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, 2018

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:	**Name of Each Exchange on Which Registered:**
Common Stock, $0.00001 par value	The NASDAQ Stock Market LLC
Warrant to Purchase Commons Stock	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of the Form 10-K or any amendment to the Form 10-K. [ ]

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	[ ]	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, 2018 (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 $25,516,058

As of March 13, 2019, there were 14,167,698 shares of common stock outstanding.

HANCOCK JAFFE LABORATORIES, INC.
TABLE OF CONTENTS

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. 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 development stage 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. HJLI's products are being developed to address large unmet medical needs by either offering treatments where none currently exist or by substantially increasing the existing 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. Our third product is a Bioprosthetic Heart Valve ("BHV") which has the potential to be used for pediatric heart valve recipients. All of our current products are being developed for approval by the U.S. Food and Drug Administration ("FDA"). We currently receive tissue for our products from two domestic suppliers 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. For example, we developed, manufactured, and obtained FDA pre-market approval for the ProCol Vascular Bioprosthesis, a product for hemodialysis vascular access, which we sold to LeMaitre Vascular in March of 2016. Our current senior management team has been affiliated with more than 80 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 was FDA certified for commercial manufacturing of product.

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 venous 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 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. 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. Initially, the VenoValve will 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 medical or nonsurgical treatments for reflux occurring in the deep vein system. Compression garments or constant leg elevation address the symptoms, but ignore the underlying cause. Compliance with compression garments and leg elevation is extremely low, especially among the elderly. When CVI is isolated to the superficial veins, ablation or surgical excision of the affected saphenous vein is an option. For the deep vein system, valve transplants have been attempted but with very-poor results. Another potential option, the creation of valves using fibrous tissue, has only been performed in few centers worldwide. We believe that the reestablishment of proper direction of venous flow to the heart is the only reasonable remedy to the problem of reflux based CVI. Currently, however, there is no known devices or medicines available that would restore venous flow in the deep venous system.

The initial potential U.S. market for the first iteration of the VenoValve are the 2.6 million severe CVI sufferers with deep venous reflux. Future iterations of the VenoValve may also be appropriate for the superficial vein system, which would increase the potential market to all of the 4.8 million severe CVI sufferers with deep vein or superficial vein reflux.

Clinical Status

HJLI has had several Pre-FDA meetings to discuss the pre-clinical and clinical pathway for FDA approval for the VenoValve. Preclinical prototype testing, including in vivo animal studies, and in vitro hemodynamic studies, have demonstrated that the VenoValve mimics the function of a normal functioning venous valve. In preclinical studies, the VenoValve has passed the following areas: hemolysis, complement activation, platelet/leukocyte, thrombogenicity, cytotoxicity, and corrosion resistance. Moreover, the VenoValve has functioned normally in animals as shown by venograms as well as with intravascular ultrasound evaluations, and has also functioned normally under various conditions in hemodynamic testing. Ascending and descending venography of the VenoValve in pre-clinical studies has demonstrated competency of the valve as well as being open in appropriate flow patterns.

Based upon feedback from the FDA, we agreed to conduct a small first-in-human study of between 5 to 10 patients for the VenoValve overseas prior to initiating our pivotal U.S. trial. The first-in-human study will provide us with valuable feedback to make any necessary product modifications or adjustments to our surgical implantation procedures prior to conducting our 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 U.S. Food and Drug Administration, for our first-in-human trial for the VenoValve. On February 19, 2019, HJLI announced that the first VenoValve was successfully implanted in a patient in Bogota, Colombia, that the VenoValve appears to be functioning as it should, and that there were no signs of any early adverse events. After continuing to follow the first patient for a few weeks, additional implantations are scheduled to take place in Bogota in March of 2019. HJLI expects preliminary results from the first-in-human study to be made public in June of 2019, with additional study results to be made available in the fourth quarter of 2019.

Patients in the first-in-human trial will be monitored at regular intervals. Endpoints for the first-in-human VenoValve study will include improvements in reflux time, as well as rVCSS measurements, VAS scores, and VEINES scores, three well known clinical assessments for venous disease and assessments of improvement in the patient’s quality of life and reduction in pain. Duplex scans will be used to measure reflux time. A duplex scan, also known as a doppler test with ultrasound, is a non-invasive evaluation of blood flow through veins and arteries. On average, patients without CVI have reflux times of about 1 second, with reflux times increasing with the increasing severity of the disease. Improvements in reflux times will be expressed as a percentage of the original duplex measurement.

The rVCSS is used to measure changes in venous disease severity and response to treatment and includes ten descriptors or subcategories of venous disease which are rated from 0 to 3 by the clinician. Once an initial baseline rVCSS is established for each patient, changes in rVCSS scores will be tracked and may be expressed as a percentage change from the original or previous scoring. The VAS or Visual Analogue Scale is widely used in clinical research to measure intensity and frequency of pain. Scores are marked along a continuum between "no pain" and "worst pain". VEINES is a disease specific, quality of life measurement associated with venous ulcers. The VEINES instrument consists of 35 items in two categories that generate two summary scores: a quality-of-life questionnaire (VEINES-QOL) comprising of 25 items that quantify disease effect on quality of life; and a symptom questionnaire (VEINES-Sym) which consists of 10 items that measure physical symptoms. In addition to being painful, prone to infection, and hampering mobility, venous ulcers are known to impact work capacity, social activity, self-care and personal hygiene, and to cause depression, anxiety, and social isolation.

