most severe cases of CVD.

Chronic Venous Insufficiency ("CVI") is a subset of CVD and is generally used to describe patients with C4 to C6 CVD. CVI is a condition that affects the venous system of the leg causing pain, swelling, edema, skin changes, and ulcerations. The venous vasculature of the human leg includes the superficial venous system, the deep vein system, and the perforator system which connects the superficial veins and deep veins. In order for blood to return to the heart from the foot, ankle, and lower leg, the calf muscle pushes the blood up the veins of the leg and through a series of one-way valves. Each valve is supposed to open as blood passes through, and then close as blood moves up the leg to the next valve. CVI has two primary causes: obstruction, which occurs when a blood clot in the veins of the leg hardens and prevents the free flow of blood; and valvular incompetence which is usually the result of injury to the valves from blood clots, which occurs when the one-way valves in the leg do not close as they should, causing blood to flow in the wrong direction (reflux) and to pool in the lower leg, resulting in increased venous pressure (venous hypertension). CVI can occur in the superficial vein system, the deep vein system, or in both. The initial version of the VenoValve is being developed to treat CVI resulting from valvular incompetence in the deep vein system of the leg.

Estimates indicate that approximately 4.8 million people in the U.S. have C5 to C6 CVI including patients that develop venous leg ulcers from CVI (C6 patients). Over one million new severe cases of CVI occur each year in the U.S., mostly from patients who have experienced a deep vein thrombosis (blood clot). Of those patients suffering from severe CVI, approximately 55% (2.4 million) have reflux in the deep vein system, or both the deep vein system and the superficial vein system. The average patient seeking treatment of a venous ulcer spends as much as $30,000 a year on wound care, and the total direct medical costs from venous ulcer sufferers in the U.S. has been estimated to exceed $38 billion a year. Aside from the direct medical costs, severe CVI sufferers experience a significantly reduced quality of life. Daily activities such as preparing meals, housework, and personal hygiene (washing and bathing) become difficult due to reduced mobility. For many severe CVI sufferers, intense pain, which frequently occurs at night, prevents patients from getting adequate sleep. Severe CVI sufferers are known to miss about 40% more work days than the average worker. A high percentage of venous ulcer patients also experience severe itching, leg swelling, and an odorous discharge. Wound dressing changes which occur several times a week can be extremely painful. In addition, venous ulcers are very difficult to heal, and a significant percentage of venous ulcers remain unhealed for more than a year. Even if healed, recurrence rates for venous ulcers are known to be high (20% to 40%) within the first year.

The Opportunity

The VenoValve is a porcine based valve developed at HJLI to be implanted in the deep vein system of the leg to treat CVI. CVI occurs when the valves in the veins of the leg fail, causing blood to flow backwards and pool in the lower leg and ankle. The backwards flow of the blood is called reflux. Reflux results in increased pressure in the veins of the leg, known as venous hypertension. Venous hypertension leads to swelling, discoloration, severe pain, and open sores called venous ulcers. By reducing reflux, and lowering venous hypertension, the VenoValve has the potential to reduce or eliminate the symptoms of deep venous, severe CVI, including venous leg ulcers. The VenoValve is designed to be surgically implanted into the patient on an outpatient basis via a 5 to 6 inch incision in the upper thigh.

There are presently no FDA approved medical devices to address valvular incompetence, or effective treatments for deep venous CVI. Current treatment options include compression garments, or constant leg elevation. These treatments are generally ineffective for patients with severe deep venous CVI, as they attempt to alleviate the symptoms of CVI without addressing the underlying causes of the disease. In addition, we believe that compliance with compression garments and leg elevation is extremely low, especially among the elderly. Valve transplants from other parts of the body have been attempted, but with very-poor results. Many attempts to create substitute valves have also failed, usually resulting in early thromboses. The premise behind the VenoValve is that by reducing the underlying causes of CVI, reflux and venous hypertension, the debilitating symptoms of CVI will decrease, resulting in improvement in the quality of the lives of CVI sufferers.

There are approximately 2.4 million people in the U.S. that suffer from severe deep venous CVI due to valvular incompetence. The average person with a venous ulcer spends approximately $30,000 per year on wound care, resulting in approximately $38 billion of direct medical costs. For those venous ulcers that do heal, there is a 20% to 40% recurrence rate within one year.

Clinical Status

After consultation with the FDA, as a precursor to the U.S. pivotal trial, we are conducting a small first-in-man study for the VenoValve in Colombia. The first phase of the first-in-man Colombian trial included 10 patients. In addition to providing safety and efficacy data, the purpose of the first-in-man study is to provide proof of concept, and to provide valuable feedback to make any necessary product modifications or adjustments to our surgical implantation procedures for the VenoValve prior to conducting the U.S. pivotal trial. In December of 2018, we received regulatory approval from Instituto Nacional de Vigilancia de Medicamentos y Alimentos (“INVIMA”), the Colombian equivalent of the FDA. On February 19, 2019, we announced that the first VenoValve was successfully implanted in a patient in Bogota. Between April of 2019 and December of 2019, we successfully implanted VenoValves in 9 additional patients, completing the implantations for the first phase of the Colombian first-in-man study. Endpoints for the VenoValve first-in-man study include reflux, measured by doppler, a VCSS score used by the clinician to measure disease severity, and a VAS score used by the patient to measure pain.

On March 4, 2020, Dr. Jorge Hernando Ulloa, the Primary Investigator for the Company’s first-in-man VenoValve study in Colombia, presented updated VenoValve data at the 32nd Annual American Venous Forum meeting on Amelia Island, Florida. Dr. Ulloa’s presentation included data on eight VenoValve patients that are six months post VenoValve surgery (including one patient that is one year post surgery), two patients that are 90 days post-surgery, and one patient that is 60 days post-surgery. For the first patient to receive the VenoValve who is now one year post surgery, Reflux has improved 73% and is now normal, the severity of her CVI has improved 94%, and her pain has improved 75%. This patient showed continued improvement between her six month and one year visits. Because proper directional blood flow in the leg has been restored on a long term basis, the venous system has normalized and there are barely any manifestations of the disease for that patient. Overall, VenoValves have been implanted in 11 patients in Colombia. Across all 11 patients and when comparing pre-operative levels to data recorded at their most recent office visits, Reflux, VCSS Scores, and VAS scores have improved 51%, 61%, and 65% respectively. That includes one patient who is currently occluded, and whose VenoValve is currently not functioning as intended. VenoValve safety incidences have been unchanged since last reported, and include one (1) fluid pocket (which was as aspirated), intolerance from Coumadin anticoagulation therapy, and two (2) minor wound infections (treated with antibiotics).

HJLI has begun preparing for Pre-Investigational Device Exemption (“IDE”) discussions with the FDA, and hopes to file its IDE application seeking approval for the U.S. pivotal trial in the third quarter of 2020.

CoreoGraft

Background

Heart disease is the leading cause of death among men and women in the U.S. accounting for about 1 in every 4 deaths. Coronary heart disease is the most common type of heart disease, killing over 370,000 people each year. Coronary heart disease occurs when arteries around the heart become blocked or occluded, in most cases by plaque. Although balloon angioplasty with or without cardiac stents have become the norm if one or two arteries are blocked, coronary artery bypass surgery remains the treatment of choice for patients with multiple blocked arteries. Approximately 200,000 coronary artery bypass graft ("CABG") surgeries take place each year in the U.S. In the U.S., CABG surgeries are the most commonly performed cardiac procedure. CABG surgeries alone account for 55% of all cardiac surgeries, and CABG surgeries when combined with valve replacement surgeries account for approximately 62% of all cardiac surgeries. The next largest category accounts for 10% of cardiac surgeries. The number of CABG surgeries are expected to increase as the population continues to age. On average, three grafts are used for each CABG surgery.

Although CABG surgeries are invasive, improved surgical techniques over the years have lowered the fatality rate from CABG surgeries to between 1% and 3% prior to discharge from the hospital. Arteries around heart are accessed via an incision along the sternum known as a sternotomy. Once the incision is made, the sternum (chest) is divided ("cracked") to access the heart and its surrounding arteries.

CABG surgery is relatively safe and effective. In most instances, doctors prefer to use the left internal memory artery ("LIMA"), an artery running inside the ribcage and close to the sternum, to re-vascularize the left side of the heart. Use of the LIMA to revascularize the left descending coronary artery (known as the "widow maker") has become the gold standard for revascularizing the left side of the heart during CABG surgeries. For the right side of the heart, and where additional grafts are needed on the left side, the current standard of care is to harvest the saphenous vein from the patient's leg to be dissected into pieces and used as bypass grafts around the heart. Unfortunately, saphenous vein grafts ("SVGs") are not nearly as effective as the LIMA for revascularizing the heart. In fact, SVGs continue to be the weak link for CABG surgeries.

The saphenous vein harvest procedure is itself invasive. Either a long incision is made along the inner leg of the patient to harvest the vein, or the saphenous vein is extracted endoscopically. Regardless of the type of bypass procedure, bypass graft harvest remains an invasive and complication prone aspect of the CABG procedure. Present standard-of-care complications are described in recent published reports in major medical journals. The percentage of complications from the harvest procedure can be as high as 24%. This is mainly due to non-healing of the saphenous wound or development of infection in the area of the saphenous vein harvest site.

While the LIMA is known for excellent short term and long term patency rates, studies indicate that between 10% and 40% percent of SVGs that are used as conduits for CABG surgeries fail within the first year after the CABG surgery. A significant percentage fail within the first 30 days. At 10 years, the SVGs failure rate can be as high as 75%. When a graft fails, it becomes blocked or occluded, depriving the heart of blood flow. Mortality during the first year after bypass graft failure is very high, between 5% and 9%. For purposes of comparison, a 3% threshold is considered to be a high cardiac risk. In fact, a relatively recent study in Denmark has reported that mortality rates at 8 to 10 years after CABG surgery are as high as 60% to 80%. While a life expectancy of 8 to 10 years following CABG surgery may have been acceptable in the past, expectations have changed and with people now generally living longer, additional focus is now being placed on extending life expectancies following CABG surgeries.

Researchers have determined that there are two main causes of SVGs failure: size mismatch, and a thickening of the interior of the SVGs that begins immediately following the harvest procedure. Size mismatch occurs because the diameter of SVGs is often significantly larger than the diameter of the coronary arteries around the heart. This size mismatch causes flow disturbances, leading to graft thromboses and graft failure. The thickening of the cell walls of SVGs occur when a layer of endothelial cells on the inner surface of the SVGs are disturbed beginning at the harvesting procedure, starting a chain reaction which causes the cells to thicken and the inside of the graft to narrow, resulting in blood clots and graft failure.

The Opportunity

The CoreoGraft is a bovine based off the shelf conduit that could potentially be used to revascularize the heart during CABG surgery, instead of harvesting the saphenous vein from the patient’s leg. In addition to avoiding the invasive and painful SVGs harvest process, HJLI’s CoreoGraft more closely matches the size of the coronary arteries around the heart, eliminating graft failures that occur due to size mismatch. In addition, with no graft harvest needed, the CoreoGraft could also reduce or eliminate the inner thickening that burdens and leads to failure of the SVGs. It has been reported that SVGs have failure rates as high as 10% to 40% within one year of implantation when used as grafts for CABG surgery.

In addition to providing a potential alternative to SVGs, the CoreoGraft could be used when making grafts from the patients’ own arteries and veins is not an option. For example, patients with systemic arterial and vascular disease often do not have suitable vessels to be used as grafts. For other patients, such as women who have undergone radiation treatment for breast cancer and have a higher incidence of heart disease, using the LIMA may not be an option if the LIMA was damaged by radiation during breast cancer treatment. Another example are patients undergoing a second CABG surgery. Due in large part to early SVGs failures, patients may need a second CABG surgery. If the SVGs were used for the first CABG surgery, the patient may have insufficient veins to harvest. While the CoreoGraft may start out as a product for patients with no other options, if the CoreoGraft establishes good short term and long term patency rates, it could become the graft of first choice for all CABG patients in addition to the LIMA.

Approximately 200,000 CABG surgeries are performed each year in the U.S., representing more than 55% of all cardiac surgeries and accounting for between $15 Billion and $25 Billion in annual expenditures. With an average of three grafts used per surgery, we believe the potential U.S. addressable market for the CoreoGraft to be more than $2 Billion per year. There are currently no FDA approved prosthetic grafts for CABG surgeries.

Clinical Status

In January of 2020, we announced the results of a six month, nine sheep, animal feasibility study for the CoreoGraft. Bypasses were accomplished by attaching the CoreoGrafts from the ascending aorta to the left anterior descending artery, and surgeries were preformed both on-pump and off-pump. Partners for the feasibility study included the Texas Heart Institute, and American Preclinical Services.

Test subjects were evaluated via angiograms and flow monitors during the study, and a full pathology examination of the CoreoGrafts and the surrounding tissue was performed post necropsy.

The results from the feasibility study demonstrated that the CoreoGrafts remained patent (open) and fully functional at 30, 90, and 180 day intervals after implantation. In addition, pathology examinations of the grafts and surrounding tissue at the conclusion of the study showed no signs of thrombosis, infection, aneurysmal degeneration, changes in the lumen, or other problems that are known to plague and lead to failure of SVGs.

In addition to exceptional patency, pathology examinations indicated full endothelialization for grafts implanted for 180 days both throughout the CoreoGrafts and into the left anterior descending arteries. Endothelium is a layer of endothelial cells that naturally exist throughout healthy veins and arteries that acts as a barrier between blood and the surrounding tissue, which helps promote the smooth passage of blood. Endothelium are known to produce a variety anti-clotting and other positive characteristics that are essential to healthy veins and arteries. The presence of full endothelialization within the longer term CoreoGrafts indicates that the graft is being accepted and assimilated in a manner similar to natural healthy veins and arteries that exist throughout the vascular system and is an indication of long-term biocompatibility.

Since we believe the results of the CoreoGraft feasibility study were positive, HJLI will now explore the possibility of conducting a first-in-man study outside of the U.S., where the CoreoGrafts would be implanted and tested in humans.

Government Regulation

Our product candidates and our operations are subject to extensive regulation by the FDA, and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our product candidates are subject to regulation as medical devices in the United States under the Federal Food Drug and Cosmetic Act ("FFDCA"), as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FFDCA.

FDA Pre-market Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) pre-market notification, or approval of a FDA Premarket Approval ("PMA") application. Under the FFDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) pre-market notification requirement, manufacturers of most Class II devices are required to submit to the FDA a pre-market notification under Section 510(k) of the FFDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) pre-market notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA.

510(k) Marketing Clearance Pathway

The 510(k) clearance process is for proposed medical devices that are "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. Because each of our two lead products are unique, and we believe are not substantially equivalent to products already on the market, and because we believe that that the VenoValve and the CoreoGraft are Class III medical devices, we do not anticipate that the VenoValve or the CoreoGraft would be appropriate for 510(k) approval.

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed although some pre-amendment Class III devices for which FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If FDA accepts the application for review, it has 180 days under the FFDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval. Certain changes to an approved device, such as changes in manufacturing facilities, methods or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. We believe that the VenoValve and the CoreoGraft will require the approval of a PMA.

Clinical Trials in Support of PMA

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations, which govern investigational device labeling, prohibit promotion of the investigational device and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. We believe that both the VenoValve and the CoreoGraft will require IDE applications prior to human testing in the United States.

An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects. During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include: establishing registration and device listing with the FDA; QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process; labeling regulations and FDA prohibitions against the promotion of investigational products, or "off-label" uses of cleared or approved products; requirements related to promotional activities; clearance or approval of product modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices; medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur; correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FFDCA that may present a risk to health; the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and post-market surveillance activities and regulations.

Regulation Outside of the U.S.

Each country or territory outside of the U.S. has its own rules and regulations with respect to the manufacture, marketing and sale of medical devices. For example, in December of 2018, we received regulatory approval from Instituto Nacional de Vigilancia de Medicamentos y Alimentos ("INVIMA"), the Colombian equivalent of the U.S. Food and Drug Administration, for our first-in-human trial for the VenoValve in Colombia. At this time, other than the first-in-human trial in Colombia, we have not determined which countries outside of the U.S., if any, for which we will seek approval for our product candidates.

Our Competitive Strengths

We believe we will offer the cardiovascular device market a compelling value proposition with the launch of our two product candidates, if approved, for the following reasons:

- We have extensive experience of proprietary processing and manufacturing methodology specifically applicable to the design, processing, manufacturing and sterilization of our biologic tissue devices. We believe that our patents, which cover certain aspects of our devices and the processing methods of biologic valvular tissue as a "bioprosthetic" device, may provide an advantage over potential competitors.
- We operate a 14,507 square foot manufacturing facility in Irvine, California. Our facility is designed expressly for the manufacture of Class III tissue based implantable medical devices and is equipped for research and development, prototype fabrication, current good manufacturing practices, or cGMP, and manufacturing and shipping for Class III medical devices, including biologic cardiovascular devices.
- We have attracted senior executives who are experienced in research and development and who have worked on over 50 medical devices that have received FDA approval or CE marking. We also have the advantage of an experienced board of directors and scientific advisory board who will provide guidance as we move towards market launch.

Intellectual Property

We possess an extensive proprietary processing and manufacturing methodology specifically applicable to the design, processing, manufacturing and sterilization of biologic devices. This includes FDA compliant quality control and assurance programs, proprietary tissue processing technologies demonstrated to eliminate recipient immune responses, trusted relationship with abattoir suppliers, and a combination of tissue preservation and gamma irradiation that enhances device functions and guarantees sterility. We have filed patent applications for our VenoValve product and Implantable Vein Frame Two product with the U.S. Patent and Trademark Office though there is no assurance that patents will be issued. We also are working on new developments for our CoreoGraft product and expect to be filing for patent protection on that product as well.

Employees

As of March 16, 2020, we had 12 full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees.

Corporate Information

We were incorporated in Delaware on December 22, 1999. Our principal executive offices are located at 70 Doppler, Irvine, California, 92618, and our telephone number is (949) 261-2900. Our corporate website address is www.hancockjaffe.com. The information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

ITEM 1A. Risk Factors

Risks Related to Our Business and Strategy

We have incurred significant losses since our inception, expect to incur significant losses in the future and may never achieve or sustain profitability.

We have historically incurred substantial net losses, including net losses of $7,625,397, $13,042,709, $7,791,469 and $3,387,490 for the years ended December 31, 2019, 2018, 2017 and 2016, respectively. As a result of our historical losses, we had an accumulated deficit of $56,187,925 as of December 31, 2019. Our losses have resulted primarily from costs related to general and administrative expenses relating to our operations, as well as our research programs and the development of our product candidates. Currently, we are not generating revenue from operations, and we expect to incur losses for the foreseeable future as we seek to obtain regulatory approval for our product candidates. Additionally, we expect that our general and administrative expenses will increase due to the additional operational and reporting costs associated with being a public company as well as the projected expansion of our operations. We do not expect to generate significant revenue until any of our product candidates are licensed or sold, if ever. We may never generate significant revenue or become profitable. Even if we do achieve profitability, we may be unable to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve and subsequently sustain profitability could harm our business, financial condition, results of operations and cash flows.

We currently depend entirely on the successful and timely regulatory approval and commercialization of our two product candidates, which may not receive regulatory approval or, if any of our product candidates do receive regulatory approval, we may not be able to successfully commercialize them.

We currently have two lead product candidates (the CoreoGraft and the VenoValve) and our business presently depends entirely on our ability to license and/or sell our products to larger medical device companies. In order for our product candidates to succeed the products need to be approved by regulatory authorities, which may never happen. Our product candidates are based on technologies that have not been used previously in the manner we propose. Market acceptance of our product candidates will largely depend on our ability to demonstrate their relative safety, efficacy, cost-effectiveness and ease of use. We may not be able to successfully develop and commercialize our product candidates. If we fail to do so, we will not be able to generate substantial revenues, if any.

We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other jurisdictions, including the European Medicines Agency, or EMA, in the European Union, or EU. Our product candidates are currently in development and we have not received FDA approval for our product candidates. Our product candidates may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other jurisdictions until they have received approval from the appropriate foreign regulatory agencies. Each product candidate requires significant research, development, preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval.

Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our product candidates on a timely basis, or at all. The number, size, design and focus of preclinical and clinical trials that will be required for approval by the FDA, the EMA or any other foreign regulatory agency varies depending on the device, the disease or condition that the product candidates are designed to address and the regulations applicable to any particular products. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA and other foreign regulatory agencies can delay, limit or deny approval of a product for many reasons, including, but not limited to:

- a product candidate may not be shown to be safe or effective;
- the clinical and other benefits of a product candidate may not outweigh its safety risks;
- clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;
- the results of clinical trials may not meet the level of statistical significance required by regulatory agencies for approval;
- regulatory agencies may interpret data from pre-clinical and clinical trials in different ways than we do;
- regulatory agencies may not approve the manufacturing process or determine that the manufacturing is not in accordance with current good manufacturing practices, or cGMPs;
- a product candidate may fail to comply with regulatory requirements; and/or
- regulatory agencies might change their approval policies or adopt new regulations.

If our product candidates are not approved at all or quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long-term viability may be threatened.

We have experienced negative operating cash flows since our inception and have funded our operations primarily from proceeds received from sales of our capital stock, the issuance of the convertible and non-convertible notes, and the sale of our products to larger medical device companies. We will need to seek additional funds in the future through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings to complete our product development initiatives. These financings could result in substantial dilution to the holders of our common stock, or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material and adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern.

Our present and future capital requirements will be significant and will depend on many factors, including:

- the progress and results of our development efforts for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments;
- market acceptance of our product candidates;
- the rate of progress in establishing coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the ability to achieve revenue growth and improve gross margins;
- the extent to which we acquire or in-license other products and technologies; and
- legal, accounting, insurance and other professional and business-related costs.

We may not be able to acquire additional funds on acceptable terms, or at all. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.

If we do not have, or are not able to obtain, sufficient funds, we may be required to delay development or commercialization of our product candidates. We also may have to reduce the resources devoted to our product candidates or cease operations. Any of these factors could harm our operating results.

As a result of our current lack of financial liquidity, our independent registered accounting firm has expressed substantial doubt regarding our ability to continue as a going concern.

As a result of our current lack of financial liquidity, the report of our independent registered accounting firm that accompanies our audited financial statements for the year ended December 31, 2019 contains going concern qualifications, and our independent registered public accounting firm expressed substantial doubt regarding our ability to continue as a going concern over the next twelve months from the issuance of this Form 10-K, meaning that we may be unable to continue in operation for the foreseeable future or realize assets and discharge liabilities in the ordinary course of operations. Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

In order to continue as a going concern, we will need to, among other things, achieve positive cash flow from operations and, if necessary, seek additional capital resources to satisfy our cash needs. Our plans to achieve positive cash flow include engaging in offerings of equity and debt securities and negotiating up-front and milestone payments on our product candidates and royalties from sales of our product candidates that secure regulatory approval and any milestone payments associated with such approved product candidates. Our failure to obtain additional capital would have an adverse effect on our financial position, results of operations, cash flows, and business prospects, and ultimately on our ability to continue as a going concern.

A significant portion of our historical revenue came from royalty income earned from sales by LeMaitre Vascular, Inc. in accordance with a three-year royalty term that ended on March 18, 2019.

In March 2016, LeMaitre Vascular, Inc., or LMAT, a provider of peripheral vascular devices and implants, acquired our ProCol Vascular Bioprosthesis for its dialysis access line of products for an upfront payment and a three-year royalty. Royalty income is earned on sales by LMAT pursuant to this March 2016 asset sale agreement (“LMAT Agreement”), which three-year term ended on March 18, 2019. We have earned royalty income of $31,243 and $116,152 for the years ended December 31, 2019 and 2018, respectively, or 100% and 62%, respectively of our total revenue for these years. Since the three-year term ended on March 18, 2019, we will no longer generate royalty revenue until one of our product candidates is licensed, if ever.

We may never be able to generate sufficient revenue from the commercialization of our product candidates to achieve and maintain profitability.

Our ability to operate profitably in the future will depend upon, among other items, our ability to (i) fully develop our product candidates, (ii) scale up our business and operational structure, (iii) obtain regulatory approval of our product candidates from the FDA, (iv) market and sell our product candidates to larger medical device companies, (v) successfully gain market acceptance of our product candidates, and (vi) obtain sufficient and on-time supply of components from our third-party suppliers. If our product candidates are never successfully commercialized, we may never receive a return on our investments in product development, regulatory compliance, manufacturing and quality assurance, which may cause us to fail to generate revenue and gain economies of scale from such investments.

We utilize one domestic and one international third-party suppliers for porcine and bovine tissue for our two product candidates and the loss of one or both of these suppliers could have an adverse impact on our business.

We rely on one domestic and one international third-party vendors to supply porcine and bovine tissue for our two product candidates. Our ability to supply our current and future product candidates, if approved, commercially depends, in part, on our ability to obtain this porcine and bovine tissue in accordance with our specifications and with regulatory requirements and in sufficient quantities to meet demand. Our ability to obtain porcine and bovine tissue may be affected by matters outside our control, including that these suppliers may cancel our arrangements on short notice or have disruptions to their operations.

If we are required to establish additional or replacement suppliers for the porcine and bovine tissue, it may not be accomplished quickly and our operations could be disrupted. Even if we are able to find replacement suppliers, the replacement suppliers may need to be qualified and may require additional regulatory authority approval, which could result in further delay. In the event of a supply disruption, our product inventories may be insufficient to supply our customers and the development of any future product candidates would be delayed, limited or prevented, which could have an adverse impact on our business.

We depend upon third-party suppliers for certain components of our product candidates, making us vulnerable to supply problems and price fluctuations, which could harm our business.

We rely on a number of third-party suppliers to provide certain components of our product candidates. We do not have long-term supply agreements with most of our suppliers, and, in many cases, we purchase goods on a purchase order basis. Our suppliers may encounter problems for a variety of reasons, including unanticipated demand from larger customers, failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, quality or yield problems and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from defects, reliability issues or changes in components from suppliers;
- price fluctuations due to a lack of long-term supply arrangements for key components with our suppliers;
- errors in manufacturing components, which could negatively impact the effectiveness or safety of our product candidates or cause delays in shipment of our product candidates;
- discontinued production of components, which could significantly delay our production and sales and impair operating margins;
- inability to obtain adequate supplies in a timely manner or on commercially reasonable terms;
- difficulty locating and qualifying alternative suppliers, especially with respect to our sole-source supplies;
- delays in production and sales caused by switching components, which may require product redesign and/or new regulatory submissions;
- delays due to evaluation and testing of devices from alternative suppliers and corresponding regulatory qualifications;
- non-timely delivery of components due to our suppliers supplying products for a range of customers;
- the failure of our suppliers to comply with strictly enforced regulatory requirements, which could result in disruption of supply or increased expenses; and
- inability of suppliers to fulfill orders and meet requirements due to financial hardships.