Once HJLI has accumulated sufficient positive data from the first-in-human VenoValve trial, we will present the data to the FDA and apply for an investigational device exemption ("IDE") to conduct the U.S. pivotal trial. The U.S. pivotal trial is expected to take approximately one year.

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 54% 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, 3 to 4 grafts are used for each CABG surgery.

Although CABG surgeries are invasive, improved surgical techniques over the years have lowered the fatality rate from CABAG 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. Traditionally, the patient's heart was stopped prior to the graft procedure and the patient was placed on a heart-lung bypass machine. Once the grafts are in place, the art was restarted using electric shock. In recent years, some doctors have begun to perform the CABG procedure "off -pump", meaning that CABG surgeries are performed without stooping the patient's heart and without the need for the heart lung bypass machine. In 2016, approximately 13% of the CABG surgeries were performed off-pump.

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 cut 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 saphenous vein grafts that are used as conduits for CABAG surgeries fail within the first year after the CABG surgery. A significant percentage fail within the first 30 days. At 10 years, the SVG 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 SVG failure: size mismatch, and a thickening of the interior of the SVG 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 occurs when a layer of endothelial cells on the inner surface of the SVG is 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, instead of harvesting the saphenous vein from the patient's leg. In addition to avoiding the invasive and painful SVG harvest process, HJLI's CoreoGraft closely matches the size of the coronary arteries, hopefully 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 SVGs.

In addition to providing an 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 significant 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 it was damaged by the radiation. Another example are patients undergoing a second CABG surgery. Due in large part to early SVG failures, patients may need a second CABG surgery. If the SVG was 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 choice for all CABG patients in addition to the LIMA.

Clinical Status

Several years ago HLJI obtained CE Mark certification for the CoreoGraft and the CoreoGraft was implanted in several CABG patients in Europe on a humanitarian basis. These were patients that had no other viable graft options. Although not performed under clinical conditions or as part of a controlled study, the overall impression of the CoreoGraft was very positive, and several patients lived more than one year. The CE Mark has since expired.

In October of 2018, HJLI announced a sponsored research agreement with the Texas Heart Institute with respect to the CoreoGraft. Founded in 1962 by world renowned cardiovascular surgeon Dr. Denton A. Cooley, the Texas Heart Institute is recognized internationally for research programs in cardiology, cardiovascular surgery, stem cell and gene therapy, and regenerative medicine, and is dedicated to reducing the devastating toll of cardiovascular disease through innovative and progressive programs in research, education and improved patient care.

In December of 2018, we announced our first pre-clinical trial for the CoreoGraft at the Texas Heart Institute.

The first CoreoGraft animal study will focus on short term graft patency and graft viability. Five CoreoGrafts will be surgically implanted over a three-week period and continuously monitored for thirty days for flow rates and patency using transonic probes. The implantable probe will verify flows and patency of the grafts. Following the monitoring part of the trial, the CoreoGrafts will undergo pathology examinations to look for evidence of cellular abnormalities that might lead to failure or impact graft performance.

HJLI expects to provide an update after the first implantation. The performance results of the study and the pathology are expected to be released in the second quarter 2019. Provided that the study is successful, Hancock Jaffe would then seek a Pre-FDA meeting to discuss the additional pre-clinical testing that will be necessary for in-human trials.

Bioprosthetic Heart Valve

Background

In addition to our two lead products under development, HJLI has a third product, the Bioprosthetic Heart Valve ("BHV"), that is a porcine based heart valve designed to function like a native heart valve and designed to provide a patient greater functional performance. Early pre-clinical testing has demonstrated improved function over existing surgically implanted devices and, due to these study results, we believe BHV may be suitable for the pediatric population as it accommodates its performance concomitant with the growth of the patient.

The Opportunity

We believe that pediatric patients requiring the smallest valve sizes, typically 19 to 21 mm in diameter, are not adequately treated by current market devices. The primary challenge for these patients is to provide adequate blood flow during growth and development. Typically, this requires more complex procedures or multiple successive surgeries to provide a larger valve replacement. The patient outgrows the valve size several times between ages two and twenty, requiring several surgeries before adulthood, also referred to as patient prosthetic mismatch.

Congenital heart defects are serious and common conditions that have significant impact on morbidity, mortality, and healthcare costs in children and adults. The most commonly reported incidence of congenital heart defects in the United States is between 4 and 10 per 1,000, clustering around 8 per 1,000 live births. We believe these patients could benefit from the BHV, potentially resulting in fewer follow-on surgeries.

Clinical Status

Heart valves are developed in accordance with ISO Standard 5840, as well as other international and regulatory standards. HJLI is undergoing an audit of the previous pre-clinical studies that were conducted for the BHV to determine the next steps for BHV testing. Once the audit results are complete the HJLI Board of Directors will determine whether to continue the development of the BHV.