In addition, there are a limited number of suppliers and third-party manufacturers that operate under the FDA's Quality System Regulation, or QSR, requirements, maintain certifications from the International Organization for Standardization that are recognized as harmonized standards in the European Economic Area, or EEA, and that have the necessary expertise and capacity to supply components for our product candidates. As a result, it may be difficult for us to locate manufacturers for our anticipated future needs, and our anticipated growth may strain the ability of our current suppliers to deliver products, materials and components to us. If we are unable to arrange for third-party manufacturing of components for our product candidates, or to do so on commercially reasonable terms, we may not be able to complete development of, market and sell our current or new product candidates. Further, any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components used in our product candidates would limit our ability to manufacture our product candidates. Failure to meet these commitments could result in legal action by our customers, loss of customers or harm to our ability to attract new customers, any of which could have a material and adverse effect on our business, financial condition, results of operations and growth.

If we successfully develop our product candidates and are unable to sell or license them to larger medical device companies, we may have to demonstrate to surgeons and hospitals the merits of our product candidates to facilitate adoption of our product candidates.

Surgeons continue to play a significant role in determining the devices used in the operating room and in assisting in obtaining approval by the relevant value analysis committee, or VAC. Educating surgeons on the benefits of our product candidates will require a significant commitment by a marketing team and sales organization. Surgeons and hospitals may be slow to change their practices because of familiarity with existing devices and/or treatments, perceived risks arising from the use of new devices, lack of experience using new devices, lack of clinical data supporting the benefits of such devices or the cost of new devices. There may never be widespread adoption of our product candidates by surgeons and hospitals. If surgeons and hospitals are not adequately educated about the advantages of our product candidates incorporating our technology, as compared to surgical methods which do not incorporate such technology, we may face challenges in obtaining approval by the relevant VAC, and we will not achieve significantly greater market acceptance of our product candidates, gain momentum in our sales activities, significantly grow our market share or grow our revenue and our business and financial condition will be adversely affected.

If larger medical device companies purchase or license any of our product candidates and they are unable to convince hospital facilities to approve the use of our product candidates, we may be unable to generate a substantial royalty income from our products.

In the United States, in order for surgeons to use our product candidates, the hospital facilities where these surgeons treat patients will typically require that the product candidates receive approval from the facility's VAC. VACs typically review the comparative effectiveness and cost of medical devices used in the facility. The makeup and evaluation processes for VACs vary considerably, and it can be a lengthy, costly and time-consuming effort to obtain approval by the relevant VAC. For example, even if the purchasers or licensees of our product candidates have an agreement with a hospital system for purchase of our products, in most cases, they must obtain VAC approval by each hospital within the system to sell at that particular hospital. Additionally, hospitals typically require separate VAC approval for each specialty in which our product is used, which may result in multiple VAC approval processes within the same hospital even if such product has already been approved for use by a different specialty group. VAC approval is often needed for each different product to be used by the surgeons in that specialty. In addition, hospital facilities and group purchasing organizations, or GPOs, which manage purchasing for multiple facilities, may also require the purchasers of licensees of our products to enter into a purchasing agreement and satisfy numerous elements of their administrative procurement process, which can also be a lengthy, costly and time-consuming effort. If our purchasers/licensees do not receive access to hospital facilities in a timely manner, or at all, via these VAC and purchasing contract processes, or otherwise, or if they are unable to secure contracts on commercially reasonable terms in a timely manner, or at all, their operating costs will increase, their sales may decrease and their operating results may be harmed.

We operate in a very competitive market environment and if we are unable to compete successfully against our potential competitors, our sales and operating results may be negatively affected.

The medical device industry is intensely competitive and subject to rapid and significant technological change, as well as the introduction of new products or other market activities of industry participants. Our ability to compete successfully will depend on our ability to develop future product candidates that reach the market in a timely manner, are well adopted by customers and receive adequate coverage and reimbursement from third-party payors.

We have numerous potential competitors, many of whom have substantially greater name recognition, commercial infrastructure and financial, technical and personnel resources than us. Our potential competitors develop and patent competing products or processes earlier than we can or obtain regulatory clearance or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar products or processes. Additionally, our potential competitors may, in the future, develop medical devices that render our product candidates obsolete or uneconomical.

Many of our current and potential competitors are publicly traded, or are divisions of publicly-traded, major medical device or technology companies that enjoy several competitive advantages. We face a challenge overcoming the long-standing preferences of some specialists for using the products of our larger, more established competitors. Specialists who have completed many successful procedures using the products made by these competitors may be reluctant to try new products from a source with which they are less familiar. If these specialists do not try and subsequently adopt our product candidates, we may be unable to generate sufficient revenue or growth. In addition, many of our competitors enjoy other advantages such as:

- greater financial resources for marketing and aggressive discounting;
- large and established sales, marketing and distribution networks with greater reach in both domestic and international markets;
- significantly greater brand recognition;
- established business and financial relationships with specialists, referring physicians, hospitals and medical schools;
- greater existing market share in our markets;
- greater resources devoted to research and development of competing products and greater capacity to allocate additional resources;
- greater experience in obtaining and maintaining regulatory clearances and approvals for new products and product enhancements;
- products supported by long-term clinical data;
- more expansive patent portfolios and other intellectual property rights; and
- broader product portfolios affording them greater ability to cross-sell their products or to incentivize hospitals or surgeons to use their products.

Our competitors may seek to obtain agreements, exclusive or otherwise, with the same partners or licensees that we intend to approach in order to develop and market our product candidates. In addition, our competitors may be able to meet these requirements and develop products that are comparable or superior to our product candidates or that would render our product candidates obsolete or non-competitive.

Our long-term growth depends on our ability to develop and commercialize additional product candidates.

The medical device industry is highly competitive and subject to rapid change and technological advancements. Therefore, it is important to our business that we continue to enhance our product candidate offerings and introduce new product candidates. Developing new product candidates is expensive and time-consuming. Even if we are successful in developing additional product candidates, the success of any new product candidates or enhancements to existing product candidates will depend on several factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new product candidates or enhancements in a timely manner;
- develop an effective and dedicated sales and marketing team;
- avoid infringing upon the intellectual property rights of third-parties;
- demonstrate, if required, the safety and efficacy of new product candidates with data from preclinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for new product candidates or enhancements;
- be fully FDA-compliant with marketing of new product candidates or modified product candidates;
- provide adequate training to potential users of our product candidates; and
- receive adequate coverage and reimbursement for procedures performed with our product candidates.

If we are unsuccessful in developing and commercializing additional devices in other areas, our ability to increase our revenue may be impaired.

New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and services that we plan to offer. Existing markets for surgical devices are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices. It is also important that we successfully introduce new, enhanced and competitive product candidates to meet our prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage our introduction of new product candidates. If potential customers believe that such product candidates will offer enhanced features or be sold for a more attractive price, they may delay purchases until such product candidates are available. We may also continue to offer older obsolete products as we transition to new product candidates, and we may not have sufficient experience managing transitions. If we do not successfully innovate and introduce new technology into our anticipated product lines or successfully manage the transitions of our technology to new product offerings, our revenue, results of operations and business could be adversely impacted.

Our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, industry standards, distribution reach or customer requirements. We anticipate that we will face strong competition in the future as current or future competitors develop new or improved product candidates and as new companies enter the market with novel technologies.

If we are unable to produce an adequate supply of our product candidates for use in our current and planned clinical trials or for commercialization because of our limited manufacturing resources or our facility is damaged or becomes inoperable, our regulatory, development and commercialization efforts may be delayed.

Our manufacturing resources for our product candidates are limited. We currently manufacture our product candidates for our research and development purposes at our manufacturing facility in Irvine, California. If our existing manufacturing facility experiences a disruption, we would have no other means of manufacturing our product candidates until we are able to restore the manufacturing capability at our current facility or develop alternative manufacturing facilities. Additionally, any damage to or destruction of our facilities or our equipment, prolonged power outage or contamination at our facilities would significantly impair our ability to produce our product candidates and prepare our product candidates for clinical trials.

Additionally, in order to produce our product candidates in the quantities that will be required for commercialization, we will have to increase or "scale up" our production process over the current level of production. We may encounter difficulties in scaling up our production, including issues involving yields, controlling and anticipating costs, quality control and assurance, supply and shortages of qualified personnel. If our scaled-up production process is not efficient or results in a product that does not meet quality or other standards, we may be unable to meet market demand and our revenues, business and financial prospects would be adversely affected. Further, third parties with whom we may develop relationships may not have the ability to produce the quantities of the materials we may require for clinical trials or commercial sales or may be unable to do so at prices that allow us to price our products competitively.

Our facility and 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 earthquakes, flooding, fire, vandalism and power outages, which may render it difficult to operate our business for some period of time. While we have taken precautions to safeguard our facilities, any inability to operate our business during such periods could lead to the loss of customers or harm to our reputation. We also possess insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

We currently have no sales and marketing infrastructure and if we are unable to successfully sell and/or license our product candidates to larger medical device companies, we may be unable to commercialize our product candidates on our own, if approved, and may never generate sufficient revenue to achieve or sustain profitability.

In order to commercialize products that are approved by regulatory agencies, our current business model is to license or sell our product candidates to large medical device companies. We may not be able to enter into license or sale agreements on acceptable terms or at all, which would leave us unable to progress our current business plan. Our ability to reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to maintain or reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of our product candidates, reduce or delay development programs, delay potential commercialization of our product candidates or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Moreover, even if we are able to maintain and/or enter into such collaborations, such collaborations may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- disagreements with collaborators might cause delays or termination of the research, development or commercialization of our product candidates, might lead to additional responsibilities for us with respect to such devices, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators could independently develop or be associated with products that compete directly or indirectly with our product candidates;
- collaborators could have significant discretion in determining the efforts and resources that they will apply to our arrangements with them, and thus we may have limited or no control over the sales, marketing and distribution activities;
- should any of our product candidates achieve regulatory approval, a collaborator with marketing and distribution rights to our product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to either find alternative collaborators (which we may be unable to do) or raise additional capital to pursue further development or commercialization of our product candidates on our own.

Our business would be materially or perhaps significantly harmed if any of the foregoing or similar risks comes to pass with respect to our key collaborations.

If it becomes necessary for us to establish a sales and marketing infrastructure, we may not realize a positive return on this investment. We would have to compete with established and well-funded medical device companies to recruit, hire, train and retain sales and marketing personnel. Once hired, the training process is lengthy because it requires significant education of new sales representatives to achieve the level of clinical competency with our products expected by specialists. Upon completion of the training, we expect our sales representatives would typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, or if our sales representatives do not achieve the productivity levels in the time period we expect them to reach, our revenue will not grow at the rate we expect and our business, results of operations and financial condition will suffer. Also, to the extent we hire sales personnel from our competitors, we may be required to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories. Any of these risks may adversely affect our ability to increase sales of our product candidates. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our product candidates, which would adversely affect our business, results of operations and financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities, limit sales of our existing product candidates and limit commercialization of any products that we may develop.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, distribution, and sale of medical devices. This risk exists even if a device is cleared or approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Manufacturing and marketing of our commercial devices and clinical testing of our product candidates under development, may expose us to product liability and other tort claims. Furthermore, surgeons may misuse our product candidates or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Regardless of the merit or eventual outcome, product liability claims may result in:

- significant litigation costs;
- decreased demand for our product candidates and any product candidates that we may develop;
- damage to our reputation;
- withdrawal of clinical trial participants;
- substantial monetary awards to trial participants, patients or other claimants;
- loss of revenue; and
- the inability to commercialize any product candidates that we may develop.

Although we intend to maintain liability insurance, the coverage limits of our insurance policies may not be adequate, and one or more successful claims brought against us may have a material adverse effect on our business and results of operations. If we are unable to obtain insurance in the future at an acceptable cost or on acceptable terms with adequate coverage, we will be exposed to significant liabilities.

We bear the risk of warranty claims on our product candidates.

We provide limited product warranties against manufacturing defects of the ProCol Vascular Bioprosthesis, including component parts manufactured by third parties. Our product warranty requires us to repair defects arising from product design and production processes, and if necessary, replace defective components. Thus far, we have not accrued a significant liability contingency for potential warranty claims.

If we experience warranty claims in excess of our expectations, or if our repair and replacement costs associated with warranty claims increase significantly, we will incur liabilities for potential warranty claims that may be greater than we expect. An increase in the frequency of warranty claims or amount of warranty costs may harm our reputation and could have a material adverse effect on our business, results of operations and financial condition.

The loss of our executive officers or our inability to attract and retain qualified personnel may adversely affect our business, financial conditions and results of operations.

Our business and operations depend to a significant degree on the skills, efforts and continued services of our executive officers who have critical industry experience and relationships. Although we have entered into employment agreements with our executive officers, they may terminate their employment with us at any time. Accordingly, these executive officers may not remain associated with us. The efforts of these persons will be critical to us as we continue to develop our product candidates and business. We do not carry key person life insurance on any of our management, which would leave our company uncompensated for the loss of any of our executive officers.

Further, competition for highly-skilled and qualified personnel is intense. As such, our future viability and ability to achieve sales and profit will also depend on our ability to attract, train, retain and motivate highly qualified personnel in the diverse areas required for continuing our operations. If we were to lose the services one or more of our current executive officers or if we are unable to attract, hire and retain qualified personnel, we may experience difficulties in competing effectively, developing and commercializing our products and implementing our business strategies, which could have a material adverse effect on our business, operations and financial condition.

Our ability to use our net operating loss carry-forwards and certain other tax attributes may be limited.

As of December 31, 2019 and 2018, we had available federal and state net operating loss carryforwards, or NOLs, of approximately $26.1 and $17.4 million, respectively. Pre-2018 federal and state NOLs carryovers may be carried forward for twenty years and begin to expire in 2029. Under the Tax Act, post-2017 federal NOLs can be carried forward indefinitely and the annual limit of deduction equals 80% of taxable income. As of December 31, 2019, we also had federal research and development tax credit carryforwards of approximately $0.2 million which begin to expire in 2027. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” (generally defined as a cumulative change in equity ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period) may be subject to limitations on its ability to utilize its NOLs and certain credit carryforwards to offset future taxable income and taxes. We are currently analyzing the tax impacts of any potential ownership changes on our federal NOLs and credit carryforwards. Future changes in our stock ownership, including this or future offerings, as well as other changes that may be outside of our control, could result in ownership changes. Our NOLs and credit carryforwards may also be limited under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets.

Risks Related to Regulatory Approval and Other Governmental Regulations

Our business and product candidates are subject to extensive governmental regulation and oversight, and our failure to comply with applicable regulatory requirements could harm our business.

Our product candidates and operations are subject to extensive regulation in the United States by the FDA and by regulatory agencies in other countries where we anticipate conducting business activities. The FDA regulates the development, testing, manufacturing, labeling, storage, record-keeping, promotion, marketing, sales, distribution and post-market support and reporting of medical devices in the United States. The regulations to which we are subject are complex and may become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, a company must, among other things, apply for and obtain Institutional Review Board, or IRB, approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an IDE application. Our product candidates are considered significant risk devices requiring IDE approval prior to investigational use. We may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the United States for any new devices we intend to market in the United States in the future. If we obtain such approvals, we may not be able to conduct studies which comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations. It is uncertain whether clinical trials will meet desired endpoints, produce meaningful or useful data and be free of unexpected adverse effects, or that the FDA will accept the validity of foreign clinical study data, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue.

Our product candidates may be subject to extensive governmental regulation in foreign jurisdictions, such as the EU, and our failure to comply with applicable requirements could cause our business, results of operations and financial condition to suffer.

In the EEA, our product candidates will need to comply with the Essential Requirements set forth in Medical Device Regulation. Compliance with these requirements is a prerequisite to be able to affix the CE mark to a product, without which a product cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE mark to our product candidates, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. The conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. The Notified Body would audit and examine the Technical File and the quality system for the manufacture, design and final inspection of our products. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure and quality management system audit conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical products after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical products and their manufacturers with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. However, the pre-approval and post-market clinical requirements are much more rigorous. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

The FDA regulatory approval, clearance and license process is complex, time-consuming and unpredictable.

In the United States, our product candidates are expected to be regulated as medical devices. Before our medical device product candidates can be marketed in the United States, we must submit, and the FDA must approve a PMA application. For the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. In addition, modifications to products that are approved through a PMA application generally need FDA approval. The time required to obtain approval, clearance or license by the FDA to market a new therapy is unpredictable but typically takes many years and depends upon many factors, including the substantial discretion of the FDA.

Our product candidates could fail to receive regulatory approval, clearance or license for many reasons, including the following:

- the FDA may disagree with the design or implementation of our clinical trials or study endpoints;
- we may be unable to demonstrate to the satisfaction of the FDA that our product candidates are safe and effective for their proposed indications or that our product candidates provide significant clinical benefits;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA for approval, clearance or license or may not support approval of a label that could command a price sufficient for us to be profitable;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the opportunity for bias in the clinical trials as a result of the open-label design may not be adequately handled and may cause our trial to fail;
- our product candidates may be subject to an FDA advisory committee review, which may be requested at the sole discretion of the FDA, and which may result in unexpected delays or hurdles to approval;
- the FDA may determine that the manufacturing processes at our facilities or facilities of third-party manufacturers with which we contract for clinical and commercial supplies are inadequate; and
- the approval, clearance or license policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we were to obtain approval, clearance or license, the FDA may grant approval, clearance or license contingent on the performance of costly post-marketing clinical trials, or may approve our product candidates with a label that does not include the labeling claims necessary or desirable for successful commercialization of our product candidates. Any of the above could materially harm our product candidates' commercial prospects.

Even if our product candidates are approved by regulatory authorities, if we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our product candidates, our product candidates could be subject to restrictions or withdrawal from the market.

The manufacturing processes, post-approval clinical data and promotional activities of any product candidate for which we or our collaborators obtain marketing approval will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of our product candidates is granted in the United States, the approval may be subject to limitations on the indicated uses for which the product candidates may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or effectiveness of the product. Later discovery of previously unknown and unanticipated problems with our product candidates, including but not limited to unanticipated severity or frequency of adverse events, delays or problems with the manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such product candidates or manufacturing processes, withdrawal of the product candidates from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for our product candidates or to manufacture, market or distribute our product candidates after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in the U.S. Congress that could significantly change the statutory provisions governing the regulation of medical devices or the reimbursement thereof. In addition, the FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our product candidates. For example, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance or approval. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to manufacture, market or distribute our product candidates or future products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional testing prior to obtaining clearance or approval;
- changes to manufacturing methods;
- recall, replacement or discontinuance of our systems or future products; or
- additional record keeping.

Any of these changes could require substantial time and cost and could harm our business and our financial results.

The highly publicized PIP scandal (use of non-medical grade silicone in breast implants) in 2010 led to publishing the first version of EU Medical Device Regulation (MDR) by European Commission in 2012. After 347 amendments by European Parliament in 2014, followed by various versions, the final version of the new EU Medical Device Regulation (MDR 2017/745) was published on May 5, 2017. The official entry to force of the MDR started on May 26, 2017 with the transition period of 3 years. The date of application of all existing and new medical devices under MDR is May 26, 2020; however, Notified Bodies are currently not accepted any new CE Mark applications under MDD (Medical Device Directives). All existing MDD CE certificates become void on May 26, 2024. EU requires that all existing and new medical device undergo assessment under MDR as if they are new product application.

The changes from EU Medical Device Directives (MDD) to Medical Device Regulation (MDR) are significant, with stricter clinical requirements and post-market surveillance, shift from pre-approval to Life-cycle approach, centralized EUDAMED database for public transparency (e.g. Periodic Safety Update Reports) and device registration, more device specific requirements (e.g. Common Specifications), legal liability for defective devices, etc. The QMS audit under MDR will be much more rigorous, including audits and assessment of suppliers and device testing. In addition, EU MDR introduces new stakeholders participating during the application review process, which will result in a longer and more burdensome assessment of our new products. The new stakeholders will include Medical Device Coordination Group (MDCG) established by Member States and Expert Panels appointed by European Union.

Further, under the FDA's Medical Device Reporting or MDR regulations, we are required to report to the FDA any incident in which our product candidates may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Any adverse event involving our products could result in future voluntary corrective actions, such as product actions or customer notifications, or regulatory authority actions, such as inspection, mandatory recall or other enforcement action. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our product candidates in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results.

Moreover, depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our product candidates, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, withdrawals or clearances or approvals or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our product candidates in the future.

We are required to report certain malfunctions, deaths and serious injuries associated with our product once approved by regulatory bodies, which can result in voluntary corrective actions or agency enforcement actions.

All manufacturers marketing medical devices in the EEA are legally bound to report incidents involving devices they produce or sell to the regulatory agency, or competent authority, in whose jurisdiction the incident occurred. Under the EU Medical Devices Directive (Directive 93/42/EEC), an incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. In addition, under the EU MDR, the manufacturers are obligated to publish Periodic Safety Update Report (annually for high risk devices) which will be uploaded to EUDAMED and require conformity assessment by Notified Bodies.

Malfunction or misuse of our product candidates could result in future voluntary corrective actions, such as recalls, including corrections (e.g., customer notifications), or agency action, such as inspection or enforcement actions. If malfunctions or misuse do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions or misuse, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products or the instructions for use for those products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, may distract management from operating our business, and may harm our business, results of operations and financial condition.

We are subject to federal, state and foreign healthcare laws and regulations, and a finding of failure to comply with such laws and regulations could have a material and adverse effect on our business.

Our operations are, and will continue to be, directly and indirectly affected by various federal, state or foreign healthcare laws, including, but not limited to, those described below. These laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert 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 False Claims Act. Violations of the federal Anti-kickback Statute may result in substantial civil or criminal penalties, including criminal fines of up to $25,000, imprisonment of up to five years, civil penalties under the Civil Monetary Penalties Law of up to $50,000 for each violation, plus three times the remuneration involved, civil penalties under the federal False Claims Act of up to $11,000 for each claim submitted, plus three times the amounts paid for such claims and exclusion from participation in the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, the government may impose penalties of not less than $5,500 and not more than $11,000, plus three times the amount of the damages that the government sustains due to the submission of a false claim and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- HIPAA, as amended by the HITECH Act, and their respective implementing regulations, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $50,000 per violation, not to exceed $1.5 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can bring a civil action to enjoin a HIPAA violation or to obtain statutory damages up to $25,000 per violation on behalf of residents of his or her state. HIPAA also imposes criminal penalties for fraud against any healthcare benefit program and for obtaining money or property from a healthcare benefit program through false pretenses and provides for broad prosecutorial subpoena authority and authorizes certain property forfeiture upon conviction of a federal healthcare offense. Significantly, the HIPAA provisions apply not only to federal programs, but also to private health benefit programs. HIPAA also broadened the authority of the U.S. Office of Inspector General of the U.S. Department of Health and Human Services to exclude participants from federal healthcare programs;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, or PPACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and their immediate family members. Manufacturers are required to submit reports to CMS by the 90th day of each calendar year. Failure to submit the required information may result in civil monetary penalties up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third- party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Any failure by us to ensure that our employees and agents comply with applicable state and foreign laws and regulations could result in substantial penalties or restrictions on our ability to conduct business in those jurisdictions, and our results of operations and financial condition could be materially and adversely affected.

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. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with surgeons and other healthcare providers, some of whom recommend, purchase and/or prescribe our product candidates, and our distributors, could be subject to challenge under one or more of such laws.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Regulatory healthcare reform measures and other legislative changes may have a material and adverse effect on business, results of operations and financial condition.

FDA regulations and guidance are often revised or reinterpreted by FDA and such actions may significantly affect our business and our product candidates. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times for our product candidates. Delays in receipt of, or failure to receive, regulatory approvals for our product candidates would have a material and adverse effect on our business, results of operations and financial condition.

In March 2010, the PPACA was signed into law, which includes a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, that began on January 1, 2013. Although a two year moratorium was placed on the medical device excise tax in 2016 and extended through December 31, 2019, it was permanently repealed on December 20, 2019. Other elements of the PPACA, including comparative effectiveness research, an independent payment advisory board and payment system reforms, including shared savings pilots and other provisions, may significantly affect the payment for, and the availability of, healthcare services and result in fundamental changes to federal healthcare reimbursement programs, any of which may materially affect numerous aspects of our business, results of operations and financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012, or the ATRA, was signed into law which further reduced Medicare payments to certain providers, including hospitals.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates, if approved, and services or additional pricing pressures.

Our relationships with physician consultants, owners and investors could be subject to additional scrutiny from regulatory enforcement authorities and could subject us to possible administrative, civil or criminal sanctions.

Federal and state laws and regulations impose restrictions on our relationships with physicians who are consultants, owners and investors. We may enter into consulting agreements, license agreements and other agreements with physicians in which we provide cash as compensation. We have or may have other written and oral arrangements with physicians, including for research and development grants and for other purposes as well.

We could be adversely affected if regulatory agencies were to interpret our financial relationships with these physicians, who may be in a position to influence the ordering of and use of our product candidates for which governmental reimbursement may be available, as being in violation of applicable laws. If our relationships with physicians are found to be in violation of the laws and regulations that apply to us, we may be required to restructure the arrangements and could be subject to administrative, civil and criminal penalties, including exclusion from participation in government healthcare programs, imprisonment, and the curtailment or restructuring of our operations, any of which could negatively impact our ability to operate our business and our results of operations.

Our company and many of our collaborators and potential collaborators are required to comply with the Federal Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act and implementing regulation affecting the transmission, security and privacy of health information, and failure to comply could result in significant penalties.

Numerous federal and state laws and regulations, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, govern the collection, dissemination, security, use and confidentiality of health information that identifies specific patients. HIPAA and the HITECH Act require our surgeon and hospital customers and potential customers to comply with certain standards for the use and disclosure of health information within their companies and with third parties. The Privacy Standards and Security Standards under HIPAA establish a set of standards for the protection of individually identifiable health information by health plans, health care clearinghouses and certain health care providers, referred to as Covered Entities, and the business associates with whom Covered Entities enter into service relationships pursuant to which individually identifiable health information may be exchanged. Notably, whereas HIPAA previously directly regulated only these Covered Entities, the HITECH Act makes certain of HIPAA's privacy and security standards also directly applicable to Covered Entities' business associates. As a result, both Covered Entities and business associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards.