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 FDCA 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 investigational device exemption ("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 FDCA 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 three 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 80 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, decades long and trusted relationship with abattoir suppliers, and a combination of tissue preservation and gamma irradiation that enhances device functions and guarantees sterility. Our patents pertaining to the unique design advantages and processing methods of valvular tissue as a bioprosthetic device provide further functional advantages over potential competitors. The critical design components and function relationships unique to the BHV are protected by U.S. Patent No. 7,815,677, issued on October 19, 2010 and expiring on July 9, 2027. Two patent applications have been filed for the VenoValve with the U.S. Patent and Trademark Office.

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 $13,042,709, $7,791,469, $3,387,490 and $1,604,013 for the years ended December 31, 2018, 2017, 2016 and 2015, respectively. As a result of our historical losses, we had an accumulated deficit of $48,562,528 as of December 31, 2018. 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 significant 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 three 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 one additional product candidate (the Bioprosthetic Heart Valve), 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, 2018 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 over the next twelve months from the issuance of this Form 10-K.

A significant portion of our revenue comes from royalty income earned from sales by LMAT and once the three-year royalty term ends on March 18, 2019, we will no longer receive royalties.

In March 2016, 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, which three-year term ends on March 18, 2019. We have earned royalty income of $116,152 and $137,711 for the years ended December 31, 2018 and 2017, respectively, or 62% and 33%, respectively of our total revenue for these years. When the three-year term ends on March 18, 2019, we will no longer generate royalty revenue until one of our product candidates is licensed, if ever. As a result, once the royalty agreement ends, a material and adverse effect on our revenue and results of operations could result.

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

We rely on two domestic and one international third-party vendors to supply porcine and bovine tissue for our three 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, 2018 and 2017, we had available federal and state net operating loss carryforwards, or NOLs, of approximately $17.4 million and $11.1 million, respectively. Pre-2018 federal and state NOLs carryovers may be carried forward for twenty years and begin to expire in 2026. 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, 2018, we also had federal research and development tax credit carryforwards of approximately $0.2 million. 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. 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, its reinstatement thereafter is uncertain, but if it is reinstated, it may adversely affect our results of operations and cash flows. 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 and are actively pursuing patent applications for our product candidates and manufacturing processes. As of December 31, 2018, the critical design components and function relationships for our bioprosthetic heart valve are protected by U.S. patent 7,815,677 issued on October 19, 2010, and we owned 2 issued U.S. patents, no foreign patents, 2 pending U.S. patent applications and no pending foreign patent applications. Assuming all required fees are paid, individual patents or applications owned by us will expire between July 20, 2027 and November 20, 2029.

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.

It is anticipated that our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, will beneficially own or control 5,927,488 shares of our common stock, which in the aggregate will represent approximately 39.1% of the outstanding shares of our common stock. 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 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.

We expect that 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 likely need to raise additional capital within the next 12 months. 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.

We do not anticipate dividends to be paid on the common stock, and investors may lose the entire amount of their investment.

Cash dividends have never been declared or paid on our common stock, and we do not anticipate such a declaration or payment for the foreseeable future. We expect to use future earnings, if any, to fund business growth. Therefore, stockholders will not receive any funds absent a sale of their shares. We cannot assure stockholders of a positive return on their investment when they sell their shares, nor can we assure that stockholders will not lose the entire amount of their investment.

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, in addition to the offering, 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.

ITEM 1B. Unresolved Staff Comments

None

ITEM 2. Properties and Facilities

We lease a 14,507 square foot manufacturing facility in Irvine, California, which is certified under the ISO 13485 medical device manufacturing standard for medical devices and operates under the FDA's QSR. 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 25, 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 to supply bovine tissue. The Company is disputing the amount owed and that the Agreement called for a fixed monthly fee regardless of tissue delivered. The Company believes it has numerous defenses and rights of setoff including without limitation: that ATSCO had an obligation to mitigate the fees when they were not delivering tissues and not incurring any costs; $173,400 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% as described in Note 4 to the Financial Statements – Significant Accounting Policies - *Investments*) and is not the obligation of HJLI; the Company has a right of setoff against any amounts owed to ATSCO for 120,000 shares of HJLI stock transferred to ATSCO's principal and owner; the yields of the materials delivered by ATSCO to HJLI was inferior; and the Agreement was constructively terminated. The Company recorded the disputed invoices in accounts payable and as of December 31, 2018, the Company has fully accrued for the outstanding claim against the Company. On January 18, 2019, the Superior Court granted a Right to Attach Order and Order for Issuance of Writ of Attachment in the amount of $810,055, which the Company plans on appealing. The attachment order is not a binding ruling on the merits of the case and the Company plans on filing a Cross-Complaint for abuse of process and excessive and wrongful attachment as $173,400 of the claim is to a wholly separate company, and over $500,000 of the claim is attributable to invoices sent without delivery of any tissue. The Company has entered into new supply relationships with two domestic and one international company to supply porcine and bovine tissues. A Mandatory Settlement Conference is scheduled for July 26, 2019 and the Jury Trial is scheduled for September 9, 2019.

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, 2018, the Company has fully accrued for the outstanding claim against the Company.

The Company has been contacted by an individual that claims to be owed a fee for introducing the Company to Alexander Capital. The Company has conducted its own factual investigation and legal analysis and believes that the claim is without merit. The individual has threatened to file a lawsuit, and in the event that a lawsuit is filed, the Company would have numerous defenses including without limitation that the individual was unlicensed to provide the services he alleges he provided.