HIPAA requires Covered Entities (like many of our customers and potential customers) and business associates to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. The HITECH Act expands the notification requirement for breaches of patient-identifiable health information, restricts certain disclosures and sales of patient-identifiable health information and provides for civil monetary penalties for HIPAA violations. The HITECH Act also increased the civil and criminal penalties that may be imposed against Covered Entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA.

Any new legislation or regulation in the area of privacy and security of personal information, including personal health information, could also adversely affect our business operations. If we do not comply with existing or new applicable federal or state laws and regulations related to patient health information, we could be subject to criminal or civil sanctions and any resulting liability could adversely affect our financial condition.

In addition, countries around the world have passed or are considering legislation that would impose data breach notification requirements and/or require that companies adopt specific data security requirements. If we experience a data breach that triggers one or more of these laws, we may be subject to breach notification obligations, civil liability and litigation, all of which could also generate negative publicity and have a negative impact on our business.

Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of some suppliers such as us from certain markets, which could have an adverse effect on our business, results of operations or financial condition.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to aggregate purchasing power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers, including us, from important market segments as GPOs, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal

pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our product candidates and may adversely impact our business, results of operations or financial condition.

If coverage and reimbursement from third-party payors for procedures using our product candidates significantly decline, surgeons, hospitals and other healthcare providers may be reluctant to use our product candidates and our sales may decline.

In the United States, healthcare providers who may purchase our product candidates, if approved, will generally rely on third-party payors, principally Medicare, Medicaid and private health insurance plans, to pay for all or a portion of the cost of our product candidates in the procedures in which they are employed. Because there is often no separate reimbursement for instruments and supplies used in surgical procedures, the additional cost associated with the use of our product candidates can impact the profit margin of the hospital or surgery center where the surgery is performed. Some of our target customers may be unwilling to adopt our product candidates in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse our customers for the procedures using our product candidates may make it difficult for existing customers to continue using, or adopt, our products and could create additional pricing pressure for us. We may be unable to sell our product candidates, if approved, on a profitable basis if third-party payors deny coverage or reduce their current levels of reimbursement.

To contain costs of new technologies, governmental healthcare programs and third-party payors are increasingly scrutinizing new and even existing treatments by requiring extensive evidence of favorable clinical outcomes. Surgeons, hospitals and other healthcare providers may not purchase our product candidates if they do not receive satisfactory reimbursement from these third-party payors for the cost of the procedures using our product candidates.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used. Because the cost of our product candidates generally will be recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates could directly impact the demand for our products. An example of payment updates is the Medicare program's updates to hospital and physician payments, which are done on an annual basis using a prescribed statutory formula. With respect to physician payments, in the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. In April 2015, however, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, was signed into law, which repealed and replaced the statutory formula for Medicare payment adjustments to physicians. MACRA provides a permanent end to the annual interim legislative updates that had previously been necessary to delay or prevent significant reductions to payments under the Medicare Physician Fee Schedule. MACRA extended existing payment rates through June 30, 2015, with a 0.5% update for July 1, 2015 through December 31, 2015, and for each calendar year through 2019, after which there will be a 0% annual update each year through 2025. In addition, MACRA requires the establishment of the Merit-Based Incentive Payment System, beginning in 2019, under which physicians may receive performance-based payment incentives or payment reductions based on their performance with respect to clinical quality, resource use, clinical improvement activities and meaningful use of electronic health records. MACRA also requires Centers for Medicare & Medicaid Services, or CMS, beginning in 2019, to provide incentive payments for physicians and other eligible professionals that participate in alternative payment models, such as accountable care organizations, that emphasize quality and value over the traditional volume-based fee-for-service model. It is unclear what impact, if any, MACRA will have on our business and operating results, but any resulting decrease in payment may result in reduced demand for our products.

Moreover, some healthcare providers in the United States have adopted or are considering a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may attempt to control costs by authorizing fewer surgical procedures or by requiring the use of the least expensive devices available. Additionally, as a result of reform of the U.S. healthcare system, changes in reimbursement policies or healthcare cost containment initiatives may limit or restrict coverage and reimbursement for our product candidates and cause our revenue to decline.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for laparoscopic procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales of our product candidates, if approved, may decline.

We are currently, and in the future may be, subject to various governmental regulations related to the manufacturing of our product candidates, and we may incur significant expenses to comply with, experience delays in our product commercialization as a result of, and be subject to material sanctions if we or our contract manufacturers violate these regulations.

Our manufacturing processes and facility are required to comply with the FDA's QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of our product candidates. Although we believe we are compliant with the QSRs, the FDA enforces the QSR through periodic announced or unannounced inspections of manufacturing facilities. We have been, and anticipate in the future being, subject to such inspections, as well as to inspections by other federal and state regulatory agencies. We are required to register our manufacturing facility with the FDA and list all devices that are manufactured. We also operate an International Organization for Standards, or ISO, 13485 certified facility and annual audits are required to maintain that certification. The suppliers of our components are also required to comply with the QSR and are subject to inspections. We have limited ability to ensure that any such third-party manufacturers will take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. Failure to comply with applicable FDA requirements, or later discovery of previously unknown problems with our products or manufacturing processes, including our failure or the failure of one of our third-party manufacturers to take satisfactory corrective action in response to an adverse QSR inspection, can result in, among other things:

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties;
- recall or seizure of our product candidates;
- total or partial suspension of production or distribution;
- the FDA's refusal to grant future clearance or pre-market approval for our product candidates;
- withdrawal or suspension of marketing clearances or approvals;
- clinical holds;
- warning letters;
- refusal to permit the import or export of our product candidates; and
- criminal prosecution of us or our employees.

Any of these actions, in combination or alone, could prevent us from marketing, distributing, or selling our products and would likely harm our business. In addition, a product defect or regulatory violation could lead to a government-mandated or voluntary recall by us. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could expose us to product liability or other claims, including contractual claims from parties to whom we sold products and harm our reputation with customers. A recall involving any of our product candidates would be particularly harmful to our business and financial results and, even if we remedied a particular problem, would have a lasting negative effect on our reputation and demand for our products.

Risks Related to Our Intellectual Property

If we are unable to adequately protect our proprietary technology or maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which could harm our business, financial condition and results of operations.

Our success may depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technologies. If we do not adequately protect our intellectual property and proprietary technologies, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We have filed patent applications for our VenoValve product and Implantable Vein Frame Two product with the U.S. Patent and Trademark Office but there are no assurances that patents will be issued. We also are working on new developments for our CoreoGraft product and expect to be filing for patent protection on that product as well.

Our patents may not have, or our pending patent applications that mature into issued patents may not include, claims with a scope sufficient to protect our products, any additional features we develop for our current products or any new products. Other parties may have developed technologies that may be related or competitive to our products, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our implant systems.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If any of these developments were to occur, they each could have a negative impact on our business and competitive position.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor’s or potential competitor’s product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, our financial position and results of operations could be negatively impacted. In addition, if a court found that valid, enforceable patents held by third parties covered one or more of our products, our financial position and results of operations could be harmed.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we will seek to protect, in part, by entering into confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission requirements, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payments such as maintenance and annuity fee payments and other provisions during the patent procurement process as well as over the life span of an issued patent. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. Our business, product candidates and methods could infringe the patents or other intellectual property rights of third parties.

The medical device industry is characterized by frequent and extensive litigation regarding patents and other intellectual property rights. Many medical device companies with substantially greater resources than us have employed intellectual property litigation as a way to gain a competitive advantage. We may become involved in litigation, interference proceedings, oppositions, reexamination, protest or other potentially adverse intellectual property proceedings as a result of alleged infringement by us of the rights of others or as a result of priority of invention disputes with third parties, either in the United States or internationally. We may also become a party to patent infringement claims and litigation or interference proceedings declared by the USPTO to determine the priority of inventions. Third parties may also challenge the validity of any of our issued patents and we may initiate proceedings to enforce our patent rights and prevent others from infringing on our intellectual property rights. Any claims relating to the infringement of third-party proprietary rights or proprietary determinations, even if not meritorious, could result in costly litigation, lengthy governmental proceedings, diversion of our management's attention and resources, or entrance into royalty or license agreements that are not advantageous to us. In any of these circumstances, we may need to spend significant amounts of money, time and effort defending our position. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material and adverse effect on us. If we are unable to avoid infringing the intellectual property rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of intellectual property in court or redesign our product candidates.

Our collaborations with outside scientists and consultants may be subject to restriction and change.

We work with scientists at academic and other institutions, and consultants who assist us in our research, development, and regulatory efforts, including the members of our medical advisory board. These scientists and consultants have provided, and we expect that they will continue to provide, valuable advice on our programs. These scientists and consultants are not our employees, may have other commitments that would limit their future availability to us and typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we will be unable to prevent them from establishing competing businesses or developing competing products. For example, if a key scientist acting as a principal investigator in any of our clinical trials identifies a potential product or compound that is more scientifically interesting to his or her professional interests, his or her availability to remain involved in our clinical trials could be restricted or eliminated.

We have entered into or intend to enter into non-competition agreements with certain of our employees. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. However, under current law, we may be unable to enforce these agreements against certain of our employees and it may be difficult for us to restrict our competitors from gaining the expertise our former employees gained while working for us. If we cannot enforce our employees' non-compete agreements, we may be unable to prevent our competitors from benefiting from the expertise of our former employees.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks or names. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential customers in our markets of interest. In addition, third parties may register trademarks similar and identical to our trademarks in foreign jurisdictions, and may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, results of operations and financial condition may be adversely affected.

Risks Related to Ownership of Our Securities

The market price of our securities may be highly volatile.

The trading price of our securities is likely to be volatile and could be subject to wide fluctuations in response to a variety of factors, which include:

- whether we achieve our anticipated corporate objectives;
- actual or anticipated fluctuations in our financial condition and operating results;
- changes in financial or operational estimates or projections;
- the development status of our product candidates and when our product candidates receive regulatory approval if at all;
- our execution of our sales and marketing, manufacturing and other aspects of our business plan;
- performance of third parties on whom we rely to manufacture our product candidate components and product candidates, including their ability to comply with regulatory requirements;
- the results of our preclinical studies and clinical trials;
- results of operations that vary from those of our competitors and the expectations of securities analysts and investors;
- our announcement of significant contracts, acquisitions or capital commitments;
- announcements by our competitors of competing products or other initiatives;
- announcements by third parties of significant claims or proceedings against us;
- regulatory and reimbursement developments in the United States and internationally;
- future sales of our common stock;
- product liability claims;
- healthcare reform measures in the United States;
- additions or departures of key personnel; and
- general economic or political conditions in the United States or elsewhere.

In addition, the stock market in general, and the stock of medical device companies like ours, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the issuer. These market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our capital stock and will be able to exert a controlling influence over our business affairs and matters submitted to stockholders for approval.

Our named officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own or control 3,900,165 shares of our common stock as of December 31, 2019, which in the aggregate represents approximately 21.7% of the outstanding shares of our common stock as of that date. As a result, if some of these persons or entities act together, they will have the ability to exercise significant influence over matters submitted to our stockholders for approval, including the election and removal of directors, amendments to our certificate of incorporation and bylaws, the approval of any business combination and any other significant corporate transaction. These actions may be taken even if they are opposed by other stockholders. This concentration of ownership may also have the effect of delaying or preventing a change of control of our company or discouraging others from making tender offers for our shares, which could prevent our stockholders from receiving a premium for their shares. Some of these persons or entities who make up our principal stockholders may have interests different from yours.

Our failure to meet the continued listing requirements of Nasdaq could result in a de-listing of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements, minimum stockholders' equity requirement or the minimum closing bid price requirement, Nasdaq may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with Nasdaq Marketplace Rules, but our common stock may not be listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the Nasdaq Marketplace Rules.

On October 14, 2019, we received notice from The NASDAQ Stock Market ("Nasdaq") indicating that, because the closing bid price for the Company's common stock had fallen below $1.00 per share for 30 consecutive business days, the Company no longer complies with the minimum bid price requirement for continued listing on the Nasdaq Capital Market under Rule 5550(a)(2) of Nasdaq Listing Rules. Nasdaq's notice has no immediate effect on the listing of the Company's common stock on the Nasdaq Capital Market. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A), the Company has been provided an initial compliance period of 180 calendar days, or until April 13, 2020, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days prior to April 13, 2020. If we are unable to resolve the situation to allow for continued listing on the Nasdaq Capital Market, this will result in a de-listing of our common stock.

Additionally, as of December 31, 2019, our stockholders' equity is $1.0 million and the Company no longer complies with the minimum stockholders' equity requirement of $2.5 million for continued listing on the Nasdaq Capital Market under Rule 5550(a)(2) of Nasdaq Listing Rules. We expect to receive a delisting notice from Nasdaq regarding this failure.

We will need to raise additional capital to meet our business requirements in the future, and such capital raising may be costly or difficult to obtain and can be expected to dilute current stockholders' ownership interests.

We will need to raise additional capital in the future. Such additional capital may not be available on reasonable terms or at all. Any future issuance of our equity or equity-backed securities may dilute then-current stockholders' ownership percentages. If we are unable to obtain required additional capital, we may have to curtail our growth plans or cut back on existing business.

We may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes, restricted stock, stock options and warrants, which may adversely impact our financial condition.

You may experience dilution of your ownership interests because of the future issuance of additional shares of common stock.

Any future issuance of our equity or equity-backed securities may dilute then-current stockholders' ownership percentages and could also result in a decrease in the fair market value of our equity securities, because our assets would be owned by a larger pool of outstanding equity. As stated above, we intend to conduct additional rounds of financing in the future and we may need to raise additional capital through public or private offerings of our common stock or other securities that are convertible into or exercisable for our common stock. We may also issue securities in connection with hiring or retaining employees and consultants (including stock options issued under an equity incentive plan), as payment to providers of goods and services, in connection with future acquisitions or for other business purposes. Our Board of Directors may at any time authorize the issuance of additional common stock without stockholder approval, subject only to the total number of authorized common shares set forth in our articles of incorporation. The terms of equity securities issued by us in future transactions may be more favorable to new investors, and may include dividend and/or liquidation preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect. Also, the future issuance of any such additional shares of common stock or other securities may create downward pressure on the trading price of the common stock. There can be no assurance that any such future issuances will not be at a price (or exercise prices) below the price at which shares of the common stock are then traded on Nasdaq or other then-applicable over-the-counter quotation system or exchange.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We may remain an emerging growth company until as late as December 2023 (the fiscal year-end following the fifth anniversary of the completion of our initial public offering), though we may cease to be an emerging growth company earlier under certain circumstances, including (1) 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 (2) if our gross revenue exceeds $1.07 billion in any fiscal year. Emerging growth companies may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors could find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also 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 of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore 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 exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Provisions of our charter documents or Delaware law could delay or prevent an acquisition of us, even if the acquisition would be beneficial to our stockholders, which could make it more difficult for you to change management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include, but are not limited to:

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director;
- a requirement that special meetings of the stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors;
- an advance notice requirement for stockholder proposals and nominations;
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our amended and restated certificate of incorporation.

In addition, the Delaware General Corporate Law, or DGCL, prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns, or within the last three years has owned, 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, the DGCL may discourage, delay or prevent a change in control of our company.

Furthermore, our amended and restated certificate of incorporation specifies that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of the DGCL by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future and, as such, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, and any future loan arrangements we enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

ITEM 1B. Unresolved Staff Comments

None

ITEM 2. Properties and Facilities

We lease a 14,507 square foot manufacturing facility in Irvine, California. We renewed our lease on September 20, 2017, effective October 1, 2017, for five years with an option to extend the lease for an additional 60-month term at the end of lease term. Our facility is designed expressly for the manufacture of biologic vascular grafts and is equipped for research and development, prototype fabrication, cGMP manufacturing and shipping for Class III medical devices, including biologic cardiovascular devices. We believe that our facilities are sufficient for the near future as there is present capacity to manufacture up to 24,000 venous valves per year to meet potential market demands.

ITEM 3. Legal Proceedings

From time to time we may be subject to litigation and arbitration claims incidental to its business. Such claims may not be covered by its insurance coverage, and even if they are, if claims against us are successful, they may exceed the limits of applicable insurance coverage.

On September 21, 2018, ATSCO, Inc., filed a complaint with the Superior Court seeking payment of $809,520 plus legal costs for disputed invoices to the Company dated from 2015 to June 30, 2018. The Company had entered into a Services and Material Supply Agreement ("Agreement"), dated March 4, 2016 for ATSCO to supply porcine and bovine tissue. The Company is disputing the amount owed and that the Agreement called for a fixed monthly fee regardless of whether tissue was delivered to the Company. On January 18, 2019, the Orange County Superior Court granted a Right to Attach Order and Order for Issuance of Writ of Attachment in the amount of $810,055. We contend at least $188,000 of the ATSCO claim relates to a wholly separate company, and over $500,000 of the claim is attributable to invoices sent without delivery of any tissue to the Company. The Company also believes it has numerous defenses and rights of setoff including without limitation: that ATSCO had an obligation to mitigate claimed damages, particularly when they were not delivering tissues; $188,000 of the amount that ATSCO is seeking are for invoices to Hancock Jaffe Laboratory Aesthetics, Inc. (in which the Company owns a minority interest of 28.0%) and is not the obligation of the Company; the Company has a right of setoff against any amounts owed to ATSCO for 120,000 shares of the Company's stock transferred to ATSCO's principal and owner; the yields of the materials delivered by ATSCO to the Company were inferior; and the Agreement was constructively terminated. On March 26, 2019, ATSCO filed a First Amended Complaint with the Superior Court increasing its claim to $1,606,820 plus incidental damages and interest, on the basis of an alleged additional oral promise not alleged in its original Complaint. The Company recently deposed ATSCO's sole owner and principal and believes that the merits of the Company's key defenses have been buttressed and supported as a result. While the Company expects and intends to continue a vigorous defense, the Company and ATSCO have recently agreed to proceed with informal settlement discussions. A trial date of July 20, 2020 has been set by the court. The Company recorded the disputed invoices in accounts payable and as of December 31, 2019, the Company believes that it has fully accrued for the outstanding claims against the Company. The Company has entered into new supply relationships with one domestic and one international company to supply porcine and bovine tissues.

On October 8, 2018, Gusrae Kaplan Nusbaum PLLC ("Gusrae") filed a complaint with the Supreme Court of the State of New York seeking payment of $178,926 plus interest and legal costs for invoices to the Company dated from November 2016 to December 2017. In July 2016, the Company retained Gusrae to represent the Company in connection with certain specific matters. The Company believes that Gusrae has not applied all of the payments made by the Company along with billing irregularities and errors and is disputing the amount owed. The Company recorded the disputed invoices in accounts payable and as of December 31, 2019, the Company has fully accrued for the outstanding claim against the Company.

ITEM 4. Mine and Safety Disclosure

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 began trading on The Nasdaq Capital Market under the symbol "HJLI" on May 31, 2018. Our warrants issued to the public in our initial public offering began trading on The Nasdaq Global Market under the symbol "HJLIW" on May 31, 2018.

Holders of Record

On March 16, 2020, the closing price per share of our common stock and listed warrants were $0.33 and $0.185, respectively as reported on The Nasdaq Capital Market. We had approximately 1,680 stockholders of record and 209 listed warrant holders of record as of January 21, 2020. On March 16, 2020 there were 19,231,857 shares of our common stock issued and outstanding and 5,749,239 shares of common stock issuable upon exercise of listed warrants issued and outstanding. In addition, we believe that a significant number of beneficial owners of our common stock and listed warrants hold their shares in street name.

Securities Authorized for Issuance under Equity Compensation Plan

Plan Category	Number of securities to issued upon exercise of outstanding options and restricted stock units	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	2,687,367	$ 4.44	2,237,118
Equity compensation plans not approved by security holders	-	-	-
	2,687,367	$ 4.44	2,237,118

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We do not anticipate paying cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects, the requirements of current or then-existing debt instruments and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None

Repurchases of Equity Securities by Our Company

None.

ITEM 6. Selected Financial Data

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide this information.

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

The following discussion should be read in conjunction with our consolidated financial statements and the related notes contained elsewhere in this Annual Report on Form 10-K and in our other Securities and Exchange Commission filings. The following discussion may contain predictions, estimates, and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These risks could cause our actual results to differ materially from any future performance suggested below.

Overview

Hancock Jaffe Laboratories, Inc. is a medical device company developing tissue based solutions that are designed to be life sustaining or life enhancing for patients with cardiovascular disease, and peripheral arterial and venous disease. The Company's products are being developed to address large unmet medical needs by either offering treatments where none currently exist or by substantially increasing the current standards of care. Our two lead products which we are developing are: the VenoValve®, a porcine based device to be surgically implanted in the deep venous system of the leg to treat a debilitating condition called chronic venous insufficiency; and the CoreoGraft®, a bovine based conduit to be used to revascularize the heart during coronary artery bypass graft surgeries. Both of our current products are being developed for approval by the U.S. Food and Drug Administration. We currently receive tissue for development of our products from one domestic supplier and one international supplier. Our current business model is to license, sell, or enter into strategic alliances with large medical device companies with respect to our products, either prior to or after FDA approval. Our current senior management team has been affiliated with more than 50 products that have received FDA approval or CE marking. We currently lease a 14,507 sq. ft. manufacturing facility in Irvine, California, where we manufacture products for our clinical trials and which has previously been FDA certified for commercial manufacturing of product.

Each of our product candidates will be required to successfully complete clinical trials and other testing to demonstrate the safety and efficacy of the product candidate before it will be approved by the FDA. The completion of these clinical trials and testing will require a significant amount of capital and the hiring of additional personnel.

We are in the process of developing the following bioprosthetic implantable devices for cardiovascular disease:

VenoValve

The VenoValve is a porcine based valve developed at HJLI to be implanted in the deep vein system of the leg to treat CVI. CVI occurs when the valves in the veins of the leg fail, causing blood to flow backwards and pool in the lower leg and ankle. The backwards flow of the blood is called reflux. Reflux results in increased pressure in the veins of the leg, known as venous hypertension. Venous hypertension leads to swelling, discoloration, severe pain, and open sores called venous ulcers. By reducing reflux, and lowering venous hypertension, the VenoValve has the potential to reduce or eliminate the symptoms of deep venous, severe CVI, including venous leg ulcers. The VenoValve is designed to be surgically implanted into the patient on an outpatient basis via a 5 to 6 inch incision in the upper thigh.

There are presently no FDA approved medical devices to address valvular incompetence, or effective treatments for deep venous CVI. Current treatment options include compression garments, or constant leg elevation. These treatments are generally ineffective for patients with severe deep venous CVI, as they attempt to alleviate the symptoms of CVI without addressing the underlying causes of the disease. In addition, we believe that compliance with compression garments and leg elevation is extremely low, especially among the elderly. Valve transplants from other parts of the body have been attempted, but with very-poor results. Many attempts to create substitute valves have also failed, usually resulting in early thromboses. The premise behind the VenoValve is that by reducing the underlying causes of CVI, reflux and venous hypertension, the debilitating symptoms of CVI will decrease, resulting in improvement in the quality of the lives of CVI sufferers.

There are approximately 2.4 million people in the U.S. that suffer from severe deep venous CVI due to valvular incompetence. The average person with a venous ulcer spends approximately $30,000 per year on wound care, resulting in approximately $38 billion of direct medical costs. For those venous ulcers that do heal, there is a 20% to 40% recurrence rate within one year.

After consultation with the FDA, as a precursor to the U.S. pivotal trial, we are conducting a small first-in-man study for the VenoValve in Colombia. The first phase of the first-in-man Colombian trial included 10 patients. In addition to providing safety and efficacy data, the purpose of the first-in-man study is to provide proof of concept, and to provide valuable feedback to make any necessary product modifications or adjustments to our surgical implantation procedures for the VenoValve prior to conducting the U.S. pivotal trial. In December of 2018, we received regulatory approval from Instituto Nacional de Vigilancia de Medicamentos y Alimentos ("INVIMA"), the Colombian equivalent of the FDA. On February 19, 2019, we announced that the first VenoValve was successfully implanted in a patient in Bogota. Between April of 2019 and December of 2019 we successfully implanted VenoValves in 9 additional patients, completing the implantations for the first phase of the Colombian first-in-man study. Endpoints for the VenoValve first-in-man study include reflux, measured by doppler, a VCSS score used by the clinician to measure disease severity, and a VAS score used by the patient to measure pain.

On March 4, 2020, Dr. Jorge Hernando Ulloa, the Primary Investigator for the Company's first-in-man VenoValve study in Colombia, presented updated VenoValve data at the 32nd Annual American Venous Forum meeting on Amelia Island, Florida. Dr. Ulloa's presentation included data on eight VenoValve patients that are six months post VenoValve surgery (including one patient that is one year post surgery), two patients that are 90 days post-surgery, and one patient that is 60 days post-surgery. For the first patient to receive the VenoValve who is now one year post surgery, Reflux has improved 73% and is now normal, the severity of her CVI has improved 94%, and her pain has improved 75%. This patient showed continued improvement between her six month and one year visits. Because proper directional blood flow in the leg has been restored on a long term basis, the venous system has normalized and there are barely any manifestations of the disease for that patient. Overall, VenoValves have been implanted in 11 patients in Colombia. Across all 11 patients and when comparing pre-operative levels to data recorded at their most recent office visits, Reflux, VCSS Scores, and VAS scores have improved 51%, 61%, and 65% respectively. That includes one patient who is currently occluded, and whose VenoValve is currently not functioning as intended. VenoValve safety incidences have been unchanged since last reported, and include one (1) fluid pocket (which was as aspirated), intolerance from Coumadin anticoagulation therapy, and two (2) minor wound infections (treated with antibiotics).

HJLI has begun preparing for IDE discussions with the FDA, and hopes to file its IDE application seeking approval for the U.S. pivotal trial in the third quarter of 2020.

CoreoGraft

The CoreoGraft is a bovine based off the shelf conduit that could potentially be used to revascularize the heart during CABG surgery, instead of harvesting the saphenous vein from the patient's leg. In addition to avoiding the invasive and painful SVGs harvest process, HJLI's CoreoGraft more closely matches the size of the coronary arteries around the heart, eliminating graft failures that occur due to size mismatch. In addition, with no graft harvest needed, the CoreoGraft could also reduce or eliminate the inner thickening that burdens and leads to failure of the SVGs. It has been reported that SVGs have failure rates as high as 10% to 40% within one year of implantation when used as grafts for CABG surgery.

In addition to providing a potential alternative to SVGs, the CoreoGraft could be used when making grafts from the patients' own arteries and veins is not an option. For example, patients with systemic arterial and vascular disease often do not have suitable vessels to be used as grafts. For other patients, such as women who have undergone radiation treatment for breast cancer and have a higher incidence of heart disease, using the LIMA may not be an option if the LIMA was damaged by radiation during breast cancer treatment. Another example are patients undergoing a second CABG surgery. Due in large part to early SVGs failures, patients may need a second CABG surgery. If the SVGs were used for the first CABG surgery, the patient may have insufficient veins to harvest. While the CoreoGraft may start out as a product for patients with no other options, if the CoreoGraft establishes good short term and long term patency rates, it could become the graft of first choice for all CABG patients in addition to the LIMA.

Approximately 200,000 CABG surgeries are performed each year in the U.S., representing more than 55% of all cardiac surgeries and accounting for between $15 Billion and $25 Billion in annual expenditures. With an average of three grafts used per surgery, we believe the potential U.S. addressable market for the CoreoGraft to be more than $2 Billion per year. There are currently no FDA approved prosthetic grafts for CABG surgeries.

In January of 2020, we announced the results of a six month, nine sheep, animal feasibility study for the CoreoGraft. Bypasses were accomplished by attaching the CoreoGrafts from the ascending aorta to the left anterior descending artery, and surgeries were preformed both on-pump and off-pump. Partners for the feasibility study included the Texas Heart Institute, and American Preclinical Services.

Test subjects were evaluated via angiograms and flow monitors during the study, and a full pathology examination of the CoreoGrafts and the surrounding tissue was performed post necropsy.

The results from the feasibility study demonstrated that the CoreoGrafts remained patent (open) and fully functional at 30, 90, and 180 day intervals after implantation. In addition, pathology examinations of the grafts and surrounding tissue at the conclusion of the study showed no signs of thrombosis, infection, aneurysmal degeneration, changes in the lumen, or other problems that are known to plague and lead to failure of SVGs.

In addition to exceptional patency, pathology examinations indicated full endothelialization for grafts implanted for 180 days both throughout the CoreoGrafts and into the left anterior descending arteries. Endothelium is a layer of endothelial cells that naturally exist throughout healthy veins and arteries that acts as a barrier between blood and the surrounding tissue, which helps promote the smooth passage of blood. Endothelium are known to produce a variety anti-clotting and other positive characteristics that are essential to healthy veins and arteries. The presence of full endothelialization within the longer term CoreoGrafts indicates that the graft is being accepted and assimilated in a manner similar to natural healthy veins and arteries that exist throughout the vascular system and is an indication of long-term biocompatibility.

Since we believe the results of the CoreoGraft feasibility study were positive, HJLI will now explore the possibility of conducting a first-in-man study outside of the U.S., where the CoreoGrafts would be implanted and tested in humans.

Results of Operations

Comparison of the year ended December 31, 2019 to the year ended December 31, 2018

Financial Highlights

We reported net losses of $7,625,397 and $13,042,709 for the years ended December 31, 2019 and 2018, respectively, representing a decrease in net loss of $5,417,312 or 42%, resulting from a decrease in amortization of debt discount of $6,562,736 (see below), a decrease in operating expenses of $603,969, a decrease of $348,076 in interest expense, net, partially offset by a decrease in the gain on extinguishment of convertible note payable of $1,481,317 (see below), an increase in the loss on impairment of $269,187 (see below), a decrease in the gain on the change in fair value of derivative liabilities of $191,656 (see below) and a decrease of gross profit of $155,309.

Revenues

Revenues earned during the year ended December 31, 2019 decreased by $155,309 to $31,243 from $186,552 for the year ended December 31, 2018 as royalty income and contract research – related party decreased by $84,909 and $70,400, respectively. Royalty income was earned pursuant to the terms of our March 2016 asset sale agreement with LeMaitre Vascular, Inc., which three-year term ended on March 18, 2019. Since March 18, 2019, we no longer generate royalty revenue and we do not expect to generate any other royalty revenues until one of our product candidates secure regulatory approval and is licensed or otherwise marketed, if ever. The contract research revenue is related to research and development services performed pursuant to a Development and Manufacturing Agreement dated April 1, 2016 (the "HJLA Agreement") with Hancock Jaffe Laboratory Aesthetics, Inc. ("HJLA") and no research and development services were performed during 2019.

As a developmental stage company, our revenue, if any, is expected to be diminutive and dependent on our ability to commercialize our product candidates.

Selling, General and Administrative Expenses

For the year ended December 31, 2019, selling, general and administrative expenses decreased by $1,571,340 or 24%, to $4,911,613 from $6,482,953 for the year ended December 31, 2018. The decrease is primarily due to a decrease of approximately $980,000 in non-cash stock compensation expense from fewer awards in 2019 of common stock and warrants to consultants and stock options and restricted stock units to employees and directors, decrease in severance expenses of $300,000 from the accrual in 2018 for the termination of the prior CFO, decrease in salaries and benefits of approximately $551,000 as certain personnel focused on research and development activities in 2019 (which is recorded as a research and development expense), partially offset by an increase of approximately $179,000 in insurance expenses primarily in D&O insurance from being a public company during the full year of 2019 as compared to being a private company for the first five months of 2018 and an increase in D&O premiums in 2019.

Research and Development Expenses

For the year ended December 31, 2019, research and development expenses increased by $967,371 or 78%, to $2,206,120 from $1,238,749 for the year ended December 31, 2018. The increase is primarily due to increased salaries and benefits expenses of $690,000 as certain personnel focused on research and development activities in 2019 and increased supplies, consulting, packaging and outside services of $240,000 associated with research and development activities supporting the first-in-human trials for the VenoValve occurring in Columbia, which started in February 2019, along with an increase of $66,000 in preclinical animal studies.

Interest (Income) Expense, Net

For the year ended December 31, 2019, interest (income) expense, net decreased by $348,076 or 117%, to $49,915 in interest income, net from $298,161 in interest expense, net for the year ended December 31, 2018, due to the conversion of the convertible notes issued during the period from June 2017 through January 2018 ("Notes") into shares of our common stock upon the consummation of our IPO on June 4, 2018. On this date, principal and interest totaling $5,743,391 owed in connection with the Notes were converted into 1,650,537 shares of our common stock at a conversion price of $3.50 per share. Interest income of $50,848 and $25,219 was earned during the year ended December 31, 2019 and 2018, respectively.

Net Gain on Extinguishment of Convertible Notes Payable

During the year ended December 31, 2018, we recognized non-cash gain on the extinguishment of convertible notes payable of $1,481,317. On February 28, 2018, the Notes were amended such that the maturity date was extended to May 15, 2018, the warrants issued in connection with the convertible notes issued in 2017 became exercisable for the number of shares of common stock equal to 100% of the total shares issuable upon conversion and the warrants issued in connection with the convertible notes issued in 2018 became exercisable for the number of shares of common stock equal to 75% of the total shares issuable upon the conversion. The amendment of the Notes was deemed to be a debt extinguishment. Since the Notes were converted on June 4, 2018 into common stock in connection with the Company's IPO, there was no extinguishment of convertible notes payable in the year ended December 31, 2019.

Amortization of Debt Discount

During the year ended December 31, 2018, we recognized non-cash amortization of debt discount expense of $6,562,736 related to the embedded conversion option in the Notes as well as the warrants issued with the Notes. Since the Notes were converted on June 4, 2018 into common stock in connection with the Company's IPO, there was no amortization of debt discount in the year ended December 31, 2019.

Change in Fair Value of Derivative Liability

For the year ended December 31, 2018, we recorded a gain on the change in fair value of derivative liabilities of $191,656. The derivative liabilities are related to warrants issued in connection with our Series A preferred stock and Series B preferred stock financings during the period of 2016 to 2017 ("Preferred Stock"), plus warrants issued in connection with the Notes, as well as the embedded conversion options in the Notes. Since the Notes and Preferred Stock were converted on June 4, 2018 into common stock in connection with the Company's IPO, there was no change in fair value of derivative liabilities in the year ended December 31, 2019.

Loss on Impairment

On May 10, 2013, the Company purchased United States Patent 7,815,677, "lntraparietal Aortic Valve Reinforcement Device and a Reinforced Biological Aortic Valve" from Leman Cardiovascular, S.A, which protects the critical design components and function relationships unique to the Company's bio-prosthetic heart valve ("BHV"). The BHV is a bioprosthetic, pig heart valve designed to function like a native heart valve and early clinical testing has demonstrated that the BHV may be suitable for the pediatric population, as it accommodates for the growth concomitant with the patient. In accordance with Accounting Standards Codification 360-10 - Impairment of Long-Lived and Disposable Assets, the Company is required to test for impairment if certain criteria are present. The Company determined during the fourth quarter 2019 that based on limited R&D resources that are currently devoted to the development of the VenoValve and CoreoGraft products, it unlikely to continue the development of the BHV in the near future. Therefore, the Company recorded an impairment loss of $588,822, equal to the remaining unamortized value of the BHV as of December 31, 2019.

On April 1, 2016, the Company acquired the exclusive rights to develop and manufacture a derma filler product for which HJLA holds a patent, for aggregate consideration of $445,200. The right to provide development and manufacturing services to HJLA expires on December 31, 2025. In accordance with Accounting Standards Codification 360-10 - Impairment of Long-Lived and Disposable Assets, the Company is required to test for impairment if certain criteria are present. The Company determined during the fourth quarter 2018 that based on limited R&D resources that are devoted to new product development, it will cease R&D activities with respect to this technology once the remaining contract research and development activities totaling $33,000 are

completed. Therefore, based on the expectation that without continued research and development it is highly unlikely that the Company will manufacture derma-fill for HJLA, the Company recorded an impairment loss of $319,635, equal to the remaining unamortized value as of December 31, 2018.

Deemed Dividend

We recorded a deemed dividend of $3,310,001 for the year ended December 31, 2018. The deemed dividend for the year ended December 31, 2018 resulted primarily from the 8% cumulative dividend on the Preferred Stock. Since the Preferred Stock were converted on June 4, 2018 into common stock in connection with the Company's IPO, there was no deemed dividend in the year ended December 31, 2019.

Liquidity and Capital Resources

We have incurred losses since inception and negative cash flows from operating activities for the year ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of $56,187,925. Since inception, we have funded our operations primarily through our IPO, private and public offerings of equity and private placement of convertible debt securities as well as modest revenues from royalties, contract research and sales of the ProCol Vascular Bioprosthesis.

Net cash used in operating activities for the year ended December 31, 2019 decreased by $459,438, or 7%, to $5,896,400 from $6,355,838 for the year ended December 31, 2018 from lower operating expenses and decreases in working capital for the year ended December 31, 2019 as compared to the comparable period in 2018.

Purchase of property and equipment for the year ended December 31, 2019 was $363,891 and primarily consisted of approximately $210,000 for software to manage compliance, reporting and risk management of the VenoValve clinical study by providing live access, tracking and multiple project management reports to enhance study data and metrics reporting, approximately $120,000 for Hydrodynamic Test System for measuring characteristics of the VenoValve, approximately $24,000 for computer equipment and software and approximately $11,000 for engineering design software. Purchase of property and equipment for the year ended December 31, 2018 was $12,422 for computer equipment and software.

On March 12, 2019, the Company raised $2,317,276 in net proceeds in the private placement offering of its common stock to certain accredited investors.

On June 14, 2019, the Company raised $3,319,656 in net proceeds in the public follow-on offering of its common stock.

We measure our liquidity in a variety of ways, including the following

	December 31, 2019	December 31, 2018
Cash (excluding restricted cash)	$ 1,307,231	$ 2,740,645
Working capital (deficiency)	$ (452,434)	$ 1,313,980

Based upon our cash and working capital as of December 31, 2019, we will require additional capital resources in order to meet our obligations as they become due within one year after the date of this Annual Report and sustain operations. These factors, among others, raise substantial doubt about our ability to continue as a going concern for the next twelve months from the issuance of this Form 10-K.

We will require significant amounts of additional capital to continue to fund our operations and complete our research and development activities. If we are not able to obtain additional cash resources, we will not be able to continue operations. We will continue seeking additional financing sources to meet our working capital requirements, to make continued investment in research and development and to make capital expenditures needed for us to maintain and expand our business. We may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on projects that are not successful, our ability to continue to support our business growth, continue research and to respond to business challenges could be significantly limited, or we may have to cease our operations. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

As a “smaller reporting company” as defined by Item 10 of Regulation S-K, we are not required to provide the information requested by paragraph (a)(5) of this Item.

Critical Accounting Policies and Estimates

Basis of Presentation

The accompanying audited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”).

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. Significant estimates and assumptions include the valuation allowance related to the Company’s deferred tax assets, and the valuation of warrants and derivative liabilities.

Investments

Equity investments over which the Company exercises significant influence, but does not control, are accounted for using the equity method, whereby investment accounts are increased (decreased) for the Company’s proportionate share of income (losses), but investment accounts are not reduced below zero.

The Company holds a 28.0% ownership investment, consisting of founders’ shares acquired at nominal cost, in HJLA. To date, HJLA has recorded cumulative losses. Since the Company’s investment is recorded at $0, the Company has not recorded its proportionate share of HJLA’s losses. If HJLA reports net income in future years, the Company will apply the equity method only after its share of HJLA’s net income equals its share of net losses previously incurred.

Net Loss per Share

The Company computes basic and diluted loss per share by dividing net loss attributable to common stockholders by the weighted average number of common stock outstanding during the period. Net loss income attributable to common stockholders consists of net loss, adjusted for the convertible preferred stock deemed dividend resulting from the 8% cumulative dividend on the Preferred Stock in 2018. Since the Preferred Stock were converted on June 4, 2018 into common stock in connection with the Company's IPO, there was no deemed dividend in the year ended December 31, 2019.

Basic and diluted net loss per common share are the same since the inclusion of common stock issuable pursuant to the exercise of warrants and options, plus the conversion of preferred stock or convertible notes, in the calculation of diluted net loss per common shares would have been anti-dilutive.

The following table summarizes net loss attributable to common stockholders used in the calculation of basic and diluted loss per common share:

	For the Years Ended December 31,	
	2019	**2018**
Net loss	$ (7,625,397)	$ (13,042,709)
Deemed dividend to Series A and B preferred stockholders	-	(3,310,001)
Net loss attributable to common stockholders	$ (7,625,397)	$ (16,352,710)

The following table summarizes the number of potentially dilutive common stock equivalents excluded from the calculation of diluted net loss per common share as of December 31, 2019 and 2018:

	December 31,	
	2019	**2018**
Shares of common stock issuable upon exercise of warrants	4,366,960	3,780,571
Shares of common stock issuable upon exercise of options and restricted stock units	2,687,367	2,883,256
Potentially dilutive common stock equivalents excluded from diluted net loss per share	7,054,327	6,663,827

Revenue Recognition

The Company recognizes revenue when goods or services are transferred to customers in an amount that reflects the consideration which it expects to receive in exchange for those goods or services. Revenue is recognized from contracts with customers either at a “point in time” or “over time”, depending on the facts and circumstances of the arrangement that the Company evaluates using the following five-step analysis: (i) identification of contract with customer; (ii) determination of performance obligations; (iii) measurement of the transaction price; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The following table summarizes the Company’s revenue recognized in the accompanying statements of operations:

	For the Years Ended December 31,	
	2019	**2018**
Royalty income	31,243	116,152
Contract research - related party	-	70,400
Total Revenues	$ 31,243	$ 186,552

Royalty income was earned pursuant to the terms of our March 2016 asset sale agreement with LeMaitre Vascular, Inc., which three-year term ended on March 18, 2019. After March 18, 2019, we will not receive any royalty revenue from LeMaitre Vascular, Inc.

Contract research – related party revenue is related to research and development services performed pursuant to a five-year Development and Manufacturing Agreement dated April 1, 2016 with HJLA.

Information on Remaining Performance Obligations and Revenue Recognized from Past Performance

Information about remaining performance obligations pertaining to contracts that have an original expected duration of one year or less is not disclosed. The transaction price allocated to remaining unsatisfied or partially unsatisfied performance obligations with an original expected duration exceeding one year was not material at December 31, 2019.

Contract Balances

The timing of our revenue recognition may differ from the timing of payment by our customers. A receivable is recorded when revenue is recognized prior to payment and the Company has an unconditional right to payment. Alternatively, when payment precedes the provision of the related services, deferred revenue is recorded until the performance obligations are satisfied. The Company had deferred revenue of $33,000 as of December 31, 2019 and December 31, 2018 related to cash received in advance for contract research and development services pursuant to the HJLA Agreement.

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and recognized over the period services are required to be provided in exchange for the award, usually the vesting period. Forfeitures of unvested stock options are recorded when they occur.

Concentrations

The Company maintains cash with major financial institutions. Cash held in United States bank institutions is currently insured by the Federal Deposit Insurance Corporation (“FDIC”) up to $250,000 at each institution. There were aggregate uninsured cash balances of $1,867,286 and $2,490,645 as of December 31, 2019 and 2018, respectively.

During the year ended December 31, 2019, 100% of the Company’s revenues were from royalties earned from the sale of product by LeMaitre. The three-year Post-Acquisition Supply Agreement from which the Company earned royalty from the sale of product by LeMaitre ended on March 18, 2019. During the year ended December 31, 2018, 62% of the Company’s revenues were from royalties earned from the sale of product by LeMaitre and 38% were from contract research revenue related to research and development services performed pursuant to the HJLA Agreement.

Subsequent Events

The Company evaluated events that have occurred after the balance sheet date through the date the financial statements were issued in the Form 10-K filed with the Securities and Exchange Commission. Based upon the evaluation and transactions, the Company did not identify any other subsequent events that would have required adjustment or disclosure in the financial statements, except as disclosed in Note 14 to the Financial Statements - Subsequent Events.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," ("ASU 2016-02"). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. ASU 2016-02 will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. As a result of the new standard, all of our leases greater than one year in duration will be recognized in our Balance Sheet as both operating lease liabilities and right-of-use assets upon adoption of the standard. We adopted the standard using the prospective approach.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects of the income tax accounting guidance, including requirements such as tax basis step-up in goodwill obtained in a transaction that is not a business combination, ownership changes in investments, and interim-period accounting for enacted changes in tax law. ASU 2019-12 is effective for public business entities for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years, and early adoption is permitted. We are currently evaluating the impact that this guidance will have on our consolidated financial statements.

ITEM 7A. Quantitative and Qualitative Disclosure About Market Risk

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide information required by this Item.

ITEM 8. Financial Statements and Supplementary Data

Please see the financial statements beginning on page F-1 following the signature pages in this Annual Report on Form 10-K and incorporated herein by reference.

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

Not Applicable.

ITEM 9A. Controls and Procedures

Evaluation of Controls and Procedures

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer (who is our Principal Executive Officer) and our Chief Financial Officer (who is our Principal Financial Officer and Principal Accounting Officer), of the effectiveness of the design of our disclosure controls and procedures (as defined by Exchange Act Rules 13a-15(e) or 15d-15(e)) as of December 31, 2019, pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2019 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure and are effective to provide reasonable assurance that such information is recorded, processed, summarized and reported within the time periods specified by the Securities and Exchange Commission's rules and forms.

Inherent Limitations on Effectiveness of Controls

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system will be met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there is only reasonable assurance that our controls will succeed in achieving their goals under all potential future conditions.

Management's Report on Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Exchange Act Rule 13a-15(d) during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Management, including the principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. Controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our management, including the principal executive officer and principal financial officer, we conducted an evaluation as to the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, our management used the criteria for effective internal control set forth by the Committee of Sponsoring Organizations of the Treadway Commission in the 2013 Internal Control – Integrated Framework. Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to a permanent exemption of the Commission that permits the Company to provide only management's report in this Annual Report on Form 10-K. Accordingly, our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2019 has not been audited by our auditors, Marcum LLP.

Item 9B. Other Information

Not Applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Listed below are the names of the directors and executive officers of the Company, their ages as of December 31, 2019, their positions held and the year they commenced service with the Company

Name	Age	Position(s) Held	Year of Service Commencement
Robert A. Berman	56	Director, Chief Executive Officer	2018
Francis Duhay, M.D.	59	Director	2018
Dr. Sanjay Shrivastava	52	Director	2018
Matthew M. Jenusaitis	58	Director	2019
Robert C. Gray	72	Director	2019
Marc H. Glickman, M.D.	70	Senior Vice President and Chief Medical Officer	2016
Robert Rankin	67	Chief Financial Officer, Secretary & Treasurer	2018

Robert A. Berman has served as our Chief Executive Officer and a member of our board of directors since April 2018. From September 2017 to March 2018, Mr. Berman worked as an independent strategic business consultant. From September 2012 to July 2017, he served as the President, Chief Executive Officer, and a member of the board of directors of ITUS Corporation (now called Anixa Biosciences), a Nasdaq listed company, that develops a liquid biopsy technology for early cancer detection. Prior to ITUS Corporation, Mr. Berman was the Chief Executive Officer of VIZ Technologies, a start-up company which developed and licensed a beverage dispensing cap, and he was the founder of IP Dispute Resolution Corporation, a company focused on intellectual property licensing. From 2000 to March 2007, Mr. Berman was the Chief Operating Officer and General Counsel of Acacia Research Corporation, which was a publicly traded company engaged in the licensing and enforcement of patented technologies. Mr. Berman was a Director of Business Development at QVC where he developed and selected products for on-air sales and distribution. Mr. Berman started his career at the law firm of Blank Rome LLP. He has a Bachelor of Science in Entrepreneurial Management from the Wharton School of the University of Pennsylvania and holds a Juris Doctorate degree from the Northwestern University Pritzker School of Law, where he serves as an adjunct faculty member. We believe Mr. Berman is qualified to serve as a member of our board of directors because of his experience in broad variety of areas including healthcare, finance, acquisitions, marketing, compliance, turnarounds, and the development and licensing of emerging technologies.

Dr. Francis Duhay has served as member of our board of directors since October 2018. A trained cardiac and thoracic surgeon, has served the President and Chief Operating officer of Aegis Surgical Inc. and Atrius Inc., makers of cardiac accessory devices, since 2016, and as a Partner in K5_Ventures, an early stage venture fund since 2017. Dr. Duhay is the former Chief Medical Officer at Edwards Life Sciences, a world leader in heart valve products, where he led medical and clinical affairs for transcatheter and surgical heart valves. During his tenure at Edwards Life Sciences, from 2008 to 2016, Dr. Duhay led the preparation and submission, and ultimate regulatory approval, of two FDA Premarket Approval (PMA) applications for transcatheter and surgical heart valve therapies and was responsible for the design and execution of the applicable clinical trials. Dr. Duhay was also the Vice President and General Manager of the Ascendra™ transcatheter heart valve business unit at Edwards, where he grew the unit from sixteen to eighty employees and contributed to annual growth in sales from $3 million to $250 million. From 1998 to 2003, Dr. Duhay served as the Chief of the Department of Cardiothoracic Surgery and Cardiology at Kaiser Permanente. Dr. Duhay has also served as an industry representative and clinical expert, and a member of the working group for ISO 5840, the international quality standard for the design, development, and testing of heart valves. Dr. Duhay received his MBA from the University of Hawaii - Shidler College of Business and received his board certification for Cardiothoracic Surgery and General Surgery from the Duke University School of Medicine and from the University of California, San Francisco, respectively. We believe that Dr. Duhay is qualified to serve as a member of our board of directors because he is a trained cardiac and thoracic surgeon and former Chief Medical Officer at Edwards Life Sciences.

Dr. Sanjay Shrivastava has served as a member of our board of directors since October 2018. He has been involved in developing, commercializing, evaluating, and acquiring medical devices for more than 18 years, including serving in Chief Executive Officer and board of director positions at several medical device start-ups, and leadership positions in research and development, business development, and marketing at BTG (from 2017 to 2018), Medtronic (2007 to 2017), Abbott Vascular (2003 to 2007), and Edwards Life Sciences (2000 to 2003). He is presently the Vice President of Marketing and Business Development at U.S. Vascular, LLC and a co-founder and board member of BlackSwan Vascular, Inc. While working as a vice president, upstream marketing and strategy at BTG, a medical device and specialty pharmaceutical company with annual revenue of about $800 million, Dr. Shrivastava worked on several acquisition and investment deals. At Medtronic, Dr. Shrivastava was the Director of Global Marketing for the Cardiac and Vascular Group where he helped build the embolization business, from its initiation to a substantial revenue with a very high CAGR over a period of six years. Dr. Shrivastava was a Manager of Research and Development for the peripheral vascular business at Abbott Vascular and a Principal Research and Development Engineer for Trans-Catheter heart valves at Edwards Life Sciences. Dr. Shrivastava received his Bachelor of Science in engineering at the Indian Institute of Technology, and his Doctorate of Philosophy in materials science and engineering from the University of Florida. We believe that Dr. Shrivastava is qualified to serve as a member of our board of directors because of having served in Chief Executive Officer and board of director positions at several medical device start-ups, and leadership positions in research and development, business development, and marketing at BTG, Medtronic, Abbott Vascular, and Edwards Life Sciences.

Matthew M. Jenusaitis has served as a member of our board of directors since September 2019. He has over 30 years of health care experience with an emphasis on building and selling companies that develop medical devices to treat vascular diseases. Since March 2015, Mr. Jenusaitis has been the Chief of Staff and Chief of Innovation and Transformation for the UC San Diego Health System. From June 2009 to March 2015, Mr. Jenusaitis was President and CEO of OCTANe Foundation for Innovation, a non-profit focused on the development of innovation in Orange County, CA. Over the course of his career, Mr. Jenusaitis has been on the board of directors of Pulsar Vascular (2008-2017), which was sold to Johnson and Johnson, Creagh Medical (2008-2015), which was sold to SurModics, and Precision Wire Components (2009-2014), which was sold to Creganna Medical. Mr. Jenusaitis was also a Senior Vice President at ev3 (April 2006 to July 2008), which was sold to Covidian and later purchased by Medtronics. In addition, Mr. Jenusaitis was the President of the Peripheral Division at Boston Scientific (July 2003 to August 2005) and was an Executive in Residence at Warburg Pincus (September 2005 to March 2006). Mr. Jenusaitis has an MBA from the University of California, Irvine, a Masters Degree in Biomedical Engineering from Arizona State University, and a Bachelors Degree in Chemical Engineering from Cornell University. We believe that Mr. Jenusaitis is qualified to serve as a member of our board of directors because of over 30 years of health care experience with an emphasis on building and selling companies that develop medical devices to treat vascular diseases and his prior board experiences.