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 $6.00 warrants issued as part of unit consisting of one share of common stock and one warrant to purchase commons stock sold to the public through the initial public offering began trading on The Nasdaq Global Market under the symbol "HJLIW" on May 31, 2018.

Holders of Record

On March 12, 2019, the closing price per share of our common stock and listed warrants were $1.46 and $.47, respectively as reported on The Nasdaq Capital Market. We had approximately 737 stockholders of record and 230 listed warrant holders of record as of February 11, 2019. On March 13, 2019 there were 14,167,698 shares of our common stock issued and outstanding and 4,004,375 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	2,883,256	$ 7.07	1,616,744
Equity compensation plans not approved by security holders	-	-	-
	2,883,256	$ 7.07	1,616,744

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

On November 27, 2018, the Company elected to issue 3,334 shares of common stock for the 25% of the $15,000 monthly fee per the Service Agreement with our Chief Medical Officer Outside the United States 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.

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 development stage company developing biologic-based solutions that are designed to be life sustaining or life enhancing for patients with cardiovascular disease, and peripheral arterial and venous disease. HJLI's products are being developed to address large unmet medical needs by either offering treatments where none currently exist or by substantially increasing the type of treatment. 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. Our third product is a Bioprosthetic Heart Valve ("BHV") which has the potential to be used for pediatric heart valve recipients. All of our current products are being developed for approval by the U.S. Food and Drug Administration ("FDA"). 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. For example, we developed, manufactured, and obtained FDA pre-market approval for the ProCol Vascular Bioprosthesis, a product for hemodialysis vascular access, which we sold to LeMaitre Vascular in March of 2016. Our current senior management team has been affiliated with more than 80 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 was FDA certified for commercial manufacturing of product.

Each of our product candidates will be required to successfully complete significant clinical trials to demonstrate the safety and efficacy of the product candidate before it will be able to be approved by the FDA. The completion of these clinical trials 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. 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. Initially, the VenoValve will 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 medical or nonsurgical treatments for reflux occurring in the deep vein system. Compression garments or constant leg elevation address the symptoms, but ignore the underlying cause. Compliance with compression garments and leg elevation is extremely low, especially among the elderly. When CVI is isolated to the superficial veins, ablation or surgical excision of the affected saphenous vein is an option. For the deep vein system, valve transplants have been attempted but with very-poor results. Another potential option, the creation of valves using fibrous tissue, has only been performed in few centers worldwide. We believe that the reestablishment of proper direction of venous flow to the heart is the only reasonable remedy to the problem of reflux based CVI. Currently, however, there is no known devices or medicines available that would restore venous flow in the deep venous system.

The initial potential U.S. market for the first iteration of the VenoValve are the 2.6 million severe CVI sufferers with deep venous reflux. Future iterations of the VenoValve may also be appropriate for the superficial vein system, which would increase the potential market to all of the 4.8 million severe CVI sufferers with deep vein or superficial vein reflux.

CoreoGraft

The CoreoGraft is a bovine based off the shelf conduit that could potentially be used to revascularize the heart, instead of harvesting the saphenous vein from the patient's leg. In addition to avoiding the invasive and painful SVG harvest process, HJLI's CoreoGraft closely matches the size of the coronary arteries, 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 SVGs.

In addition to providing an 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 significant 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 it was damaged by the radiation. Another example are patients undergoing a second CABG surgery. Due in large part to early SVG failures, patients may need a second CABG surgery. If the SVG was 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 choice for all CABG patients in addition to the LIMA.

Bioprosthetic Heart Valve

In addition to our two lead products under development, HJLI has a third product, the Bioprosthetic Heart Valve ("BHV"), that is a porcine based heart valve designed to function like a native heart valve and designed to provide a patient greater functional performance. Early pre-clinical testing has demonstrated improved function over existing surgically implanted devices and, due to these study results, we believe BHV may be suitable for the pediatric population as it accommodates its performance concomitant with the growth of the patient.

We believe that pediatric patients requiring the smallest valve sizes, typically 19 to 21 mm in diameter, are not adequately treated by current market devices. The primary challenge for these patients is to provide adequate blood flow during growth and development. Typically, this requires more complex procedures or multiple successive surgeries to provide a larger valve replacement. The patient outgrows the valve size several times between ages two and twenty, requiring several surgeries before adulthood, also referred to as patient prosthetic mismatch.

Congenital heart defects are serious and common conditions that have significant impact on morbidity, mortality, and healthcare costs in children and adults. The most commonly reported incidence of congenital heart defects in the United States is between 4 and 10 per 1,000, clustering around 8 per 1,000 live births. We believe these patients could benefit from the BHV, potentially resulting in fewer follow-on surgeries.

Results of Operations

Comparison of the year ended December 31, 2018 to the year ended December 31, 2017

Financial Highlights

We reported net losses of $13,042,709 and $7,791,469 for the years ended December 31, 2018 and 2017, respectively, representing an increase in net loss of $5,251,240 or 67%, resulting primarily from increases in non-cash amortization of debt discount related to an embedded conversion options, increases in operating expenses of 1,616,003 and non-cash loss from impairment of $319,635 and partially offset by a $1,223,688 non-cash gain on extinguishment of convertible notes payable.