Robert C. Gray has served as a member of our board of directors since September 2019. He had a 20-year career at Highmark, Inc., one of America's largest health insurance organizations, which serves over 20 million subscribers, and includes Highmark Blue Cross Blue Shield Pennsylvania, Highmark Blue Cross Blue Shield Delaware, and Highmark Blue Cross Blue Shield West Virginia, which he retired from in 2008. While at Highmark, Mr. Gray helped increase revenues to $12.3 billion from $6.9 billion, and helped generate an operating gain of $375 million from an operating loss of $91 million. In addition to being the board chairman, Chief Executive Officer, and President of several of Highmark's subsidiaries and affiliated companies, Mr. Gray was the Chief Financial Officer of Highmark's parent company and was the primary contact to Highmark's board of directors for Highmark's audit, investment and compensation (incentive plans) committees. His many responsibilities at Highmark included rate setting and reimbursement negotiations. Following Highmark, Mr. Gray co-founded U.S. Holdings LLC (U.S. Implants LLC.), a national distributor of orthopedic implants, and has served as Vice President since 2009. Since 2011, Mr. Gray has also been self-employed as a strategy and financial consultant. Mr. Gray engaged in Postgraduate Studies at the University of North Carolina–Chapel Hill and has an undergraduate degree from Bucknell University. We believe that Mr. Gray is qualified to serve as a member of our board of directors because of his financial and medical reimbursement expertise having served as the Chief Financial Officer at Highmark, Inc., one of America's largest health insurance organization.

Marc H. Glickman, M.D. has served as our Senior Vice President and Chief Medical Officer since May 2016 and served as member of our board of directors from July 2016 to August 2017. In 1981, Dr. Glickman started a vascular practice in Norfolk, Virginia. He established the first Vein Center in Virginia and also created a dialysis access center. He was employed by Sentara Health Care as director of Vascular Services until he retired in 2014. Dr. Glickman is a board certified vascular surgeon. Dr. Glickman received his Doctor of Medicine from Case Western Reserve, in Cleveland, Ohio and completed his residency at the University of Washington, Seattle. He is board certified in Vascular Surgery and was the past president of the Vascular Society of the Americas. He has served on the advisory boards of Possis Medical, Cohesion Technologies, Thoratec, GraftCath, Inc., TVA medical, Austin, Texas.

Robert Rankin has served as our Chief Financial Officer since July 2018. Mr. Rankin has more than twenty years of relevant experience helping to shape the operations and financial health of companies across multiple industries. Prior to joining our company, from November 2015 to December 2017, Mr. Rankin was the Chief Financial Officer of Horsburgh & Scott, a privately held company focused on the design, engineering, manufacturing and repair of heavy duty quality gears and gearboxes. From November 2009 to December 2014, Mr. Rankin was Chief Financial Officer, Chief Operating Officer and Secretary of Process Fab, Inc., a privately held engineering, design and manufacturing firm that provides flight hardware, ground support equipment and tooling to the spaceflight, aerospace and defense markets. Mr. Rankin also served as Vice President of Finance of TBGA LLC, the post-acquisition parent company of Process Fab, Inc., from December 2014 to August 2015. Prior to Process Fab, Inc., from 2004 to 2008, Mr. Rankin served as Chief Financial Officer, Chief Operating Officer and Director of the House of Taylor Jewelry, Inc. and Chief Financial Officer of Small World Kids, Inc., both publicly traded companies. Other experience as Chief Financial Officer for publicly traded companies included serving as Chief Financial Officer from 1992 to 1998 of DeCrane Aircraft Holdings, Inc. Mr. Rankin holds a Masters of Science degree in Industrial Administration from the Tepper School of Business at Carnegie Mellon University and a Bachelors of Science degree in Mechanical Engineering from Carnegie Mellon University.

Family Relationships

There are no arrangements between our directors and any other person pursuant to which our directors were nominated or elected for their positions. There are no family relationships between any of our directors or executive officers.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and ten percent stockholders to file initial reports of ownership and reports of changes in ownership of our common stock with the Commission. Directors, executive officers and ten percent stockholders are also required to furnish us with copies of all Section 16(a) forms that they file. Based upon a review of these filings, we believe that all required Section 16(a) reports were made on a timely basis during fiscal year 2019 other than as follows:

Matthew M. Jenusaitis failed to file a Form 3 reporting his security holdings prior to becoming a director in September 2019 and failed to file a Form 4 reporting the grant pursuant to Rule 16b-3(d) of (i) an option to purchase 60,000 shares of the Company's common stock which vests quarterly in equal amounts over a three year period with an exercise price of $2.00 per share and (ii) $75,000 of restricted stock units which vests annually in equal amounts over a three year period.

Board Composition

Our business and affairs are organized under the direction of our board of directors, which currently consists of five members. Our directors hold office until the earlier of their death, incapacity, removal or resignation, or until their successors have been elected and qualified. Our board of directors does not have a formal policy on whether the roles of a Chief Executive Officer and Chairman of our board of directors should be separate. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis. Our bylaws provide that the authorized number of directors may be changed only by resolution of the board of directors.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Our amended and restated certificate of incorporation divides our board of directors into three classes, with staggered three-year terms, as follows:

Class I Directors (serving until the 2021 Annual Meeting of Stockholders, or until their earlier death, disability, resignation or removal):

Dr. Francis Duhay* and Dr. Sanjay Shrivastava*

Class II Directors (serving until the 2022 Annual Meeting of Stockholders, or until their earlier death, disability, resignation or removal):

Matthew M. Jenusaitis*, Robert A. Berman

Class III Director (serving until the 2020 Annual Meeting of Stockholders, or until his earlier death, disability, resignation or removal):

Robert C. Gray*

(*) Independent Director.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently five members. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock.

Director Independence

The Nasdaq Marketplace Rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq Marketplace Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act.

Under Rule 5605(a)(2) of the Nasdaq Marketplace Rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 of the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has reviewed the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of Dr. Duhay, Mr. Gray, Mr. Jenusaitis and Dr. Shrivastava is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. Our board of directors also determined that Mr. Gray, Mr. Jenusaitis and Dr. Shrivastava will serve on our audit committee, Mr. Gray and Mr. Jenusaitis and Dr. Shrivastava will serve on our compensation committee, and Dr. Duhay, Mr. Jenusaitis and Dr. Shrivastava will serve on our nominating and corporate governance committee, and that each of the committees satisfy the independence standards for such committees established by the SEC and the Nasdaq Marketplace Rules, as applicable. In making such determinations, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Meetings of the Board and Stockholders

Our board of directors met in person and telephonically five times during 2019 and also acted by unanimous written consent. There were four Audit Committee meetings, one Compensation meeting and one Nominating and Corporate Governance meeting held in 2019. Our board of directors had 100% attendance for the Annual Meeting that was held on December 6, 2019. It is our policy that all directors must attend all stockholder meetings, barring extenuating circumstances.

Board Committees

Our board of directors has established three standing committees—audit, compensation, and nominating and corporate governance—each of which operates under a charter that has been approved by our board of directors. Copies of each committee's charter are posted on the Investors section of our website, which is located at www.hancockjaffe.com. Each committee has the composition and responsibilities described below. Our board of directors may from time to time establish other committees.

Audit Committee

Our audit committee consists of Mr. Gray, who is the chair of the committee, Mr. Jenusaitis and Dr. Shrivastava. Our board of directors has determined that each of the members of our audit committee satisfies the Nasdaq Marketplace Rules and SEC independence requirements. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented; and
- reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that Mr. Gray qualifies as an "audit committee financial expert" within the meaning of applicable SEC regulations and meets the financial sophistication requirements of the Nasdaq Marketplace Rules. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Compensation Committee

Our compensation committee consists of Dr. Shrivastava, who is the chair of the committee, Mr. Gray and Mr. Jenusaitis. Our board of directors has determined that each of the members of our compensation committee is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, and satisfies the Nasdaq Marketplace Rules independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and approving the compensation, the performance goals and objectives relevant to the compensation, and other terms of employment of our Chief Executive Officers and our other executive officers;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption “Compensation Discussion and Analysis” in our periodic reports or proxy statements to be filed with the SEC; and
- preparing the report that the SEC requires in our annual proxy statement.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Dr. Duhay, who is the chair of the committee, Mr. Jenusaitis and Dr. Shrivastava. Our board of directors has determined that each of the members of this committee satisfies the Nasdaq Marketplace Rules independence requirements. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- evaluating director performance on our board of directors and applicable committees of our board of directors and determining whether continued service on our board of directors is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors; and
- evaluating nominations by stockholders of candidates for election to our board of directors.

Code of Conduct

Our board of directors has adopted a written code of conduct 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. We have posted on our website a current copy of the code and all disclosures that are required by law or Nasdaq Marketplace Rules concerning any amendments to, or waivers from, any provision of the code.

Board Leadership Structure

Our board of directors is free to select the Chairman of the board of directors and a Chief Executive Officer in a manner that it considers to be in the best interests of our company at the time of selection. Currently, Robert A. Berman serves as our Chief Executive Officer. The office of the Chairman of the board of directors remains vacant since the voluntary resignation of Mr. Yury Zhivilo in May 2019. We currently believe that this leadership structure is in our best interests and strikes an appropriate balance between our Chief Executive Officer's responsibility for the day-to-day management of our company and the Chairman of the board of directors' responsibility to provide oversight, including setting the board of directors' meeting agendas and presiding at executive sessions of the independent directors. Additionally, four of our five members of our board of directors have been deemed to be "independent" by the board of directors, which we believe provides sufficient independent oversight of our management. Our board of directors has not designated a lead independent director.

Our board of directors, as a whole and also at the committee level, plays an active role overseeing the overall management of our risks. Our Audit Committee reviews risks related to financial and operational items with our management and our independent registered public accounting firm. Our board of directors is in regular contact with our Chief Executive Officer, who reports directly to our board of directors and who supervises day-to-day risk management.

Role of Board in Risk Oversight Process

Our board of directors believes that risk management is an important part of establishing, updating and executing on our business strategy. Our board of directors has oversight responsibility relating to risks that could affect the corporate strategy, business objectives, compliance, operations, and the financial condition and performance of our company. Our board of directors focuses its oversight on the most significant risks facing us and on our processes to identify, prioritize, assess, manage and mitigate those risks. Our board of directors receives regular reports from members of our senior management on areas of material risk to us, including strategic, operational, financial, legal and regulatory risks. While our board of directors has an oversight role, management is principally tasked with direct responsibility for management and assessment of risks and the implementation of processes and controls to mitigate their effects on us.

Certain Legal Proceedings

None of the Company's directors or executive officers have been involved, in the past ten years and in a manner material to an evaluation of such director's or officer's ability or integrity to serve as a director or executive officer, in any of those "Certain Legal Proceedings" more fully detailed in Item 401(f) of Regulation S-K, which include but are not limited to, bankruptcies, criminal convictions and an adjudication finding that an individual violated federal or state securities laws.

ITEM 11. Executive Compensation

The following table sets forth total compensation paid to our named executive officers for the years ended December 31, 2019 and 2018. Individuals we refer to as our "named executive officers" include our current Chief Executive Officer and both of our previous Co-Chief Executive Officers, our current and previous Chief Financial Officer and our two other most highly compensated executive officers whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2019.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Robert A. Berman	2019	400,000					15,285(12)	415,285
Chief Executive Officer	2018	293,308(1)		507,697(8)			7,692(13)	808,697
Benedict Broennimann, M.D.								
Former Co-Chief Executive Officer (2)	2018	120,000(2)	-		-	-	120,000(2)	240,000
Steven A. Cantor								
Former Co-Chief Executive Officer (3)	2018	71,539(3)		-	-	-	4,892(14)	76,431
Robert A. Rankin	2019	250,000					44,195(15)	294,195
Chief Financial Officer, Secretary and Treasurer	2018	110,577(4)		165,000(9)			17,297(16)	292,874
William R. Abbott								
Former Chief Financial Officer (5)	2018	173,077(5)					150,991(17)	324,068
Marc H. Glickman, M.D.	2019	322,115(6)		49,095(10)			50,814(18)	422,024
Chief Medical Officer and Senior Vice President	2018	300,000	-	-	-	-	62,640(19)	362,640
Chris Sarner								
Former Vice President Regulatory Affairs and Quality Assurance (7)	2019	212,885(7)		87,000(11)			47,457(20)	347,342

(1) Beginning March 30, 2018, Mr. Berman's annual base salary rate under his employment agreement was $400,000. Amounts in this column for Mr. Berman reflect his base salary earned for 2018.

(2) Dr. Broennimann served as our Co-Chief Executive Officer from August 2017 to April 2018. Dr. Broennimann's annual base salary rate under his employment agreement was $360,000. On May 1, 2018, Dr. Broennimann entered into a Service Agreement to perform the role of Chief Medical Officer (Out of US) for a fee of $15,000 monthly. Amounts in this column for Dr. Broennimann reflect his base salary earned for 2018 as Co-Chief Executive Officer.

(3) Mr. Cantor served as our Co-Chief Executive Officer from August 2017 until Mr. Cantor's employment with the Company was terminated on March 20, 2018. Amounts in this column for Mr. Cantor reflect base salary earned for 2018.

(4) Beginning July 16, 2018, Mr. Rankin's annual base salary rate under his employment agreement was $250,000. Amounts in this column for Mr. Rankin reflect his base salary earned for 2018.

(5) Mr. Abbott's annual base salary rate under his employment agreement was $300,000. Mr. Abbott's employment with the Company was terminated on July 20, 2018. Amounts in this column for Mr. Abbott reflect base salary earned for 2018.

(6) Beginning July 26, 2019, Dr. Glickman's annual base salary rate under his employment agreement dated July 26, 2019, which superseded his prior employment agreement, was $350,000. Amounts in this column for Dr. Glickman reflect his base salary earned for 2019.

(7) Beginning January 2, 2019, Ms. Sarner's annual base salary under her employment agreement was $225,000. Ms. Sarner resigned her employment with the Company effective December 2, 2019. Amounts in this column for Ms. Sarner reflect base salary earned for 2019.

(8) Represents the grant date fair value of 1,080,207 stock options granted on September 24, 2018 pursuant to the terms of his Employment Agreement dated March 30, 2018, computed in accordance with FASB ASC Topic 718. The options vested 20% on the date of his Employment Agreement and the remaining 80% vests ratably on a monthly basis over the 24 months following the date of his Employment Agreement.

(9) Represents the grant date fair value of 150,000 stock options granted on July 16, 2018, computed in accordance with FASB ASC Topic 718. 50,000 options vest on the first anniversary of Mr. Rankin's employment with the Company and the remaining 100,000 vest on a quarterly basis over the following two-year period.

(10) Represents the grant date fair value of 180,000 stock options granted on July 26, 2019, computed in accordance with FASB ASC Topic 718. The options vest quarterly over a three year period. Also included is the fair value of his existing 184,500 options that were repriced from $10.00 per share to $2.00 per share in connection with entering the July 26, 2019 employment agreement.

(11) Represents the grant date fair value of 150,000 stock options granted on January 7, 2019, computed in accordance with FASB ASC Topic 718. 50,000 options vest on the first anniversary of Ms. Sarner's employment with the Company and the remaining 100,000 vest on a quarterly basis over the following two-year period.

(12) Includes company paid healthcare of $1,285 and 401(k) match of $14,000.

(13) Includes company paid 401(k) match of $7,692.

(14) Includes company paid healthcare of $4,892.

(15) Includes company paid healthcare of $31,695 and 401(k) match of $12,500.

(16) Includes company paid healthcare of $12,490 and 401(k) match of $4,808.

(17) Includes severance of $126,923 and company paid healthcare of $16,567 and 401(k) match of $7,500.

(18) Includes company paid healthcare of $36,814 and 401(k) match of $14,000.

(19) Includes company paid healthcare of $35,043, 401(k) match of $15,000 and relocation expense reimbursement of $12,597.

(20) Includes company paid healthcare of $37,116 and 401(k) match of $10,341.

Employment Agreements

We have entered into various employment agreements with certain of our executive officers. Set forth below is a summary of many of the material provisions of such agreements, which summaries do not purport to contain all of the material terms and conditions of each such agreement. For purposes of the following employment agreements:

- "Cause" generally means the executive's (i) willful misconduct or gross negligence in the performance of his or her duties to us; (ii) willful failure to perform his or her duties to us or to follow the lawful directives of the Chief Executive Officer (other than as a result of death or disability); (iii) indictment for, conviction of or pleading of guilty or nolo contendere to, a felony or any crime involving moral turpitude: (iv) repeated failure to cooperate in any audit or investigation of our business or financial practices; (v) performance of any material act of theft, embezzlement, fraud, malfeasance, dishonesty or misappropriation of our property; or (vi) material breach of his or her employment agreement or any other material agreement with us or a material violation of our code of conduct or other written policy.
- "Good reason" generally means, subject to certain notice requirements and cure rights, without the executive's consent, (i) material diminution in his or her base salary or annual bonus opportunity; (ii) material diminution in his or her authority or duties (although a change in title will not constitute "good reason"), other than temporarily while physically or mentally incapacitated, as required by applicable law; (iii) relocation of his or her primary work location by more than 25 miles from its then current location; or (iv) a material breach by us of a material term of the employment agreement.
- "Change of control" generally means (i) the acquisition, other than from us, by any individual, entity or group (within the meaning of Section 13(d)(3) or Section 14(d)(2) of the Exchange Act), other than us or any subsidiary, affiliate (within the meaning of Rule 144 promulgated under the Securities Act) or employee benefit plan of ours, of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than 50% of the combined voting power of our then outstanding voting securities entitled to vote generally in the election of directors; (ii) a reorganization, merger, consolidation or recapitalization of us, other than a transaction in which more than 50% of the combined voting power of the outstanding voting securities of the surviving or resulting entity immediately following such transaction is held by the persons who, immediately prior to the transaction, were the holders of our voting securities; or (iii) a complete liquidation or dissolution of us, or a sale of all or substantially all of our assets.

Robert A. Berman

On March 30, 2018, we entered into an employment agreement with Robert A. Berman, our current Chief Executive Officer and director. Pursuant to the terms of his employment agreement, Mr. Berman's base salary is $400,000, subject to annual review and adjustment at the discretion of our compensation committee, and he will be eligible for an annual year-end discretionary bonus of up to 50% of his base salary, subject to the achievement of key performance indicators, as determined by our compensation committee. The initial term of Mr. Berman's employment agreement may be terminated at anytime with or without cause and with or without notice or for good reason thereunder. In connection with his employment, Mr. Berman received an initial equity grant of an option to purchase
1,080,207 options with 216,041 vesting on the date of his Employment Agreement, March 30, 2018, and the remaining 80% vesting ratably on a monthly basis over the following 24 months.

Mr. Berman is entitled to participate in our employee benefit, pension and/or profit sharing plans, and we will pay certain health and dental premiums on his behalf. Mr. Berman's employment agreement prohibits him from inducing, soliciting or entertaining any of our employees to leave our employ during the term of the agreement and for 12 months thereafter.

Pursuant to the terms of his employment agreement, Mr. Berman is entitled to severance in the event of certain terminations of employment. In the event Mr. Berman's employment is terminated by us without cause and other than by reason of disability or he resigns for good reason, subject to his timely executing a release of claims in our favor and in addition to certain other accrued benefits, he is entitled to receive 6 month of base salary if termination occurred prior to the second anniversary of his employment or 12 months of continued base salary on and after the second anniversary of his employment (or 24 months if such termination occurs within 24 months following a change of control).

Robert A. Rankin

On July 16, 2018, the Company entered into an employment agreement with Mr. Rankin which provides for an annual base salary of $250,000 as well as standard employee insurance and other benefits. Pursuant to this agreement, Mr. Rankin is eligible for annual salary increases at the discretion of our board of directors as well as an annual year-end discretionary bonus of up to 30% of his base salary, subject to the achievement of key performance indicators, as determined by the board and the Chief Executive Officer of the Company in their sole discretion. In connection with his employment, Mr. Rankin received an initial equity grant of an option to purchase 150,000 options with 50,000 options vesting on July 16, 2019 and the remaining 100,000 vesting on a quarterly basis over the following two-year period.

Mr. Rankin's employment agreement provides for severance payments in the event of termination without Cause or he resigns for Good Reason (as defined in the agreement), equal to three months of base salary for each year that he has been employed by the Company at the time of termination, up to a total of one year of his base salary, provided, that if such termination results from a Change of Control (as defined in the agreement), Mr. Rankin's severance will not be less than six months of his base salary

Mr. Rankin's employment with the Company is "at-will" and may be terminated at any time, with or without cause and with or without notice by either Mr. Rankin or the Company.

Marc H. Glickman, M.D.

On July 22, 2016, we entered into an employment agreement with Marc H. Glickman, M.D., our Senior Vice President and Chief Medical Officer (the "Pre-existing Employment Agreement"). Pursuant to the terms of his Pre-existing Employment Agreement, Dr. Glickman's base salary is $300,000, subject to annual review and adjustment at the discretion of our board of directors, and he will be eligible for an annual year-end discretionary bonus of up to 50% of his base salary, subject to the achievement of key performance indicators, as determined by our board of directors. In connection with his Pre-existing Employment Agreement, Dr. Glickman received an initial equity grant of an option to purchase up to 184,500 shares of our common stock with 20% of the shares vesting immediately and 80% vesting on a monthly basis over 24 months thereafter. The initial term of Dr. Glickman's Pre-existing Employment Agreement ended on December 31, 2018 and was automatically extended for additional three-year terms.

On July 26, 2019, we entered into an employment agreement with Dr. Glickman (the "New Employment Agreement") that supersedes the terms of the Pre-existing Employment Agreement. Pursuant to the terms of the New Employment Agreement, Dr. Glickman's base salary is $350,000 per year, subject to annual review and adjustment at the discretion of the Board. In connection with entering into the New Employment Agreement, Dr. Glickman's existing one hundred and eighty four thousand five hundred (184,500) options ("Existing Options") to purchase Company common stock at ten dollars ($10.00) per share until October 1, 2026, were repriced to two dollars ($2.00) per share. Additionally, Dr. Glickman, in connection to the New Employment Agreement, was granted stock options for the right to purchase one hundred and eighty thousand (180,000) common stock at a price equal to two dollars ($2.00) per share exercisable until July 26, 2029, which shall vest quarterly over a three (3) year period.

Pursuant to the terms of the New Employment Agreement, Dr. Glickman is an at-will employee and is entitled to severance in the event of certain terminations of his employment. In the event that Dr. Glickman's employment is terminated by the Company without Cause (as defined in the New Employment Agreement), other than by reason of Disability (as defined in the New Employment Agreement), or he resigns for Good Reason (as defined in the New Employment Agreement), subject to his timely executing a release of claims in favor of the Company and in addition to certain other accrued benefits, Dr. Glickman is entitled to receive three months of his base salary for each year that he has been employed by the Company at the time of termination, up to a total of one year of his base salary.

Chris Sarner

On November 7, 2018, we entered into an employment agreement with Chris Sarner, our Vice President Regulatory Affairs and Quality Assurance. Pursuant to the terms of her employment agreement, Ms. Sarner's start date was January 2, 2019 and provides for an annual base salary of $225,000 as well as standard employee insurance and other benefits. Pursuant to this agreement, Ms. Sarner is eligible for annual salary increases at the discretion of our Chief Executive Officer. In connection with her employment, Ms. Sarner received an initial equity grant of an option to purchase 150,000 options with 50,000 options vesting on February 6, 2020 and the remaining 100,000 vesting on a quarterly basis over the following two-year period.

Ms. Sarner's employment agreement provides for severance payments in the event of termination without Cause or she resigns for Good Reason (as defined in the agreement), equal to three months of base salary for each year that she has been employed by the Company at the time of termination, up to a total of one year of her base salary.

Ms. Sarner's employment with the Company is "at-will", and may be terminated at any time, with or without cause and with or without notice by either Ms. Sarner or the Company.

Effective December 2, 2019, Ms. Sarner resigned from the Company.

Potential Payments Upon Termination or Change-in-Control

Pursuant to the terms of the employment agreements discussed above, we will pay severance in the event of certain terminations of employment. In the event employment is terminated by us without cause and other than by reason of disability or if the executive resigns for good reason, subject to his or her timely executing a release of claims in our favor and in addition to certain other accrued benefits, he or she is entitled to receive severance pursuant to the terms of his or her employment agreements discussed above.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information regarding equity awards held by our named executive officers as of December 31, 2019.

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date
Robert A. Berman, Chief Executive Officer	972,186(1)	108,021(1)	N/A	$ 4.99	September 23, 2028
Robert A. Rankin Chief Financial Officer, Secretary and Treasurer	62,500(2)	87,500(2)	N/A	$ 2.98	July 15, 2028
Marc H. Glickman, M.D. Chief Medical Officer and Senior Vice President	15,000(3)	165,000(3)	N/A	$ 2.00	July 25, 2029
	184,500(3)	-	N/A	$ 2.00	October 1, 2026

(1) Options were granted on September 24, 2018, and vested 20% on the date of his Employment Agreement, March 30, 2018, and the remaining 80% vests ratably on a monthly basis over the 24 months following the date of his Employment Agreement.

(2) Options were granted on July 16, 2018, and 50,000 options vested on the first anniversary of Mr. Rankin's employment, July 16, 2019, with the Company and the remaining 100,000 vest on a quarterly basis over the following two-year period.

(3) On July 26, 2019, the Company entered a new employment agreement with Dr. Glickman that superseded the terms of his existing employment agreement. In connection with entering into the new employment agreement, Dr. Glickman's existing 184,500 options that were granted on October 1, 2016 were repriced from $10.00 to $2.00 per share. Additionally, on July 26, 2019, Dr. Glickman was granted 180,000 options at $2.00 per share vesting quarterly over a three-year period.

Employee Benefit Plans

Amended and Restated 2016 Omnibus Incentive Plan

On October 1, 2016, our board of directors and our stockholders adopted and approved the Hancock Jaffe Laboratories, Inc. 2016 Omnibus Incentive Plan, and, subsequently on April 26, 2018, our board of directors and our stockholders adopted and approved the Amended and Restated 2016 Omnibus Incentive Plan ("2016 Plan"). The principal features of the 2016 Plan are summarized below. This summary is qualified in its entirety by reference to the text of the 2016 Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Share Reserve

We have reserved 4,924,485 shares of our common stock for issuance under the 2016 Plan, plus an annual increase on each anniversary of April 26th equal to 3% of the total issued and outstanding shares of our common stock as of such anniversary (or such lesser number of shares as may be determined by our board of directors), all of which may be granted as incentive stock options under Code Section 422. The shares of common stock issuable under the 2016 Plan will consist of authorized and unissued shares, treasury shares or shares purchased on the open market or otherwise, all as determined by our company from time to time.

If any award is canceled, terminates, expires or lapses for any reason prior to the issuance of shares or if shares are issued under the 2016 Plan and thereafter are forfeited to us, the shares subject to such awards and the forfeited shares will not count against the aggregate number of shares of common stock available for grant under the 2016 Plan. In addition, the following items will not count against the aggregate number of shares of common stock available for grant under the 2016 Plan: (1) shares issued under the 2016 Plan repurchased or surrendered at no more than cost or pursuant to an option exchange program, (2) any award that is settled in cash rather than by issuance of shares of common stock, (3) shares surrendered or tendered in payment of the option price or purchase price of an award or any taxes required to be withheld in respect of an award or (4) awards granted in assumption of or in substitution for awards previously granted by an acquired company.

Administration

The 2016 Plan may be administered by our board of directors or our compensation committee. Our compensation committee, in its discretion, selects the individuals to whom awards may be granted, the time or times at which such awards are granted and the terms and conditions of such awards. Our board of directors also has the authority, subject to the terms of the 2016 Plan, to amend existing options (including to reduce the option's exercise price), to institute an exchange program by which outstanding options may be surrendered in exchange for options that may have different exercise prices and terms, restricted stock, and/or cash or other property.

Eligibility

Awards may be granted under the 2016 Plan to officers, employees, directors, consultants and advisors of us and our affiliates. Incentive stock options may be granted only to employees of us or our subsidiaries.

Awards

The 2016 Plan permits the granting of any or all of the following types of awards:

- *Stock Options*. Stock options entitle the holder to purchase a specified number of shares of common stock at a specified price (the exercise price), subject to the terms and conditions of the stock option grant. Our compensation committee may grant either incentive stock options, which must comply with Code Section 422, or nonqualified stock options. Our compensation committee sets exercise prices and terms and conditions, except that stock options must be granted with an exercise price not less than 100% of the fair market value of our common stock on the date of grant (excluding stock options granted in connection with assuming or substituting stock options in acquisition transactions). Unless our compensation committee determines otherwise, fair market value means, as of a given date, the closing price of our common stock. At the time of grant, our compensation committee determines the terms and conditions of stock options, including the quantity, exercise price, vesting periods, term (which cannot exceed 10 years) and other conditions on exercise.
- *Stock Appreciation Rights*. Our compensation committee may grant SARs, as a right in tandem with the number of shares underlying stock options granted under the 2016 Plan or as a freestanding award. Upon exercise, SARs entitle the holder to receive payment per share in stock or cash, or in a combination of stock and cash, equal to the excess of the share's fair market value on the date of exercise over the grant price of the SAR. The grant price of a tandem SAR is equal to the exercise price of the related stock option and the grant price for a freestanding SAR is determined by our compensation committee in accordance with the procedures described above for stock options. Exercise of a SAR issued in tandem with a stock option will reduce the number of shares underlying the related stock option to the extent of the SAR exercised. The term of a freestanding SAR cannot exceed 10 years, and the term of a tandem SAR cannot exceed the term of the related stock option.
- *Restricted Stock, Restricted Stock Units and Other Stock-Based Awards*. Our compensation committee may grant awards of restricted stock, which are shares of common stock subject to specified restrictions, and restricted stock units, or RSUs, which represent the right to receive shares of our common stock in the future. These awards may be made subject to repurchase, forfeiture or vesting restrictions at our compensation committee's discretion. The restrictions may be based on continuous service with us or the attainment of specified performance goals, as determined by our compensation committee. Stock units may be paid in stock or cash or a combination of stock and cash, as determined by our compensation committee. Our compensation committee may also grant other types of equity or equity-based awards subject to the terms and conditions of the 2016 Plan and any other terms and conditions determined by our compensation committee.
- *Performance Awards*. Our compensation committee may grant performance awards, which entitle participants to receive a payment from us, the amount of which is based on the attainment of performance goals established by our compensation committee over a specified award period. Performance awards may be denominated in shares of common stock or in cash, and may be paid in stock or cash or a combination of stock and cash, as determined by our compensation committee. Cash-based performance awards include annual incentive awards.

Clawback

All cash and equity awards granted under the 2016 plan will be subject to all applicable laws regarding the recovery of erroneously awarded compensation, any implementing rules and regulations under such laws, any policies we adopted to implement such requirements and any other compensation recovery policies as we may adopt from time to time.

Change in Control

Under the 2016 Plan, in the event of a change in control (as defined in the 2016 Plan), outstanding awards will be treated in accordance with the applicable transaction agreement. If no treatment is provided for in the transaction agreement, each award holder will be entitled to receive the same consideration that stockholders receive in the change in control for each share of stock subject to the award holder's awards, upon the exercise, payment or transfer of the awards, but the awards will remain subject to the same terms, conditions and performance criteria applicable to the awards before the change in control, unless otherwise determined by our compensation committee. In connection with a change in control, outstanding stock options and SARs can be cancelled in exchange for the excess of the per share consideration paid to stockholders in the transaction, minus the option or SARs exercise price.

Subject to the terms and conditions of the applicable award agreements, awards granted to non-employee directors will fully vest on an accelerated basis, and any performance goals will be deemed to be satisfied at target. For awards granted to all other service providers, vesting of awards will depend on whether the awards are assumed, converted or replaced by the resulting entity.

- For awards that are not assumed, converted or replaced, the awards will vest upon the change in control. For performance awards, the amount vesting will be based on the greater of (1) achievement of all performance goals at the "target" level or (2) the actual level of achievement of performance goals as of our fiscal quarter end preceding the change in control, and will be prorated based on the portion of the performance period that had been completed through the date of the change in control.
- For awards that are assumed, converted or replaced by the resulting entity, no automatic vesting will occur upon the change in control. Instead, the awards, as adjusted in connection with the transaction, will continue to vest in accordance with their terms and conditions. In addition, the awards will vest if the award recipient has a separation from service within two years after a change in control by us other than for "cause" or by the award recipient for "good reason" (each as defined in the applicable award agreement). For performance awards, the amount vesting will be based on the greater of (1) achievement of all performance goals at the "target" level or (2) the actual level of achievement of performance goals as of our fiscal quarter end preceding the change in control, and will be prorated based on the portion of the performance period that had been completed through the date of the separation from service.

Amendment and Termination of the 2016 Plan

Unless earlier terminated by our board of directors, the 2016 Plan will terminate, and no further awards may be granted, 10 years after October 1, 2016, the date on which it was approved by our stockholders. Our board of directors may amend, suspend or terminate the 2016 Plan at any time, except that, if required by applicable law, regulation or stock exchange rule, stockholder approval will be required for any amendment. The amendment, suspension or termination of the 2016 Plan or the amendment of an outstanding award generally may not, without a participant's consent, materially impair the participant's rights under an outstanding award.

Limitation of Liability and Indemnification Matters

Our amended and restated certificate of incorporation limits the liability of our directors for monetary damages for breach of their fiduciary duties, except for liability that cannot be eliminated under the DGCL. Consequently, our directors will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following:

- any breach of their duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated bylaws also provide that we will indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors' and officers' liability insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person's services as a director or executive officer or at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is incorporated by reference as an exhibit to the registration statement to which this prospectus forms a part.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and may be unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Director Compensation

The Board determines the form and amount of director compensation after its review of recommendations made by the Compensation Committee. A substantial portion of each director's annual retainer is in the form of equity. Under the Company's nonemployee director compensation program members of the Board who are not also Company employees ("Non-Employee Directors") are granted twenty thousand (20,000) options and restricted stock units ("RSUs") worth up to twenty-five thousand dollars ($25,000) per annum (the "Annual Award"). A Non-Employee Director who is newly appointed to the Board other than in connection with an annual meeting of stockholders will generally receive a grant of sixty-thousand (60,000) options and RSUs worth up to seventy-five thousand dollars ($75,000) upon appointment (an "Initial Award"), which covers their compensation for their first three years of service. The Initial Award and Annual Award to Non-Employee Directors will vest as long as they remain directors in equal annual portions over three years following the date in which the award is granted.

The table below shows the compensation paid to our non-employee directors during 2019 and 2018.

Name		Fees earned or paid in cash	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation($)	Total ($)
Francis Duhay,	2019	-	-	-	-	-	-	-
M.D.	2018		$57,491(1)	$33,600(2)				$91,091
Dr. Sanjay	2019	-	-	-	-	-	-	-
Shrivastava	2018		$57,491(1)	$33,600(2)				$91,091
Robert Gray	2019		$75,000(3)	$ 7,800(4)				$82,800
Matthew Jenusaitis	2019		$75,000(3)	$ 7,800(4)				$82,800
Yury Zhivilo	2019	-	-	-	-	-	-	-
Former Chairman of the BOD (5)	2018	-	-	-	-	-	-	-
Marcus Robins,	2019	-	-	-	-	-	-	-
Former Director (6)	2018		$57,491(1)	$33,600(2)				$91,091
Robert A. Anderson, Former Director	2018	-	-	$ 9,960(7)	-	-	-	$ 9,960
Robert W. Doyle, Former Director	2018	-	-	$ 9,960(7)	-	-		$ 9,960
Steven Girgenti, Former Director	2018	-	-	$ 9,000(7)	-	-	-	$ 9,000

(1) Under the Company's nonemployee director compensation program, Dr. Duhay and Dr. Shrivastava in connection with their appointment to the BOD on October 2, 2018 were each granted 29,183 Restricted Stock units on November 27, 2018, which based on the Company's closing stock price on the grant date were valued at $1.97 per unit. These units vest in equal annual portions on the 10/2/2019, 10/2/2020 and 10/2/2021.

(2) Under the Company's nonemployee director compensation program, Dr. Duhay and Dr. Shrivastava in connection with their appointment to the BOD on October 2, 2018 were each granted 60,000 options to purchase shares of our common stock on November 27, 2018 at an exercise price of $2.57 per share. The options were valued at $.56 per share as of the date of the grant. All of these options vest in equal quarterly portions over a 3 year period starting from October 2, 2018 and valued in accordance with FASB ASC Topic 718.

(3) Under the Company's nonemployee director compensation program, Messrs. Gray and Jenusaitis in connection with their appointment to the BOD on September 13, 2019 were each granted 78,125 Restricted Stock units, which based on the Company's closing stock price on the grant date were valued at $.96 per unit. These units vest in equal annual portions on the 9/13/2020, 9/13/2021 and 9/3/2022.

(4) Under the Company's nonemployee director compensation program, Messrs. Gray and Jenusaitis in connection with their appointment to the BOD on September 13, 2019 were each granted 60,000 options to purchase shares of our common stock at an exercise price of $2.00 per share. The options were valued at $.13 per share as of the date of the grant. All of these options vest in equal quarterly portions over a 3 year period starting from September 13, 2019 and valued in accordance with FASB ASC Topic 718.

(5) On May 23, 2019, Mr. Zhivilo resigned as chairman of the board of directors for the Company.

(6) In April 2019, Mr. Robins passed away.

(7) Messrs. Anderson, Doyle and Girgenti resigned as Directors on Oct 1, 2018. Effective upon their resignation, each resigning director received a grant of 10,000 options to purchase shares of our common stock at an exercise price of $2.90, the closing price of our common stock on October 1, 2018. The options were valued at $.50 per share as of the date of the grant. All of these options were vested in full as of the date of grant and valued in accordance with FASB ASC Topic 718. Per the Amended and Restated 2016 Omnibus Incentive Plan, the options that were awarded in prior years to the resigning directors and vested, would have to be exercised within 90 days of their resignation date or be forfeited As part of their resignation agreement, all options granted to the Directors before their resignation date were modified such that they can be exercised by the resigning directors for a 10 year period from their issuance dates. These options are treated as a modification and valued in accordance with FASB ASC Topic 718. The 40,000 options to purchase shares of our common stock issued to each of our former directors Robert Doyle, Robert Anderson, and Steven Girgenti in 2017 at an exercise price of $12.00 per share were valued at $.10 per share as of the date of the modification. The 3,000 options to purchase shares of our common stock issued to each of our former directors Robert Doyle and Robert Anderson in 2017 at an exercise price of $7.00 per share were valued at $.32 per share as of the date of the modification.

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

The following table lists, as of March 1, 2020, the number of shares of common stock of our Company that are beneficially owned by (i) each person or entity known to our Company to be the beneficial owner of more than 5% of the outstanding common stock; (ii) each officer and director of our Company; and (iii) all officers and directors as a group.

Applicable percentage ownership is based on 19,231,857 shares of common stock outstanding as the date of this Form 10-K. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting or dispositive power with respect to such securities. In addition, pursuant to such rules, we deemed outstanding shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of March 1, 2020. We did not deem such shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the beneficial owners named in the table below have sole voting and dispositive power with respect to all shares of our common stock that they beneficially own, subject to applicable community property laws.

	Beneficial Ownership	
Name and Address of Beneficial Owner [1]	**Number of Shares**	**Percentage**
5% Stockholders		
Biodyne Holding, S.A.[2]	3,837,043	21.0%
Named Executive Officers and Directors		
Robert A. Berman [3]	1,062,582	5.2%
Marc Glickman, M.D.[3]	229,500	1.2%
Robert Rankin [3]	87,500	*
Francis Duhay, M.D. [3]	39,728	*
Dr. Sanjay Shrivastava [3	30,000	*
Robert Gray[3]	10,750	*
Matthew Jenusaitis [3]	10,000	*
All directors and executive officers as a group (7 persons)	1,470,060	7.1%

* Represents beneficial ownership of less than 1%.

(1) Except as otherwise noted below, the address for each person or entity listed in the table is c/o Hancock Jaffe Laboratories, Inc., 70 Doppler, Irvine, California 92618.
(2) Based on Mr. Zhivilo's public filings. Mr. Zhivilo is the controlling shareholder, President and director of Biodyne Holding, S.A., or Biodyne and was chairman of the board of directors for the Company until his resignation on May 23, 2019. The principal business address of Biodyne is 13 Rue de la Gare, 1100 Morges, Switzerland.
(3) Includes shares of common stock issuable upon exercise of options that are currently exercisable or exercisable within 60 days of March 1, 2020.

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

The following is a description of transactions since January 1, 2018 to which we were a party in which (i) the amount involved exceeded or will exceed the lesser of (A) $120,000 or (B) one percent of our average total assets at year end for the last two completed fiscal years and (ii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, any of the foregoing persons, who had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other similar arrangements, which are described under “Executive Compensation.”

Biodyne

On April 26, 2018, the Company and Biodyne agreed to convert the remaining aggregate principal and accrued interests of the loan into shares of our common stock at a conversion price of $4.30 per share. We issued to Biodyne 120,405 shares of common stock for the conversion of the loan which carried $499,000 in aggregate principal and approximately $18,742 in accrued interests.

As of December 31, 2019, Biodyne owned 3,837,043 shares of our common stock, representing an ownership interest of approximately 21.0%. Yury Zhivilo, who resigned as chairman of our board of directors on May 23, 2019, is the majority shareholder of Biodyne.

Indemnification of Officers and Directors

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the DGCL. Further, we intend to enter into indemnification agreements with each of our directors and officers, and we intend to purchase a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see "Executive Compensation—Limitations of Liability and Indemnification Matters."

To the best of our knowledge, during the past two fiscal years, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds the lesser of (A) $120,000 or (B) one percent of our average total assets at year end for the last two completed fiscal years, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest (other than compensation to our officers and directors in the ordinary course of business).

Policies and Procedures for Related Party Transactions

All future transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

ITEM 14. Principal Accounting Fees and Services

Audit Fees. The aggregate fees billed by Marcum LLP ("**Marcum**") for professional services rendered for the audit of our annual financial statements, review of the financial information included in our Forms 10-Q for the respective periods and other required filings with the SEC for the years ended December 31, 2019 and 2018 totaled $101,350 and $103,195, respectively. The above amounts include interim procedures and audit fees, as well as attendance at audit committee meetings.

Audit-Related Fees. The aggregate fees billed by Marcum for audit-related fees for the years ended December 31, 2019 and 2018 were $74,057 and $184,432, respectively. The fees were provided in consideration of services consisting of review and update procedures associated with registration statements and other SEC filings.

Tax Fees. The aggregate fees billed by Berman, Romeri & Associates, LLP for professional services rendered for tax compliance for the years ended December 31, 2019 and 2018 were $4,000 and $4,000, respectively. The fees were provided in consideration of services consisting of preparation of tax returns and related tax advice.

All Other Fees. None.

PART IV

ITEM 15. Exhibits and Financial Statements Schedules

1. Consolidated Financial Statements

Our financial statements and the notes thereto, together with the report of our independent registered public accounting firm on those financial statements, are hereby filed as part of this report beginning on page F-1.

2. Financial Statement Schedules

All financial statement schedules have been omitted since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and notes thereto.

3. Exhibits

The following is a complete list of exhibits filed as part of this Form 10-K. Exhibit numbers correspond to the numbers in the Exhibit Table of Item 601 of Regulation S-K.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on June 6, 2018).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on June 6, 2018).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
4.2	Form of Series A Preferred Stock Placement Agents' Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
4.3	Form of Series B Preferred Stock Placement Agents' Warrant (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
4.4	Form of Common Stock Purchase Warrant (issued in connection with the 2017 Notes) (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
4.5	Form of Underwriters' Warrant (incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
4.6	Form of Warrant to Purchase Shares of Common Stock (issued to Mr. Cantor) (incorporated by reference to Exhibit 4.8 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
4.7	Form of Amended and Restated Common Stock Purchase Warrant (issued in connection with the 2017 Notes) (incorporated by reference to Exhibit 4.9 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
4.8	Form of Common Stock Purchase Warrant (issued in connection with the 2018 Notes) (incorporated by reference to Exhibit 4.10 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
4.9	Form of Second Amended and Restated Common Stock Purchase Warrant (issued in connection with the 2017 Notes) (incorporated by reference to Exhibit 4.11 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
4.10	Form of Amended and Restated Common Stock Purchase Warrant (issued in connection with the 2018 Notes) (incorporated by reference to Exhibit 4.12 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
4.11	Form of Warrant Agreement (incorporated by reference to Exhibit 4.13 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 14, 2018).
4.12	Amendment to Warrant to Purchase Shares (incorporated by reference to Exhibit 4.14 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
4.13	Form of Warrant Certificate (incorporated by reference to Exhibit 4.15 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 14, 2018).
4.14	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on March 2, 2020).
10.1	Employment Agreement, dated as of August 30, 2016, by and between the Registrant and Benedict Broennimann, M.D. (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
10.2	Employment Agreement, dated as of July 22, 2016, by and between the Registrant and William R. Abbott (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
10.3	Employment Agreement, dated as of July 22, 2016, by and between the Registrant and Marc Glickman, M.D. (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
10.4	Employment Agreement, dated as of July 22, 2016, by and between the Registrant and Susan Montoya (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
10.5	Employment Agreement, dated as of July 1, 2016, by and between the Registrant and Steven Cantor (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
10.6	Asset Purchase Agreement, dated as of March 18, 2016, by and between LeMaitre Vascular, Inc. and the Registrant (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on November 6, 2017).

10.7	Loan Agreement, dated as of June 30, 2015, by and between Biodyne Holding S.A. and the Registrant (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on November 6, 2017).
10.8	First Amendment to Loan Agreement, dated as of April 1, 2016, by and between Biodyne Holding S.A. and the Registrant (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
10.9	Second Amendment to Loan Agreement, dated as of October 18, 2016, by and between Biodyne Holding S.A. and the Registrant (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
10.10	Third Amendment to Loan Agreement, dated as of December 9, 2016, by and between Biodyne Holding S.A. and the Registrant (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
10.11	Fourth Amendment to Loan Agreement, dated as of March 27, 2017, by and between Biodyne Holding S.A. and the Registrant (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on November 6, 2017).
10.12	Fifth Amendment to Loan Agreement, dated as of June 26, 2017, by and between Biodyne Holding S.A. and the Registrant (incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on November 6, 2017).
10.13	First Amendment to Employment Agreement, dated as of June 1, 2017, by and between the Registrant and William Abbott (incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on November 6, 2017).
10.14	First Amendment to Employment Agreement, dated as of December 1, 2016, by and between the Registrant and Steven Cantor (incorporated by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
10.15	Second Amendment to Employment Agreement, dated as of June 12, 2017, by and between the Registrant and Steven Cantor (incorporated by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on November 6, 2017).
10.16	Securities Purchase Agreement dated as of June 15, 2017, by and among the Registrant and each purchaser identified on the signature pages thereto (2017 Note) (incorporated by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on November 6, 2017).
10.17	Promissory Note, dated June 15, 2017, by and between the Registrant and Hancock Jaffe Laboratories Aesthetic, Inc. (incorporated by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on November 6, 2017).
10.18	Promissory Note, dated August 22, 2017, by and between the Registrant and Hancock Jaffe Laboratories Aesthetic, Inc. (incorporated by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on November 6, 2017).
10.19	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
10.20	Form of Convertible Note (2017 Note) (incorporated by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
10.21	Form of Subscription Agreement (incorporated by reference to Exhibit 10.33 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
10.22	Amendment to Securities Purchase Agreement, dated December 29, 2017, by and among the Registrant and the holders signatory thereto (2017 Note) (incorporated by reference to Exhibit 10.37 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
10.23	Form of Amended and Restated Convertible Note (2017 Note) (incorporated by reference to Exhibit 10.38 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
10.24	Form of Securities Purchase Agreement, by and between the Registrant and the holders signatory thereto (2018 Note) (incorporated by reference to Exhibit 10.39 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
10.25	Form of Convertible Note (2018 Note) (incorporated by reference to Exhibit 10.40 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
10.26	Form of Promissory Note (December Note) (incorporated by reference to Exhibit 10.41 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
10.27	Second Amendment to Securities Purchase Agreement, dated February 28, 2018, by and among the Registrant and holders signatory thereto (2017 Note) (incorporated by reference to Exhibit 10.42 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
10.28	Form of Second Amended and Restated Convertible Note (2017 Note) (incorporated by reference to Exhibit 10.43 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
10.29	Amendment to Securities Purchase Agreement, dated February 28, 2018, by and among the Registrant and the holders signatory thereto (2018 Note) (incorporated by reference to Exhibit 10.44 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
10.30	Form of Amended and Restated Convertible Note (2018 Note) (incorporated by reference to Exhibit 10.45 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).

10.31	First Amendment to Employment Agreement, dated as of April 2, 2018, by and between the Registrant and Benedict Broennimann, M.D. (incorporated by reference to Exhibit 10.46 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
10.32	Employment Agreement, dated as of March 30, 2018, by and between the Registrant and Robert A. Berman. (incorporated by reference to Exhibit 10.47 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
10.33	Sixth Amendment to Loan Agreement, dated as of January 11, 2018, by and between Biodyne Holding S.A. and the Registrant (incorporated by reference to Exhibit 10.48 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
10.34	Seventh Amendment to Loan Agreement, dated as of March 30, 2018, by and between Biodyne Holding S.A. and the Registrant (incorporated by reference to Exhibit 10.49 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
10.35	Amended and Restated 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.50 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 14, 2018).
10.36	Second Amendment to Promissory Note , dated April 26, 2018, by and between the Registrant and Leman Cardiovascular S.A. (Leman Note) (incorporated by reference to Exhibit 10.51 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 14, 2018).
10.37	Letter Agreement between the Registrant and Benedict Broennimann, M.D. (incorporated by reference to Exhibit 10.52 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 14, 2018).
10.38	Form of Promissory Note, original issue discount(May Bridge Note) (incorporated by reference to Exhibit 10.53 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 22, 2018).
10.39	Form of Promissory Note, original issue discount and interest (May Bridge Note) (incorporated by reference to Exhibit 10.54 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 22, 2018).
10.40	Form of Promissory Note, secured (May Bridge Note) (incorporated by reference to Exhibit 10.55 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 22, 2018).
10.41	Form of Share Issuance Agreement (May Bridge Note) (incorporated by reference to Exhibit 10.56 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 22, 2018).
10.42	Employment Agreement, dated as of July 16, 2018, by and between Hancock Jaffe Laboratories, Inc. and Robert Rankin (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 20, 2018).
10.43	Form of Resignation Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on October 2, 2018).
10.44	Form of Stock Option Grant under Amended and Restated 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.44 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018).
10.45	Form of Restricted Stock Unit under Amended and Restated 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.45 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018).
10.46	Share Purchase Agreement, dated as March 12, 2019, by and among the Company and the investors signatory thereto (incorporated by reference to Exhibit 10.46 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018).
10.47	Form of Placement Agency Agreement, between the Company and the placement agent signatory thereto (incorporated by reference to Exhibit 1.1 to the Registrant's Registration Statement on Form S-1 filed on June 7, 2019).
10.48	Employment Agreement, dated as of July 26, 2019, by and between Hancock Jaffe Laboratories, Inc. and Marc Glickman, M.D. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 1, 2019).
10.49	Form of Securities Purchase Agreement dated as of February 25, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 2, 2020).
23.1*	Consent of Marcum LLP, independent registered public accounting firm
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act. *
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Sarbanes-Oxley Act. *
32**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act**
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 Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.

** Furnished and not filed herewith.

ITEM 16. Form 10-K Summary

Not applicable

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 18, 2020

HANCOCK JAFFE LABORATORIES, INC.

By: */s/ Robert Berman*
Robert Berman
Chief Executive Officer
(Principal Executive Officer)

By: */s/ Robert Rankin*
Robert Rankin
Chief Financial Officer
(Principal Financing and Accounting Officer)

HANCOCK JAFFE LABORATORIES, INC.
ANNUAL REPORT ON FORM 10-K

INDEX TO AUDITED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Hancock Jaffe Laboratories, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Hancock Jaffe Laboratories (the "Company") as of December 31, 2019 and 2018, the related statements of operations, changes in stockholders' equity (deficiency) and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum LLP
Marcum LLP

We have served as the Company's auditor since 2015.