Revenues

Revenues earned during the year ended December 31, 2018 consist of royalty income and contract research - related party of $116,152 and $70,400, respectively. Revenues earned during the year ended December 31, 2017 were generated through product sales of the ProCol Vascular Bioprosthesis of $184,800, and royalty income of $137,711 and contact research revenue of $99,600. Sale of the ProCol Vascular Bioprosthesis during the year ended December 31, 2017 resulted from our contract manufacturing supply arrangement with LMAT, which we entered in connection with the sale of the ProCol Vascular Bioprosthesis to LMAT in 2016. There were no orders for product from LMAT during the year ended December 31, 2018.

Royalty income is earned pursuant to the terms of our March 2016 asset sale agreement with LMAT. The decrease in royalty income results from lower royalties earned on LMAT sales for the year ended December 31, 2018, versus the year ended December 31, 2017. We will not receive any royalty revenues from LMAT after March 2019.

The contract research revenue is related to research and development services performed on behalf of HJLA, pursuant to a Development and Manufacturing Agreement dated April 1, 2016.

As a developmental stage Company, our revenue, if any, is expected to be diminutive. The Company may license one or more of its products resulting in royalty revenues.

Gross Profit (Loss)

Cost of sales were $0 and $419,659 for the years ended December 31, 2018 and 2017, respectively, consisting primarily of labor costs and the costs of materials used for the sub-contract manufacture of the vascular bioprosthesis. The gross loss for the year ended December 31, 2017 on product sales of the ProCol Vascular Bioprosthesis was primarily the result of (i) lower than expected product sales, and (ii) high fixed costs which result from a fixed volume contract with the supplier of our raw materials. The Company has subsequently entered into new supply relationships with two domestic and one international company to supply tissues at a lower cost than previously obtained from the former supplier that we had a fixed volume contract.

Selling, General and Administrative Expenses

For the year ended December 31, 2018, selling, general and administrative expenses increased by $1,026,990 or 19%, to $6,482,953 from $5,455,963 for the year ended December 31, 2017. The increase is primarily due to increases of approximately $1,121,000 in non-cash stock compensation expense, increases of approximately $493,000 in legal, professional fees and consulting fees primarily relating to our IPO, increases in severance expenses of $300,000 and increases in insurance costs of approximately $160,000 partially offset by a decrease in salaries and benefits of approximately $574,000 primarily related to the incentive payments made in 2017 to our former Chief Executive Officer and a decrease in marketing expenses of approximately $198,000 during the period.

Research and Development Expenses

For the year ended December 31, 2018, research and development expenses increased by $589,013 or 91%, to $1,238,749 from $649,736 for the year ended December 31, 2017. The increase is primarily due to increased labor costs, benefits and supplies and materials associated with research and development activities supporting the first-in-human trial for the VenoValve scheduled for February 2019 in Columbia along with developing techniques to manufacture the Bioprosthetic Heart Valve and the pediatric bioprosthetic venous valves.

Net Gain on Extinguishment of Convertible Notes Payable

On June 4, 2018, upon the consummation of our IPO, principal and interest of $2,740,500 and $51,807, respectively, owed on the 2017 Notes were converted into 802,345 shares of our common stock at a conversion price of $3.50 per share, and principal and interest of $10,000 and $267, respectively was paid in cash. Principal and interest of $2,897,500 and 53,584, respectively owed on the 2018 Notes were converted into 848,192 shares of our common stock at a conversion price of $3.50 per share. The conversion of the Notes was deemed to be a debt extinguishment (see Note 8 to the Financial Statements – Convertible Notes and Convertible Note – Related Party) and, as a result, during the year ended December 31, 2018, we recognized a $43,474 loss on extinguishment of convertible notes payable, consisting of the fair value of the common stock issued upon the conversion of the Notes of $8,252,685, less the extinguishment of $5,743,391 of principal and interest converted and $2,465,820 of derivative liabilities associated with the embedded conversion option of the extinguished Notes. The loss on extinguishment partially offset the gain on extinguishment described above.

Interest Expense

For the year ended December 31, 2018, interest expense increased by $88,655 to $298,161 from $209,506 for the year ended December 31, 2017, principally due to the interest on the 2018 Notes prior to the conversion to common shares on June 4, 2018, upon the consummation of our IPO.

Amortization of Debt Discount

During the year ended December 31, 2018, amortization of debt discount expense increased by $4,852,606 to $6,562,736 from $1,710,130 for the year ended December 31, 2017. The increase is related to amortization of debt discount related to the embedded conversion option in the Notes, as well as the Warrants issued with the Notes during the period from June 2017 through January 2018.

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. For the year ended December 31, 2017, we recorded a loss on the change in fair value of derivative liabilities of $26,215. Our derivative liabilities are related to warrants issued in connection with our Series A preferred stock and Series B preferred stock financings, plus warrants issued in connection with the Notes, as well as the embedded conversion options in the Notes.

Loss on Impairment

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. (See Note 11 to the Financial Statements – Commitments and Contingencies - Development and Manufacturing Agreement). 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 and $459,917 for the years ended December 31, 2018 and 2017, respectively, of which $222,410 and $459,917 respectively, resulted from the 8% cumulative dividend on the Preferred Stock and $3,087,591 and $0, respectively, resulted from the beneficial conversion feature recorded in connection with the conversion of the Preferred Stock (see Note 12 to the Financial Statements – Temporary Equity).

Liquidity and Capital Resources

We have incurred losses since inception and negative cash flows from operating activities for the years ended December 31, 2018 and 2017. As of December 31, 2018, we had an accumulated deficit of $48,562,528. Since inception, we have funded our operations primarily through our IPO in 2018, private placements of equity and convertible debt securities as well as modest revenues from royalties, contract research and sales of the ProCol Vascular Bioprosthesis. As of March 12, 2019, we had a cash balance of $4,092,974, which includes $810,055 of restricted cash (see note 11 to the Financial Statements - Commitments and Contingencies)

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

	December 31, 2018	December 31, 2017
Cash	$ 2,740,645	$ 77,688
Working capital (deficiency)	$ 1,313,980	$ (8,004,171)

Based upon our cash and working capital as of December 31, 2018, 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, including the Units sold in our IPO.

For the years ended December 31, 2018 and 2017

For the years ended December 31, 2018 and 2017, we used cash of $6,355,838 and $4,202,240, respectively, in operations. Cash used during the year ended December 31, 2018 was primarily attributable to our net loss of $13,042,709, adjusted for net non-cash expenses in the aggregate amount of $7,265,272 and net cash used by changes in the levels of operating assets and liabilities of $578,401. Cash used during the year ended December 31, 2017 was primarily attributable to our net loss of $7,791,469, adjusted for net non-cash expenses in the aggregate amount of $2,496,333, and net cash provided by changes in the levels of operating assets and liabilities of $1,092,896.

During the year ended December 31, 2018, cash used by investing activities was $12,422 for computer equipment and software. During the year ended December 31, 2017, cash provided by investing activities was $165,312 of which $166,250 represented cash proceeds received in connection with the asset sale to LMAT and $216,000 was received from the repayment of advances paid to a related party partially offset by $206,000 cash paid in exchange for a note receivable to a related party and $10,938 for purchases of property and equipment.

During the year ended December 31, 2018, cash provided by financing activities was $9,031,217, of which $7,657,427 was provided in connection with net proceeds from our initial public offering, $2,603,750 from the issuance of convertible notes and warrants, $722,500 of proceeds from issuances of notes payable, partially offset by the repayments of notes payable of $1,125,000, repayments of notes payable – related party of $120,864 and payment of initial public offering costs of $706,596. During the year ended December 31, 2017, cash provided in financing activities was $4,058,102, of which $2,564,400 was provided in connection with proceeds from the issuance of convertible notes and warrants (net of issuance costs of $186,100), $1,292,400 in connection with proceeds from the issuance of Series B preferred stock and warrants (net of issuance costs of $230,349), $311,000 was provided by proceeds from the issuance of notes payable, $275,000 was provided from issuance of notes payable, partially offset by the repayments of notes payable of $174,734 and payment of initial public offering costs of $209,964.

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 28.5% 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.

Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on the guidance of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") ASC 820 "Fair Value Measurements and Disclosures" ("ASC 820") which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

FASB ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1	Quoted prices available in active markets for identical assets or liabilities trading in active markets.
Level 2	Observable inputs other than quoted prices included in Level 1, such as quotable prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
Level 3	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

Financial instruments, including accounts receivable and accounts payable are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The Company's other financial instruments include notes payable, the carrying value of which approximates fair value, as the notes bear terms and conditions comparable to market for obligations with similar terms and maturities. Derivative liabilities are accounted for at fair value on a recurring basis.

The fair value of derivative liabilities as of December 31, 2018 and 2017, by level within the fair value hierarchy appears below:

Description:	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Derivative liabilities - Preferred Stock Series A Warrants			
December 31, 2018	$ -	$ -	$ -
December 31, 2017	$ -	$ -	$ 541,990
Derivative liabilities - Preferred Stock Series B Warrants			
December 31, 2018	$ -	$ -	$ -
December 31, 2017	$ -	$ -	$ 60,551
Derivative liabilities - Convertible Debt Warrants			
December 31, 2018	$ -	$ -	$ -
December 31, 2017	$ -	$ -	$ 1,298,012
Derivative liabilities - Convertible Debt Embedded Conversion Feature			
December 31, 2018	$ -	$ -	$ -
December 31, 2017	$ -	$ -	$ 1,176,365

The following table sets forth a summary of the changes in the fair value of Level 3 derivative liabilities that are measured at fair value on a recurring basis:

	Derivative Liabilities
Balance - January 1, 2018	$ 3,076,918
Issuance of derivative liabilities - convertible debt warrants	1,942,362
Issuance of derivative liabilities - convertible debt embedded conversion feature	3,652,588
Extinguishment of derivative liabilities upon debt modification	(2,420,390)
Change in fair value of derivative liabilities	(191,656)
Extinguishment of derivative liabilities upon conversion of debt	(2,465,820)
Reclassification of warrant derivatives to equity	(3,594,002)
Balance - December 31, 2018	$ -

Preferred Stock

The Company applies the accounting standards for distinguishing liabilities from equity under U.S. GAAP when determining the classification and measurement of its Series A and Series B Preferred Stock (together, the "Preferred Stock"). Preferred stock subject to mandatory redemption is classified as a liability instrument and is measured at fair value. Conditionally redeemable preferred stock (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) is classified as temporary equity. At all other times, preferred stock is classified as permanent equity. As of the issuance date, the carrying amount of the Preferred Stock was less than the redemption value. If the Company were to determine that redemption was probable, the carrying value would be increased by periodic accretions such that the carrying value would equal the redemption amount at the earliest redemption date. Such accretion would be recorded as a preferred stock dividend (see Note 12 to the Financial Statements – Temporary Equity).