New York, NY
March 18, 2020

HANCOCK JAFFE LABORATORIES, INC.
BALANCE SHEETS

	December 31, 2019	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 1,307,231	$ 2,740,645
Accounts receivable	-	32,022
Prepaid expenses and other current assets	116,647	64,306
Total Current Assets	1,423,878	2,836,973
Property and equipment, net	344,027	26,153
Restricted cash	810,055	-
Operating lease right-of-use assets, net	826,397	-
Intangible assets, net	-	666,467
Security deposits and other assets	29,843	29,843
Total Assets	$ 3,434,200	$ 3,559,436
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,221,189	$ 1,077,122
Accrued expenses and other current liabilities	333,438	412,871
Deferred revenue - related party	33,000	33,000
Current portion of operating lease liabilities	288,685	-
Total Current Liabilities	1,876,312	1,522,993
Long-term operating lease liabilities	567,948	-
Total Liabilities	2,444,260	1,522,993
Commitments and Contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock, par value $0.00001, 10,000,000 shares authorized: no shares issued or outstanding	-	-
Common stock, par value $0.00001, 50,000,000 shares authorized, 17,931,857 and 11,722,647 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	179	117
Additional paid-in capital	57,177,686	50,598,854
Accumulated deficit	(56,187,925)	(48,562,528)
Total Stockholders' Equity	989,940	2,036,443
Total Liabilities and Stockholders' Equity	$ 3,434,200	$ 3,559,436

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

HANCOCK JAFFE LABORATORIES, INC.
STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2019	**2018**
Revenues:		
Royalty income	$ 31,243	$ 116,152
Contract research - related party	-	70,400
Total Revenues	31,243	186,552
Selling, general and administrative expenses	4,911,613	6,482,953
Research and development expenses	2,206,120	1,238,749
Loss on impairment of intangible asset	588,822	319,635
Loss from Operations	(7,675,312)	(7,854,785)
Other (Income) Expense:		
Amortization of debt discount	-	6,562,736
Gain on extinguishment of convertible notes payable	-	(1,481,317)
Interest (income) expense, net	(49,915)	298,161
Change in fair value of derivative liabilities	-	(191,656)
Total Other (Income) Expense	(49,915)	5,187,924
Net Loss	(7,625,397)	(13,042,709)
Deemed dividend to preferred stockholders	-	(3,310,001)
Net Loss Attributable to Common Stockholders	$ (7,625,397)	$ (16,352,710)
Net Loss Per Basic and Diluted Common Share:	$ (0.48)	$ (1.75)
Weighted Average Number of Common Shares Outstanding:		
Basic and Diluted	15,760,444	9,362,474

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

HANCOCK JAFFE LABORATORIES, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	(Deficiency)
Balance at January 1, 2018	6,133,678	61	24,389,307	(35,519,819)	(11,130,451)
Common stock issued in initial public offering [1]	1,725,000	17	6,082,427	-	6,082,444
Derivative liabilities reclassified to equity	-	-	3,594,002	-	3,594,002
Redeemable convertible preferred stock converted to common stock	1,743,231	18	5,170,737	-	5,170,755
Common stock issued in connection with May Bridge Notes	55,000	1	228,965	-	228,966
Common stock issued in satisfaction of Advisory Board fees payable	30,000	-	90,000	-	90,000
Common stock issued upon conversion of convertible debt and interest	1,650,537	17	8,252,669	-	8,252,686
Common stock issued upon conversion of related party convertible debt and interest	120,405	1	517,741	-	517,742
Common stock issued upon exchange of related party notes payable and interest	35,012	-	150,553	-	150,553
Common stock issued in satisfaction of deferred salary	44,444	-	200,000	-	200,000
Stock-based compensation:					
Amortization of stock options	-	-	864,625	-	864,625
Common stock issued to consultants	185,340	2	878,828	-	878,830
Warrants granted to consultants	-	-	179,000	-	179,000
Net loss	-	-	-	(13,042,709)	(13,042,709)
Balance at December 31, 2018	11,722,647	$ 117	$ 50,598,854	$ (48,562,528)	$ 2,036,443

[1] net of offering costs of $2,542,555.

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2019	11,722,647	$ 117	$ 50,598,854	$ (48,562,528)	$ 2,036,443
Common stock issued in private placement offering [2]	2,347,997	24	2,317,252	-	2,317,276
Common stock issued in public offering [3]	3,615,622	36	3,319,620	-	3,319,656
Stock-based compensation:					
Amortization of stock options and restricted stock units [4]	9,728	-	492,084	-	492,084
Common stock issued to consultants/settlement, net [5]	235,863	2	419,377	-	419,379
Warrants granted to consultants/settlement	-	-	30,499	-	30,499
Net loss	-	-	-	(7,625,397)	(7,625,397)
Balance at December 31, 2019	17,931,857	$ 179	$ 57,177,686	$ (56,187,925)	$ 989,940

[2] net of offering costs of $386,724.
[3] net of offering costs of $549,060.
[4] stock issued for vested restricted stock units.
[5] net of forfeiture of 6,137 shares.

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

HANCOCK JAFFE LABORATORIES, INC.
STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2019	**2018**
Cash Flows from Operating Activities		
Net loss	$ (7,625,397)	$ (13,042,709)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount	-	6,562,736
Gain on extinguishment of convertible notes payable	-	(1,481,317)
Stock-based compensation	941,962	1,922,455
Depreciation and amortization	123,660	133,419
Amortization of right-of-use assets	273,005	-
Change in fair value of derivatives	-	(191,656)
Loss on impairment	588,822	319,635
Changes in operating assets and liabilities:		
Accounts receivable	32,022	3,159
Prepaid expenses and other current assets	(52,341)	(6,762)
Security deposit and other assets	-	700
Accounts payable	144,067	(294,122)
Accrued expenses	(56,960)	(210,976)
Deferred revenues	-	(70,400)
Payments on lease liabilities	(265,240)	-
Total adjustments	1,728,997	6,686,871
Net Cash Used in Operating Activities	(5,896,400)	(6,355,838)
Cash Flows from Investing Activities		
Purchase of property and equipment	(363,891)	(12,422)
Net Cash Used in Investing Activities	(363,891)	(12,422)
Cash Flows from Financing Activities		
Proceeds from private placement, net [1]	2,317,276	-
Proceeds from public offering, net [2]	3,319,656	-
Proceeds from initial public offering, net [3]	-	7,657,427
Initial public offering costs paid in cash	-	(706,596)
Repayments of notes payable	-	(1,125,000)
Repayments of notes payable - related party	-	(120,864)
Proceeds from issuance of notes payable, net	-	722,500
Proceeds from issuance of convertible notes, net [4]	-	2,603,750
Net Cash Provided by Financing Activities	5,636,932	9,031,217
Net Increase (Decrease) in Cash, Cash Equivalent, and Restricted Cash	(623,359)	2,662,957
Cash, cash equivalents and restricted cash - Beginning of period	2,740,645	77,688
Cash, cash equivalents and restricted cash - End of period	$ 2,117,286	$ 2,740,645

[1] Net of cash offering costs of $386,724.
[2] Net of cash offering costs of $549,060.
[3] Net of cash offering costs of $967,573.
[4] Net of cash offering costs of $293,750.

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

HANCOCK JAFFE LABORATORIES, INC.
STATEMENTS OF CASH FLOWS - continued

	Year Ended December 31,	
	2019	**2018**
Supplemental Disclosures of Cash Flow Information:		
Cash Paid During the Period For:		
Interest paid	$ 933	$ 286,551
Income taxes paid	$ -	$ -
Non-Cash Investing and Financing Activities		
Conversion of convertible note payable - related party and accrued interest into common stock	$ -	$ 517,742
Exchange of note payable - related party and accrued interest into common stock	$ -	$ 150,553
Fair value of warrants issued in connection with convertible debt included in derivative liabilities	$ -	$ 1,046,763
Embedded conversion option in convertible debt included in derivative liabilities	$ -	$ 1,239,510
Derivative liabilities reclassified to equity	$ -	$ 6,059,823
Conversion of convertible notes payable and accrued interest into common stock	$ -	$ 5,743,391
Conversion of preferred stock into common stock	$ -	$ 5,170,755

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

HANCOCK JAFFE LABORATORIES, INC.
NOTES TO FINANCIAL STATEMENTS

Note 1 – Business Organization and Nature of Operations

Hancock Jaffe Laboratories, Inc. is a medical device company developing tissue based solutions that are designed to be life sustaining or life enhancing for patients with cardiovascular disease, and peripheral arterial and venous disease. The Company's products are being developed to address large unmet medical needs by either offering treatments where none currently exist or by substantially increasing the current standards of care. Our two lead products are: the VenoValve®, a porcine based device to be surgically implanted in the deep venous system of the leg to treat a debilitating condition called CVI; and the CoreoGraft®, a bovine based conduit to be used to revascularize the heart during CABG surgeries. Both of our current products are being developed for approval by the FDA. We currently receive tissue for our products from one domestic supplier and one international supplier. Our current business model is to license, sell, or enter into strategic alliances with large medical device companies with respect to our products, either prior to or after FDA approval. Our current senior management team has been affiliated with more than 50 products that have received FDA approval or CE marking. We currently lease a 14,507 sq. ft. manufacturing facility in Irvine, California, where we manufacture products for our clinical trials and which has previously been FDA certified for commercial manufacturing of product.

Each of our product candidates will be required to successfully complete clinical trials and other testing to demonstrate the safety and efficacy of the product candidate before it will be approved by the FDA. The completion of these clinical trials and testing will require a significant amount of capital and the hiring of additional personnel.

Note 2 – Going Concern and Management's Liquidity Plan

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern for the next twelve months from the filing of this Form 10-K. The Company incurred a net loss of $7,625,397 during the year ended December 31, 2019 and had an accumulated deficit of $56,187,925 as of December 31, 2019. Cash used in operating activities was $5,896,400 for the year ended December 31, 2019. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the issuance date of the financial statements.

As of December 31, 2019, the Company had a cash balance of $1,307,231 and working capital deficiency of $452,434.

The Company expects to continue incurring losses for the foreseeable future and will need to raise additional capital to sustain its operations, pursue its product development initiatives and penetrate markets for the sale of its products.

Management believes that the Company could have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means. However, there is a material risk that the Company will be unable to raise additional capital or obtain new financing when needed on commercially acceptable terms, if at all. The inability of the Company to raise needed capital would have a material adverse effect on the Company's business, financial condition and results of operations, and ultimately the Company could be forced to curtail or discontinue its operations, liquidate and/or seek reorganization in bankruptcy. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 3 – Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. Significant estimates and assumptions include the valuation allowance related to the Company's deferred tax assets, and the valuation of warrants and derivative liabilities.

Investments

Equity investments over which the Company exercises significant influence, but does not control, are accounted for using the equity method, whereby investment accounts are increased (decreased) for the Company's proportionate share of income (losses), but investment accounts are not reduced below zero.

The Company holds a 28.0% ownership investment, consisting of founders' shares acquired at nominal cost, in HJLA. To date, HJLA has recorded cumulative losses. Since the Company's investment is recorded at $0, the Company has not recorded its proportionate share of HJLA's losses. If HJLA reports net income in future years, the Company will apply the equity method only after its share of HJLA's net income equals its share of net losses previously incurred.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation using the straight-line method over their estimated useful lives, which range from 5 to 7 years. Leasehold improvements are amortized over the lesser of (a) the useful life of the asset; or (b) the remaining lease term. Expenditures for maintenance and repairs, which do not extend the economic useful life of the related assets, are charged to operations as incurred, and expenditures, which extend the economic life are capitalized. When assets are retired, or otherwise disposed of, the costs and related accumulated depreciation or amortization are removed from the accounts and any gain or loss on disposal is recognized.

Impairment of Long-lived Assets

The Company reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount.

Derivative Liabilities

Derivative financial instruments are recorded as a liability at fair value and are marked-to-market as of each balance sheet date. The change in fair value at each balance sheet date is recorded as a change in the fair value of derivative liabilities on the statement of operations for each reporting period. The fair value of the derivative liabilities was determined using a Monte Carlo simulation, incorporating observable market data and requiring judgment and estimates. The Company reassesses the classification of the financial instruments at each balance sheet date. If the classification changes as a result of events during the period, the financial instrument is marked to market and reclassified as of the date of the event that caused the reclassification.

On June 4, 2018, in connection with the Company's IPO, all of its previously issued convertible notes were converted and paid in full and the embedded conversion options and warrants no longer qualified as derivatives; accordingly, the derivative liabilities were remeasured to fair value on June 4, 2018 and the fair value of derivative liabilities of $3,594,002 was reclassified to additional paid in capital.

The Company recorded a gain and a loss on the change in fair value of derivative liabilities of $0.0 and $191,656 during the years ended December 31, 2019 and 2018, respectively.

Net Loss per Share

The Company computes basic and diluted loss per share by dividing net loss attributable to common stockholders by the weighted average number of common stock outstanding during the period. Net loss income attributable to common stockholders consists of net loss, adjusted for the convertible preferred stock deemed dividend resulting from the 8% cumulative dividend on the Preferred Stock.

Basic and diluted net loss per common share are the same since the inclusion of common stock issuable pursuant to the exercise of warrants and options, plus the conversion of preferred stock or convertible notes, in the calculation of diluted net loss per common shares would have been anti-dilutive.

The following table summarizes net loss attributable to common stockholders used in the calculation of basic and diluted loss per common share:

	For the Years Ended December 31,	
	2019	**2018**
Net loss	$ (7,625,397)	$ (13,042,709)
Deemed dividend to Series A and B preferred stockholders	-	(3,310,001)
Net loss attributable to common stockholders	$ (7,625,397)	$ (16,352,710)

The following table summarizes the number of potentially dilutive common stock equivalents excluded from the calculation of diluted net loss per common share as of December 31, 2019 and 2018:

	December 31,	
	2019	**2018**
Shares of common stock issuable upon exercise of warrants	4,366,960	3,780,571
Shares of common stock issuable upon exercise of options and restricted stock units	2,687,367	2,883,256
Potentially dilutive common stock equivalents excluded from diluted net loss per share	7,054,327	6,663,827

Revenue Recognition

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2016-08, "Revenue from Contracts with Customers - Principal versus Agent Considerations", in April 2016, the FASB issued ASU No. 2016-10, "Revenue from Contracts with Customers (Topic 606) - Identifying Performance Obligations and Licensing" and in May 9, 2016, the FASB issued ASU No. 2016-12, "Revenue from Contracts with Customers (Topic 606)", or ASU 2016-12. This update provides clarifying guidance regarding the application of ASU No. 2014-09 - Revenue From Contracts with Customers which is not yet effective. These new standards provide for a single, principles-based model for revenue recognition that replaces the existing revenue recognition guidance. In July 2015, the FASB deferred the effective date of ASU 2014-09 until annual and interim periods beginning on or after December 15, 2017. It has replaced most existing revenue recognition guidance under U.S. GAAP. The ASU may be applied retrospectively to historical periods presented or as a cumulative-effect adjustment as of the date of adoption. The Company adopted Topic 606 using a modified retrospective approach and was applied prospectively in the Company's financial statements from January 1, 2018 forward. Revenues under Topic 606 are required to be recognized either at a "point in time" or "over time", depending on the facts and circumstances of the arrangement, and are evaluated using a five-step model. The adoption of Topic 606 did not have a material impact on the Company's financial statements, at initial implementation nor will it have a material impact on an ongoing basis.

The Company recognizes revenue when goods or services are transferred to customers in an amount that reflects the consideration which it expects to receive in exchange for those goods or services. In determining when and how revenue is recognized from contracts with customers, the Company performs the following five-step analysis: (i) identification of contract with customer; (ii) determination of performance obligations; (iii) measurement of the transaction price; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The following table summarizes the Company's revenue recognized in the accompanying statements of operations:

	For the Years Ended December 31,	
	2019	**2018**
Royalty income	31,243	116,152
Contract research - related party	-	70,400
Total Revenues	$ 31,243	$ 186,552

Revenue from sales of products is recognized at the point where the customer obtains control of the goods and the Company satisfies its performance obligation, which generally is at the time the product is shipped to the customer. Royalty revenue, which is based on resales of ProCol Vascular Bioprosthesis to third-parties, will be recorded when the third-party sale occurs and the performance obligation has been satisfied. Contract research and development revenue is recognized over time using an input model, based on labor hours incurred to perform the research services, since labor hours incurred over time is thought to best reflect the transfer of service.

Information on Remaining Performance Obligations and Revenue Recognized from Past Performance

Information about remaining performance obligations pertaining to contracts that have an original expected duration of one year or less is not disclosed. The transaction price allocated to remaining unsatisfied or partially unsatisfied performance obligations with an original expected duration exceeding one year was not material at December 31, 2019.

Contract Balances

The timing of our revenue recognition may differ from the timing of payment by our customers. A receivable is recorded when revenue is recognized prior to payment and the Company has an unconditional right to payment. Alternatively, when payment precedes the provision of the related services, deferred revenue is recorded until the performance obligations are satisfied. The Company had deferred revenue of $33,000 and $33,000 as of December 31, 2019 and 2018, respectively, related to cash received in advance for contract research and development services.

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and recognized over the period services are required to be provided in exchange for the award, usually the vesting period. Forfeitures of unvested stock options are recorded when they occur.

Concentrations

The Company maintains cash with major financial institutions. Cash held in United States bank institutions is currently insured by the Federal Deposit Insurance Corporation (“FDIC”) up to $250,000 at each institution. There were aggregate uninsured cash balances of $1,867,286 and $2,490,645 as of December 31, 2019 and 2018, respectively.

During the year ended December 31, 2019, 100% of the Company’s revenues were from royalties earned from the sale of product by LeMaitre. The three-year Post-Acquisition Supply Agreement from which the Company earned royalty from the sale of product by LeMaitre ended on March 18, 2019. During the year ended December 31, 2018, 62% of the Company’s revenues were from royalties earned from the sale of product by LeMaitre and 38% were from contract research revenue related to research and development services performed pursuant to the HJLA Agreement.

Subsequent Events

The Company evaluated events that have occurred after the balance sheet date through the date the financial statements were issued. Based upon the evaluation and transactions, the Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements, except as disclosed in Note 14 to the Financial Statements - Subsequent Events.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842),” (“ASU 2016-02”). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. ASU 2016-02 will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. As a result of the new standard, all of our leases greater than one year in duration will be recognized in our Balance Sheets as both operating lease liabilities and right-of-use assets upon adoption of the standard. We adopted the standard using the prospective approach. Upon adoption on January 1, 2019, we recorded approximately $1.1 million in right-of-use assets and operating lease liabilities in our Balance Sheets.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects of the income tax accounting guidance, including requirements such as tax basis step-up in goodwill obtained in a transaction that is not a business combination, ownership changes in investments, and interim-period accounting for enacted changes in tax law. ASU 2019-12 is effective for public business entities for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years, and early adoption is permitted. We are currently evaluating the impact that this guidance will have on our consolidated financial statements.

Note 4 – Property and Equipment

As of December 31, 2019 and 2018, property and equipment consist of the following:

	December 31,	
	2019	2018
Laboratory equipment	$ 214,838	$ 94,905
Furniture and fixtures	93,417	93,417
Computer equipment	50,403	26,830
Leasehold improvements	158,092	158,092
Software	220,384	-
Total property and equipment	737,134	373,244
Less: accumulated depreciation	(393,107)	(347,091)
Property and equipment, net	$ 344,027	$ 26,153

Depreciation expense amounted to $46,017 and $10,112 for the years ended December 31, 2019 and 2018, respectively. Depreciation expense is reflected in general and administrative expenses in the accompanying statements of operations.

Note 5 – Right-of-Use Assets and Lease Liabilities

On September 20, 2017, the Company renewed its operating lease for its manufacturing facility in Irvine, California, effective October 1, 2017, for five years with an option to extend the lease for an additional 60-month term at the end of lease term. The initial lease rate was $26,838 per month with escalating payments. In connection with the lease, the Company is obligated to pay $7,254 monthly for operating expenses for building repairs and maintenance. The Company has no other operating or financing leases with terms greater than 12 months.

The Company adopted Accounting Standards Codification (“ASC”) Topic 842, Leases (Topic 842) effective January 1, 2019 using the modified-retrospective method and elected the package of transition practical expedients for expired or existing contracts, which does not require reassessment of previous conclusions related to contracts containing leases, lease classification and initial direct costs, and therefore the comparative periods presented are not adjusted. In addition, the Company elected to adopt the short-term lease exception and not apply Topic 842 to arrangements with lease terms of 12 months or less. On January 1, 2019, upon adoption of Topic 842, the Company recorded right-of-use assets of $1,099,400, lease liabilities of $1,121,873 and eliminated deferred rent of $22,473. The Company determined the lease liabilities using the Company’s estimated incremental borrowing rate of 8.5% to estimate the present value of the remaining monthly lease payments.

Our operating lease cost is as follows:

	For the Year Ended December 31, 2019
Operating lease cost	$ 341,966

Supplemental cash flow information related to our operating lease is as follows:

	For the Year Ended December 31, 2019
Operating cash flow information:	
Cash paid for amounts included in the measurement of lease liabilities	$ 334,203

Remaining lease term and discount rate for our operating lease is as follows:

	December 31, 2019
Remaining lease term	2.7 years
Discount rate	8.5%

Maturity of our lease liabilities by fiscal year for our operating lease is as follows:

Year ended December 31, 2020	344,229
Year ended December 31, 2021	354,561
Year ended December 31, 2022	271,854

Total	$	970,644
Less: Imputed interest		(114,011)
Present value of our lease liability	$	856,633

Note 6 – Intangible Assets

On May 10, 2013, the Company purchased United States Patent 7,815,677, "lntraparietal Aortic Valve Reinforcement Device and a Reinforced Biological Aortic Valve" from Leman Cardiovascular, S.A, (the "Patent"), which protects the critical design components and function relationships unique to the Company's BHV. The BHV is a bioprosthetic, pig heart valve designed to function like a native heart valve and early clinical testing has demonstrated that the BHV may be suitable for the pediatric population, as it accommodates for the growth concomitant with the patient. As of December 31, 2019, the Company performed an impairment analysis and determined that since it is focusing its research and development efforts on its VenoValve and CoreoGraft products and unlikely to continue the development of the BHV in the near future, the Company recorded an impairment loss of $588,822, equal to the remaining unamortized value as of December 31, 2019.

As of December 31, 2019 and 2018, the Company's intangible asset consisted of the following:

	December 31,	
	2019	2018
Patent	$ -	$ 1,100,000
Less: accumulated amortization	-	(433,533)
Total	$ -	$ 666,467

Amortization expense charged to operations for the years ended December 31, 2019 and 2018 was $77,643 and $111,893, respectively, and is reflected in general and administrative expense in the accompanying statements of operations.

Note 7 – Accrued Expenses

As of December 31, 2019 and 2018, accrued expenses consist of the following:

	December 31,	
	2019	2018
Accrued compensation costs	$ 151,858	$ 288,549
Accrued professional fees	141,310	55,300
Deferred rent	-	22,473
Accrued franchise taxes	30,270	26,985
Accrued research and development	-	17,064
Other accrued expenses	10,000	2,500
Accrued expenses	$ 333,438	$ 412,871

Included in accrued compensation costs in the table above as of December 31, 2018 is accrued severance expense of $166,154 pursuant to the terms of the employment agreement for the Company's prior Chief Financial Officer, who was terminated effective July 20, 2018, and whose severance was fully paid in 2019

Note 8 – Income Taxes

The following summarizes the Company's income tax provision (benefit):

	For the Years Ended December 31,	
	2019	**2018**
Federal:		
Current	$ -	$ -
Deferred	(1,449,778)	(1,710,997)
State and local:		
Current	-	-
Deferred	(483,259)	(570,332)
	(1,933,037)	(2,281,329)
Change in valuation allowance	1,933,037	2,281,329
Income tax provision (benefit)	$ -	$ -

The reconciliation between the U.S. statutory federal income tax rate and the Company's effective tax rate for the year's ended December 31, 2019 and 2018 is as follows:

	For the Years Ended December 31,	
	2019	**2018**
Tax benefit at federal statutory rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(7.0)%	(7.0)%
Permanent differences	0.5%	11.4%
True up adjustments	2.1%	(0.9)%
Change in valuation allowance	25.4%	17.5%
Effective income tax rate	0.0%	0.0%

Significant components of the Company's deferred tax assets at December 31, 2019 and 2018 are as follows:

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 7,329,760	$ 5,298,599
Research and development credit carryforwards	185,680	185,680
Intangible assets	309,865	152,109
Operating lease liability	239,857	-
Property and equipment	-	30,957
Stock-based compensation	329,136	526,945
Deferred rent	-	6,292
Impairment loss	136,612	136,612
Total gross deferred tax assets	8,530,910	6,337,194
Deferred tax liabilities		
Operating lease asset	(231,391)	-
Property and equipment	(29,289)	-
Total net deferred tax assets	8,270,230	6,337,194
Less: valuation allowance	(8,270,230)	(6,337,194)
Total	$ -	$ -

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss, or NOL, carryforwards and other pre-change tax attributes to offset its post-change income taxes may be limited. In accordance with Section 382 of the Internal Revenue Code, the usage of the Company's NOL carry forwards are subject to annual limitations due to a greater than 50% ownership change in 2018.

At December 31, 2019 and 2018, the Company had post-ownership change net operating loss carryforwards for federal income tax purposes of approximately $26.1 million and $17.4 million, respectively. Pre-2018 federal NOLs of $12.0 million carryovers may be carried forward for twenty years and begin to expire in 2029. Under the Tax Act, post-2017 federal NOLs in the aggregate of $14.1 million can be carried forward indefinitely and the annual limit of deduction equals 80% of taxable income. However, to the extent the Company utilizes its NOL carryforwards in the future, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities of the future period tax return in which the attribute is utilized. The Company also has federal research and development tax credit carryforwards of approximately $0.2 million which begin to expire in 2027.

As of December 31, 2019 and 2018, the Company had net operating loss carryforwards for state income tax purposes of approximately $26.1 million and $17.4 million, respectively, which can be carried forward for twenty years and begin to expire in 2029.

The Company files income tax returns in the U.S. federal jurisdiction as well as California and local jurisdictions and is subject to examination by those taxing authorities. The Company's federal income tax returns for the years beginning in 2016 remain subject to examination. The Company's state and local income tax returns for the years beginning in 2015 remain subject to examination. No tax audits were initiated during 2019 or 2018.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's financial statements as of December 31, 2019 and 2018. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date. The Company's policy is to classify assessments, if any, for tax related interest as interest expense and penalties as general and administrative expenses in the statements of operations.

Note 9 – Commitments and Contingencies

Litigations Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business. The Company records legal costs associated with loss contingencies as incurred and accrues for all probable and estimable settlements.