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 (as discussed in Note 8 to the Financial Statements - Convertible Notes and Convertible Note – Related Party), 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 (see Fair Value of Financial Instruments, above).

The Company recorded a gain on the change in fair value of derivative liabilities of $191,656 and a loss of $26,215 during the years ended December 31, 2018 and December 31, 2017, respectively.

Convertible Notes

The convertible notes payable discussed in Note 8 to the Financial Statements – Convertible Notes and Convertible Note – Related Party, had a conversion price that could be adjusted based on the Company's stock price, which resulted in the conversion feature being recorded as a derivative liability and a debt discount. The debt discount was amortized to interest expense over the life of the respective note, using the effective interest method.

On June 4, 2018, principal of $10,000 owed on the Convertible Notes was paid in cash, and all of the remaining principal and interest owed pursuant to the Convertible Notes were converted into common stock in connection with the Company's IPO. The conversion of the Convertible Notes was deemed to be a debt extinguishment; accordingly, the warrant and embedded conversion option derivative liabilities were remeasured to fair value on June 4, 2018 and reclassified to additional paid in capital (See Derivative Liabilities, above).

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 and the beneficial conversion feature recorded in connection with the conversion of the Preferred Stock (see Note 12 to the Financial Statements – Temporary Equity).

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,	
	2018	**2017**
Net loss	$ (13,042,709)	$ (7,791,469)
Deemed dividend to Series A and B preferred stockholders	(3,310,001)	(459,917)
Net loss attributable to common stockholders	$ (16,352,710)	$ (8,251,386)

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, 2018 and 2017:

	December 31,	
	2018	**2017**
Shares of common stock issuable upon conversion of preferred stock	-	$ 629,746
Shares of common stock issuable upon exercise of preferred stock warrants and the subsequent conversion of the preferred stock issued therewith	-	50,285
Shares of common stock issuable upon the conversion of convertible debt	-	229,208
Shares of common stock issuable upon exercise of warrants	$ 3,780,797	371,216
Shares of common stock issuable upon exercise of options	2,883,256	1,422,000
Potentially dilutive common stock equivalents excluded from diluted net loss per share	$ 6,663,827	$ 2,702,455

Revenue Recognition

In March 2016, the FASB issued 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 will be 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 will be 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,	
	2018	**2017**
Product sales	$ -	$ 184,800
Royalty income	116,152	137,711
Contract research - related party	70,400	99,600
Total Revenues	$ 186,552	$ 422,111

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, 2018.

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 $103,400 as of December 31, 2018 and December 31, 2017, respectively, related to cash received in advance for contract research and development services. The Company expects to satisfy its remaining performance obligations for contract research and development services and recognize the deferred revenue over the next twelve months.

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 $2,490,645 as of December 31, 2018. There were no cash balances in excess of federally insured amounts as of December 31, 2017.

During the year ended December 31, 2017, 57% of the Company's revenues from continuing operations were from the sub-contract manufacture of product for LeMaitre Vascular, Inc. ("LeMaitre"), and 43% were from royalties earned from the sale of product by LeMaitre, with whom the Company entered a three-year Post-Acquisition Supply Agreement effective March 18, 2016. During the year ended December 31, 2018, 100% of the Company's revenues from continuing operations were from royalties earned from the sale of product by LeMaitre. The three-year Post-Acquisition Supply Agreement from which the Company earns royalty from the sale of product by LeMaitre ends on March 18, 2019. The Company did not recognize any subcontract manufacturing revenues during the year ended December 31, 2018. During the years ended December 31, 2018 and 2017, 38% and 24%, respectively, of the Company's revenues were earned from contract research and development services performed for HJLA.

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 17 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 will adopt the standard using the prospective approach. Upon adoption, we expect to record approximately $1.1 million in right-of-use assets and operating lease liabilities in our Balance Sheets.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments (Topic 230)" ("ASU 2016-15"). ASU 2016-15 will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017. ASU 2016-15 requires adoption on a retrospective basis unless it is impracticable to apply, in which case the Company would be required to apply the amendments prospectively as of the earliest date practicable. The adoption of ASU 2016-15 did not have a material impact on the Company's financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718); Scope of Modification Accounting. The amendments in this ASU provide guidance that clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. If the fair value, vesting conditions or classification of the award changes, modification accounting will apply. The guidance is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The adoption of ASU 2017-09 did not have a material impact on the Company's financial statements.