On September 21, 2018, ATSCO, Inc., filed a complaint with the Superior Court seeking payment of $809,520 plus legal costs for disputed invoices to the Company dated from 2015 to June 30, 2018. The Company had entered into a Services and Material Supply Agreement ("Agreement"), dated March 4, 2016 for ATSCO to supply porcine and bovine tissue. The Company is disputing the amount owed and that the Agreement called for a fixed monthly fee regardless of whether tissue was delivered to the Company. On January 18, 2019, the Orange County Superior Court granted a Right to Attach Order and Order for Issuance of Writ of Attachment in the amount of $810,055. We contend at least $188,000 of the ATSCO claim relates to a wholly separate company, and over $500,000 of the claim is attributable to invoices sent without delivery of any tissue to the Company. The Company also believes it has numerous defenses and rights of setoff including without limitation: that ATSCO had an obligation to mitigate claimed damages, particularly when they were not delivering tissues; $188,000 of the amount that ATSCO is seeking are for invoices to Hancock Jaffe Laboratory Aesthetics, Inc. (in which the Company owns a minority interest of 28.0%) and is not the obligation of the Company; the Company has a right of setoff against any amounts owed to ATSCO for 120,000 shares of the Company's stock transferred to ATSCO's principal and owner; the yields of the materials delivered by ATSCO to the Company were inferior; and the Agreement was constructively terminated. On March 26, 2019, ATSCO filed a First Amended Complaint with the Superior Court increasing its claim to $1,606,820 plus incidental damages and interest, on the basis of an alleged additional oral promise not alleged in its original Complaint. The Company recently deposed ATSCO's sole owner and principal and believes that the merits of its key defenses have been buttressed and supported as a result. While the Company expects and intends to continue a vigorous defense, the Company and ATSCO have recently agreed to proceed with informal settlement discussions. A trial date of July 20, 2020 has been set by the court. The Company recorded the disputed invoices in accounts payable and as of December 31, 2019, the Company believes that it has fully accrued for the outstanding claims against the Company. The Company has entered into new supply relationships with one domestic and one international company to supply porcine and bovine tissues.

On October 8, 2018, Gusrae Kaplan Nusbaum PLLC ("Gusrae") filed a complaint with the Supreme Court of the State of New York seeking payment of $178,926 plus interest and legal costs for invoices to the Company dated from November 2016 to December 2017. In July 2016, the Company retained Gusrae to represent the Company in connection with certain specific matters. The Company believes that Gusrae has not applied all of the payments made by the Company along with billing irregularities and errors and is disputing the amount owed. The Company recorded the disputed invoices in accounts payable and as of December 31, 2019 and 2018, the Company has fully accrued for the outstanding claim against the Company.

On May 31, 2019, the Company entered into an agreement ("Boxer Settlement Agreement") with Allen Boxer and Donna Mason (collectively, the "Boxer Parties") for the purposes of settling a previously disclosed dispute in which the Boxer Parties claimed to be owed fees for introducing the Company to Alexander Capital and Network 1 Securities who assisted the Company for the capital raise of the convertible notes issued in 2017 and 2018, which raised over $5.6 million in gross proceeds. Pursuant to the Boxer Settlement Agreement, the Boxer Parties agreed to a complete release of claims of fees relating to past and future capital raises and the Company agreed to issue 157,000 restricted shares of common stock and a five year warrant to purchase 150,000 shares of common stock that vested immediately with an exercise price of $6.00 per share.

Employment Agreement

Senior Vice President and Chief Medical Officer

On July 22, 2016, the Company entered into an employment agreement with Marc H. Glickman, M.D., the Company's Senior Vice President and Chief Medical Officer (the "Pre-existing Employment Agreement"). On July 26, 2019, the Company entered an employment agreement with Dr. Glickman (the "New Employment Agreement") that shall supersede the terms of the Pre-existing Employment Agreement. Pursuant to the terms of the New Employment Agreement, Dr. Glickman's base salary is $350,000 per year, subject to annual review and adjustment at the discretion of the Board. In connection with entering into the New Employment Agreement, Dr. Glickman's existing one hundred and eighty four thousand five hundred (184,500) options ("Existing Options") to purchase Company common stock, $0.00001 par value per share (the "Common Stock") at ten dollars ($10.00) per share until October 1, 2026, were repriced to two dollars ($2.00) per share. This was accounted for as a modification and the excess fair value of $20,295 was expensed since the options had fully vested. Additionally, Dr. Glickman, in connection to the New Employment Agreement shall be granted stock options ("New Options") for the right to purchase one hundred and eighty thousand (180,000) Common Stock at a price equal to two dollars ($2.00) per share exercisable until July 26, 2029, which shall vest quarterly over a three (3) year period, and shall be granted in accordance with the Hancock Jaffe 2016 Omnibus Incentive Plan (the "Option Plan"), and shall be subject to such other terms and conditions as are set forth in the Option Plan and the option agreement issued pursuant to the Option Plan. The New Options had a grant date fair value of $28,800. Pursuant to the terms of the New Employment Agreement, Dr. Glickman is an at-will employee and is entitled to severance in the event of certain terminations of his employment. In the event that Dr. Glickman's employment is terminated by the Company without Cause (as defined in the New Employment Agreement), other than by reason of Disability (as defined in the New Employment Agreement), or he resigns for Good Reason (as defined in the New Employment Agreement), subject to his timely executing a release of claims in favor of the Company and in addition to certain other accrued benefits, Dr. Glickman is entitled to receive three months of his base salary for each year that he has been employed by the Company at the time of termination, up to a total of one year of his base salary.

Note 10 – Common Stock

On April 26, 2018, the Company issued 44,444 shares of common stock with an aggregate fair value of $200,000, in satisfaction of deferred salary to its Chief Medical Officer Outside the United States.

On May 30, 2018, the Company's registration statement on Form S-1 relating to its initial public offering of its common stock (the "IPO") was declared effective by the Securities and Exchange Commission ("SEC"). The Company completed the IPO with an offering of 1,500,000 units (the "Units") at $5.00 per unit on June 4, 2018, each consisting of one share of the Company's common stock, par value $0.00001 per share (the "Common Stock"), and a warrant to purchase one share of common stock with an exercise price of $6.00 per share. Aggregate gross proceeds from the IPO were $7,500,000, before underwriting discounts and commissions.

On June 8, 2018, the underwriters notified the Company of their exercise in full of their option to purchase an additional 225,000 Units (the "Additional Units") to cover over-allotments. On June 12, 2018, the underwriters purchased the Additional Units at the IPO price of $5.00 per Unit, generating $1,125,000 in gross proceeds before underwriting discounts and commissions.

On June 18, 2018, the Company issued 30,000 shares of common stock with an aggregate fair value of $90,000, in satisfaction of fees payable to its Medical Advisory Board and granted 160,000 shares of immediately vested common stock with an aggregate fair value of $798,400 to certain consultants.

On June 18, 2018, the Company also granted 20,000 shares of common stock to a consultant with a fair value of $99,800, which per the Consulting Agreement with the consultant will vest monthly over next twelve months. However, the Company terminated the Consulting Agreement with that consultant as of December 26, 2018. Per the Agreement, the 6,137 unvested shares are to be returned to the Company by the consultant. The Company recognized $69,176 of stock-based compensation expense related to the vested shares of common stock in 2018.

On May 1, 2018, Dr Broennimann entered into a Service Agreement to perform the role of Chief Medical Officer (Out of US) for a fee of $15,000 monthly provided that the Company may, at its sole option, elect to pay 25% of the monthly fee in company common stock with the number of common stock determined by dividing the 25% of the monthly fee by the closing price of the Company's common stock on the 2nd work day of each month. On November 27, 2018, the Company elected to issue 3,334 shares of common stock for the 25% of the monthly fee for the months of October and November 2018 and on December 2, 2018, the Company elected to issue 2,005 shares of common stock for the 25% of the monthly fee for the month of December 2018.

On February 7, 2019, the Company entered into an Agreement ("MZ Agreement") with MZHCI, LLC, a MZ Group Company ("MZ") for MZ to provide investor relations advisory services. The MZ Agreement is for a term of twelve (12) months and can be cancelled by either party at the end of six (6) months with thirty (30) days' notice. MZ will receive compensation of $8,000 per month and eighty-five thousand (85,000) restricted shares that vest quarterly over a year, with a 6 month cliff with an aggregate fair value of $135,150 and recognized $121,079 of stock-based compensation expense related to the vested shares in 2019.

On March 12, 2019, the Company raised $2,704,000 in gross proceeds, with cash offering costs of $386,724 in a private placement offering of its common stock to certain accredited investors (the "Offering"). The Company sold an aggregate of 2,329,615 shares of common stock in the Offering for a purchase price of $1.15 per share pursuant to a share purchase agreement between the Company and each of the investors in the Offering. Our CEO also participated in the Offering purchasing 18,382 shares at a price of $1.36 per share, the final bid price of our common stock as reported on The Nasdaq Capital Market on the date of the Offering.

On April 18, 2019, 6,137 unvested shares were returned to the Company by a consultant as a result of the December 26, 2018 termination of such consultant's consulting agreement.

On May 31, 2019, the Company issued 157,000 restricted shares of common stock to the Boxer Parties pursuant to the Boxer Settlement Agreement valued at $298,300 or $1.90 per share, the closing price of the Company's common stock on the date the shares were issued.

On June 14, 2019, the Company completed a public offering of 3,615,622 shares of its common stock at a price to the public of $1.07 per share, for total gross proceeds of $3,868,716 (the "Public Offering"), with cash offering costs of $549,060. The shares were offered pursuant to a registration statement that was declared effective on June 11, 2019.

On November 5, 2019, the Company issued 9,728 restricted shares of common stock to Dr. Francis Duhay, our director for the 9,728 restricted stock units that were granted on November 27, 2018 at a fair value of $19,164 for compensation as our director and that vested on November 5, 2019.

Note 11 - Warrants

On January 3, 2019, the Company entered into an Agreement ("Alere Agreement") with Alere Financial Partners, a division of Cova Capital Partners LLC ("Alere"), for Alere to provide capital markets advisory services. The Alere Agreement was on a month to month basis that could be cancelled by either party with thirty (30) days advance notice. The Company paid a monthly fee of $7,500 and issued to Alere five-year warrants to purchase 35,000 shares of the Company's common stock at an exercise price of $1.59, equal to the closing price of the Company's common stock on February 7, 2019, the date of approval by the Company's board of directors (the "Board"). The warrants had a grant date fair value of $14,000 using the Black-Scholes pricing model, with the following assumptions used: stock price of $1.59, risk free interest rate of 2.46%, expected term of 2.8 years, volatility of 34.4% and an annual rate of quarterly dividends of 0%. The warrants vested monthly equally over a 12 month period provided that the Alere Agreement remained in effect. On June 11, 2019, both parties agreed to terminate the Alere Agreement as of June 30, 2019 and the unvested warrants as of June 30, 2019 totaling 17,500 were forfeited with a fair value of $7,000. The net charge to the statement of operations for the year ended 2019 was $7,000.

The placement agent for the Offering on March 12, 2019 received a warrant to purchase such number of shares of the Company's common stock equal to 8% of the total shares of common stock sold in the Offering or 188,108 shares. Such warrant is exercisable for a period of five years from the date of issuance and has an exercise price of $1.50 per share.

On May 31, 2019, the Company issued a five-year warrant to purchase 150,000 shares of common stock pursuant to the Boxer Settlement Agreement that vested immediately with an exercise price of $6.00 per share to the Boxer Parties.
The warrants had a grant date fair value of $3,000 using the Black-Scholes pricing model, with the following assumptions used: stock price of $1.90, risk free interest rate of 1.93%, expected term of 2.5 years, volatility of 35.1% and an annual rate of quarterly dividends of 0%.

On May 31, 2019, the Company issued a five-year warrant to purchase 50,000 shares of common stock that vested immediately with an exercise price of $2.00 to DFC Advisory Services LLC, D.B.A. Tailwinds Research Group, LLC ("Tailwinds") to provide digital marketing services. The warrants had a grant date fair value of $20,500 using the Black-Scholes pricing model, with the following assumptions used: stock price of $1.90, risk free interest rate of 1.93%, expected term of 2.5 years, volatility of 35.1% and an annual rate of quarterly dividends of 0%.

The placement agent for the Public Offering on June 14, 2019 received a warrant to purchase such number of shares of the Company's common stock equal to 5% of the total shares of common stock sold in the Public Offering or 180,781 shares. Such warrant is exercisable for a period from December 8, 2019 through June 11, 2024 and has an exercise price of $1.284 per share.

A summary of warrant activity during the years ended December 31, 2019 and 2018 is presented below:

	Series A Preferred Stock				Common Stock			
	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Intrinsic Value	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Intrinsic Value
Outstanding, January 1, 2018	100,570	$ 5.00			371,216	12.00		
Issued					3,292,443	6.09		
Exercised								
Cancelled	-	-			-	-		
Amendment of placement agent warrants [1]	(100,570)	5.00			116,912	4.30		
Outstanding, January 1, 2019	-	$ -	-	$ -	3,780,571	$ 5.48	4.1	$ -
Issued	-	-		-	603,889	2.60		
Exercised	-	-		-	-	-		
Cancelled	-	-		-	(17,500)	1.59		
Outstanding, December 31, 2019	-	$ -	-	$ -	4,366,960	$ 5.10	3.3	$ -
Exercisable, December 31, 2019	-	$ -	-	$ -	4,349,460	$ 5.11	3.3	$ -

[1] In connection with the IPO, placement agent warrants for the purchase of Series A Preferred Stock were amended such that the warrants became exercisable for the number of common stock that would have been issued upon the exercise of the Series A warrant and subsequent conversion to common stock upon the consummation of the IPO. The exercise price was amended to the price equal to the total proceeds that would have been required upon the exercise of the original warrant, divided by the amended number of warrant shares.

The amendment was accounted for as a modification of a stock award. The Company determined that there was no incremental increase in the fair value for the amendment of the award and accordingly there was no charge to the statement of operations for the years ended December 31, 2018.

A summary of outstanding and exercisable warrants as of December 31, 2019 is presented below:

Warrants Outstanding			Warrants Exercisable	
Exercise Price	Exercisable Into	Outstanding Number of Warrants	Weighted Average Remaining Life in Years	Exercisable Number of Warrants
$ 12.00	Common Stock	183,969	3.5	183,969
$ 6.25	Common Stock	75,000	3.4	75,000
$ 6.00	Common Stock	1,875,000	3.5	1,875,000
$ 4.99	Common Stock	100,000	3.5	100,000
$ 4.62	Common Stock	138,392	2.9	138,392
$ 4.30	Common Stock	116,912	1.1	116,912
$ 4.20	Common Stock	1,441,298	2.8	1,441,298
$ 2.00	Common Stock	50,000	4.4	50,000
$ 1.59	Common Stock	17,500	4.0	-
$ 1.50	Common Stock	188,108	4.2	188,108
$ 1.28	Common Stock	180,781	4.4	180,781
		4,366,960		4,349,460

Note 12 – Stock Based Compensation

Omnibus Incentive Plan

On November 21, 2016, the board of directors approved the Company's 2016 Omnibus Incentive Plan, which enables the Company to grant stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, other share based awards and cash awards to associates, directors, consultants, and advisors of the Company and its affiliates, and to improve the ability of the Company to attract, retain, and motivate individuals upon whom the Company's sustained growth and financial success depend, by providing such persons with an opportunity to acquire or increase their proprietary interest in the Company. Stock options granted under the 2016 Plan may be non-qualified stock options or incentive stock options, within the meaning of Section 422(b) of the Internal Revenue Code of 1986, except that stock options granted to outside directors and any consultants or advisers providing services to the Company or an affiliate shall in all cases be non-qualified stock options. The option price must be at least 100% of the fair market value on the date of grant and if issued to a 10% or greater shareholder must be 110% of the fair market value on the date of the grant.

The 2016 Plan is to be administered by the Board, which shall have discretion over the awards and grants thereunder. No awards may be issued after November 21, 2026. On December 11, 2017 the board of directors approved an amendment to the 2016 Omnibus Incentive Plan, whereby the number of common shares reserved for issuance under the plan was increased from 1,650,000 to 2,500,000. On April 26, 2018, our board of directors and our stockholders adopted and approved the Amended and Restated 2016 Omnibus Incentive Plan (the "2016 Plan"), whereby the number of common shares reserved for issuance under the plan was increased from 2,500,000 to 4,500,000, plus an annual increase on each anniversary of April 26, 2018 equal to 3% of the total issued and outstanding shares of our common stock as of such anniversary (or such lesser number of shares as may be determined by our board of directors).

Stock Options

On February 7, 2019, in connection with her Employment Agreement, the Board approved the grant in accordance with the Hancock Jaffe 2016 Omnibus Incentive Plan (the "Option Plan") of 150,000 non-qualified stock options for the purchase shares of the Company's common stock at an exercise price of $1.59 to H. Chris Sarner, our Vice President Regulatory Affairs and Quality Assurances. The exercise price was equal to the closing price of our common stock on the date that the Board approved the option grant. The options have a ten-year term and 50,000 of the options will vest on the first anniversary of Ms. Sarner's employment with the Company, and the remaining 100,000 options will vest on a quarterly basis over the following two-year period. The options had grant date fair value of $0.58 per share for an aggregate grant date fair value of $87,000, using the Black Scholes method with the following assumptions used: stock price of $1.59, risk-free interest rate of 2.47%, volatility of 36.3%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years. Ms. Sarner resigned her employment with the Company effective December 2, 2019 prior to any options vesting.

On February 7, 2019, the Board approved the grant in accordance with the Option Plan of 30,000 non-qualified stock options to purchase shares of the Company's common stock to H. Jorge Ulloa as compensation for services provided as the Company's Primary Investigator for the first-in-human trials of our VenoValve in Colombia in February and April 2019. The stock options were granted at an exercise price of $1.59, equal to the closing price of our common stock on the date that the Board approved the option grant. The options vest monthly over a one (1) year period. The options had grant date fair value of $0.58 per share for an aggregate grant date fair value of $17,400, using the Black Scholes method with the following assumptions used: stock price of $1.59, risk-free interest rate of 2.47%, volatility of 36.1%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

On January 7, 2019, Dr. Peter Pappas agreed to join the Company's Medical Advisory Board for a term of two years. The Board approved in accordance with the Option Plan the grant on March 6, 2019 of 20,000 non-qualified options to purchase shares of the Company's common stock to Dr. Pappas as compensation. The stock options were granted at an exercise price of $1.38, equal to the closing price of our common stock on the date that the Board approved the option grant. The options will vest monthly in twenty-four (24) equal installments for each month that he remains a member of the Company's Medical Advisory Board. The options had grant date fair value of $0.50 per share for an aggregate grant date fair value of $10,000, using the Black Scholes method with the following assumptions used: stock price of $1.38, risk-free interest rate of 2.50%, volatility of 35.9%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

On July 3, 2019, in connection with his Employment Agreement dated June 24, 2019, the Board approved the grant in accordance with the Option Plan of 115,000 non-qualified stock options for the purchase of shares of common stock at an exercise price of $2.00 to Brian Roselauf, our Director of Research and Development. The options have a ten-year term and 38,333 of the options will vest on the first anniversary of Mr. Roselauf's employment with the Company, and the remaining 76,667 options will vest on a quarterly basis over the following two-year period. The options had grant date fair value of $0.15 per share for an aggregate grant date fair value of $17,250, using the Black Scholes method with the following assumptions used: stock price of $1.02, risk-free interest rate of 1.76%, volatility of 35.9%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

On July 3, 2019, the Company granted in accordance with the Option Plan non-qualified stock options for the purchase of an aggregate of 40,000 shares of common stock at an exercise price of $2.00 to two members of its Medical Advisory Board. The options have a ten-year term and vest monthly over two years. The options had grant date value of $0.15 per share for an aggregate grant date value of $6,000, using the Black Scholes method with the following assumptions used: stock price of $1.02, risk-free interest rate of 1.76%, volatility of 35.9%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

On July 3, 2019, the Company granted in accordance with the Option Plan non-qualified stock options for the purchase of an aggregate of 60,000 shares of common stock at an exercise price of $2.00 to three key employees: Araceli Palacios, Maria Ruiz and Lydia Sepulveda. The options have a ten-year term and vest quarterly over three years. The options had grant date value of $0.15 per share for an aggregate grant date value of $9,000, using the Black Scholes method with the following assumptions used: stock price of $1.02, risk-free interest rate of 1.76%, volatility of 35.9%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

On July 22, 2016, the Company entered into an employment agreement with Marc H. Glickman, M.D., the Company's Senior Vice President and Chief Medical Officer (the "Pre-existing Employment Agreement"). On July 26, 2019, the Company entered an employment agreement with Dr. Glickman (the "New Employment Agreement") that superseded the terms of the Pre-existing Employment Agreement. In connection with entering into the New Employment Agreement, Dr. Glickman's existing 184,500 options ("Existing Options") to purchase Company common stock at $10.00 per share until October 1, 2026 that were granted in connection with his Pre-existing Employment Agreement, were repriced to $2.00 per share. The Existing Options had the repriced date fair value of $0.11 per share for an aggregate grant date fair value of $20,295 using the Black Scholes method with the following assumptions used: stock price of $1.05, risk-free interest rate of 1.84%, volatility of 36.7%, annual rate of quarterly dividends of 0%, and a contractual term of 3.6 years. The repricing of his Existing Options was accounted for as a modification and the excess fair value of $20,295 was expensed since the options had fully vested Additionally, Dr. Glickman, in connection to the New Employment Agreement was granted in accordance with the Option Plan stock options ("New Options") to purchase 180,000 common stock at a price equal to $2.00 per share exercisable until July 26, 2029, which vest quarterly over a three (3) year period. The New Options had a grant date fair value of $0.16 per share for an aggregate grant date fair value of $28,800, using the Black Scholes method with the following assumptions used: stock price of $1.05, risk-free interest rate of 1.86%, volatility of 35.7%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

On September 13, 2019, under the Company's nonemployee director compensation program, Robert Gray and Matthew Jenusaitis in connection with their appointment to the Board were each granted 60,000 options to purchase shares of our common stock at an exercise price of $2.00 per share in accordance with the Option Plan. All of these options vest in equal quarterly portions over a 3 year period starting from the September 13, 2019 grant date. The Options had grant date fair value of $0.13 per share for an aggregate grant date fair value of $15,600 using the Black-Scholes method with the following assumptions used: stock price of $.96, risk-free interest rate of 1.75%, volatility of 35.7%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

A summary of the option activity during the years ended December 31, 2019 and 2018 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2018	1,422,000	$ 10.16		
Granted	1,520,207	4.46		
Forfeited	(146,500)	10.00		
Outstanding, December 31, 2018	2,795,707	$ 7.07	9.0	$ -
Granted	715,000	1.88		
Forfeited	(1,018,500)	8.42		
Outstanding, December 31, 2019	2,492,207	$ 4.44	8.6	$ -
Exercisable, December 31, 2019	1,702,520	$ 5.28	8.5	$ -

A summary of outstanding and exercisable options and Restricted Stock units as of December 31, 2019 is presented below:

Options Outstanding			Options Exercisable	
Exercise Price	Exercisable Into	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$ 12.00	Common Stock	120,000	7.7	120,000
$ 10.00	Common Stock	146,500	6.8	146,500
$ 7.00	Common Stock	6,000	7.9	6,000
$ 4.99	Common Stock	1,080,207	8.7	972,186
$ 4.93	Common Stock	80,000	8.5	60,000
$ 2.98	Common Stock	150,000	8.5	62,500
$ 2.90	Common Stock	30,000	8.9	30,000
$ 2.57	Common Stock	130,000	8.9	50,000
$ 2.00	Common Stock	699,500	8.9	222,834
$ 1.59	Common Stock	30,000	9.1	25,000
$ 1.38	Common Stock	20,000	9.2	7,500
	Total	2,492,207		1,702,520

The Company recognized stock-based compensation related to stock options and restricted stock units of $492,084 and $864,626 during the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, there was $517,806 of unrecognized stock-based compensation expense related to outstanding stock options and restricted stock units that will be recognized over the weighted average remaining vesting period of 1.8 years.

The employment of William Abbott, our prior Chief Financial Officer was terminated effective July 20, 2018. Pursuant to the provisions of the 2016 Omnibus Incentive Plan and terms and conditions of his stock option Award Agreement, the non-exercisable portion of his option grant or 14,649 expired upon his termination and the exercisable portion or 131,851 options remained exercisable for 90 days following his termination. The prior Chief Financial Officer failed to exercise his exercisable options within the 90 day period and they were forfeited as of October 18, 2018.

Susan Montoya, our Senior Vice President of Operations and Quality Assurance/Regulatory Affairs resigned as of November 15, 2018 from the Company. Pursuant to the provisions of the 2016 Omnibus Incentive Plan and terms and conditions of her stock option Award Agreement, the exercisable portion or 818,500 options remained exercisable for 90 days following her resignation date. Ms. Montoya failed to exercise her exercisable options within the 90 day period and they were forfeited as of February 13, 2019.

Restricted Stock Units

In April 2019, Mr. Marcus Robins, a Director on the Board passed away. Per his restricted stock unit Award Agreement, upon his death, 29,183 units representing the non-vested portion of his restricted stock units were forfeited.

On September 13, 2019, under the Company's nonemployee director compensation program, Robert Gray and Matthew Jenusaitis in connection with their appointment to the Board were each granted 78,125 restricted stock units in accordance with the Option Plan, which based on the Company's closing stock price on the grant date were valued at $0.96 per unit for an aggregate grant date value of $150,000. These units vest in equal annual portions on the September 13, 2020, September 13, 2021 and September 13, 2022.

Restricted Stock Units Exercisable

Grant Date	Exercisable Into	Outstanding Number of Units	Weighted Average Remaining Life In Years
11/27/2018	Common Stock	38,910	1.8
9/13/2019	Common Stock	156,250	2.7
	Total	195,160	

Note 13 – Related Party Transactions

Contract & Research Revenue – Related Party

During the years ended December 31, 2019 and 2018, the Company recognized $0.0 and $70,400, respectively of revenue for contract research services provided pursuant to a Development and Manufacturing Agreement with HJLA dated April 1, 2016.

Note 14 – Subsequent Events

On February 25, 2020, the Company raised $650,000 in gross proceeds through a private placement bridge offering of its common stock and warrants to purchase its common stock to certain accredited investors (the “Bridge Offering”). The Company sold an aggregate of 1,300,000 shares of common stock and warrants to purchase 1,300,000 shares of common stock at an exercise price per share equal to $0.79 in the Bridge Offering pursuant to a securities purchase agreement between the Company and each of the investors in the Bridge Offering. The Company engaged Spartan Capital Securities, LLC, a FINRA-member as the exclusive placement agent for the Bridge Offering and to pay a fee in cash equal to 10% of the aggregate gross proceeds of the Bridge Offering and a warrant to purchase 82,279 shares of the Company’s common stock containing substantially the same terms as the warrant issued to investors in the Bridge Offering.