On June 20, 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718) - Improvements to Nonemployee Share-Based Payment Accounting, which simplifies accounting for share-based payment transactions resulting for acquiring goods and services from nonemployees. ASU 2018-07 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The new standard was adopted effective April 1, 2018, using the modified retrospective approach; however, the Company did not identify or record any adjustments to the opening balance of retained earnings on adoption. The new standard did not have a material impact on the Company's 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, 2018, 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, 2018 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 (the "SEC") 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, 2018 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, 2018. 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, 2018.

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, 2018 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 the Record Date, their positions held and the year they commenced service with the Company

Name	Age	Position(s) Held	Year of Service Commencement
Yury Zhivilo	59	Director, Chairman	2007
Robert A. Berman	56	Director, Chief Executive Officer	2018
Dr. Francis Duhay	58	Director	2018
Dr. Sanjay Shrivastava	51	Director	2018
Marcus W. Robins	65	Director	2018
Benedict Broennimann, M.D.	61	Chief Medical Officer, OUS	2016
Marc H. Glickman, M.D.	69	Senior Vice President and Chief Medical Officer	2016
Robert Rankin	66	Chief Financial Officer, Secretary & Treasurer	2018

Yury Zhivilo has served as Chairman of our board of directors since September 2007. In 2004, he co-founded Leman Cardiovascular S.A., a private company that develops, manufactures and markets bioprosthetic products used in cardiovascular surgery, as well as nephrology indications. Since 2010, he has been serving as President of Leman Cardiovascular S.A., Chief Executive Officer and President of Dante-Lido Financial Limited, and as Managing Director of Biodyne, all of which are based in Morge, Switzerland. Biodyne's principal line of business is to invest in medical device technology companies. Mr. Zhivilo is also currently serving as a director of Dante-Lido Financial Limited and Biodyne. From 2004 to present, Mr. Zhivilo served as Chairman of the board of director of Leman Cardiovascular S.A. Prior to that, he served as Chairman and Chief Executive Officer of Base Metal Trading Limited from 1992 to 2004. Mr. Zhivilo received a Senior Specialist degree in economics in 1985 from Moscow State Institute of International Affairs. We believe Mr. Zhivilo is qualified to serve as a member of our board of directors because of his extensive experience in the medical device industry as both an operating executive and as a board member.

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 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.

Dr. Sanjay Shrivastava has served as 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.

Marcus W. Robins, CFA has served as member of our board of directors since October 2018. He is an experienced fund manager, publisher and equity analyst. He is currently the fund manager at Crown Capital Management LP, a new micro-cap and small-cap fund he started in July 2018. Since 2003, Mr. Robins founded and has been a registered investment advisor at Catalyst Financial Resources LLC, a provider of institutional level research for micro-cap companies. Catalyst Financial is the follow-on to *The Red Chip Review*, which Mr. Robins launched in 1993. At its peak, *Red Chip* provided research coverage on over 500 companies and had a subscriber base of over 7,000 investors, 100 brokerage offices and 25 money managers. In addition to *Red Chip*, Mr. Robins has been published in numerous national publications including *The Wall Street Journal*, *Bloomberg, Investor's Business Daily, Kiplinger's*, and *Forbes,* where he had his own column for 8 years. Mr. Robins received his Bachelor's degree in Chemistry from Willamette University and a MBA from Willamette University – Atkinson Graduate School of Management.

Benedict Broennimann, M.D. has served as our Chief Medical Officer, Outside of United States, or OUS, since April 2018. He served as our Chief Executive Officer from September 2016 to August 2017, and our Co-Chief Executive Officer from August 2017 to April 2018. From 2006 to 2008, Dr. Broennimann served as our Chairman and Chief Executive Officer, and from 2009 to 2015 he was engaged by us as a consultant to facilitate our efforts to gain various regulatory approvals in Europe. From 2012 to 2016, he served as Chief Executive Officer and Chief Medical Officer of OstomyCure AS, where he was responsible for achieving CE marking of a Class IIb medical implant and leading strategic alliances and negotiations. From 2004 to 2008, he was also Chief Executive Officer of Leman Cardiovascular S.A., where he spearheaded fundraising and cardiovascular device developments. Dr. Broennimann served as Principal at Heidrick & Struggles from 2000 to 2002 and Highland Partners from 2003 to 2004. He also served as a Senior Partner at Rosewall from 2008 to 2011. Dr. Broennimann attended the University of Bern in Switzerland, where he received his Doctor of Medicine, and was Chief Resident in the Department of General Surgery and Transplantation at the Centre Hospitalier Universitaire Vaudois in Lausanne, Switzerland. Dr. Broennimann is also board certified in general surgery and pharmaceutical medicine.

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 2018

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 will be amended and restated to 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 2019 Annual Meeting of Stockholders, or until their earlier death, disability, resignation or removal):

Marc W. Robins*, Robert A. Berman

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

Yury Zhivilo

(*) 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 Mr. Robins and Drs. Duhay and 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. Robins and Drs. Duhay and Shrivastava, who will each serve on our audit committee, our compensation committee, and our nominating and corporate governance committee, 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 5 times during 2018 and also acted by unanimous written consent. Each member of our board of directors was present at least 60% of the board of directors meetings held. 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. Prior to the completion of this offering, copies of each committee's charter will be 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. Robins, who is the chair of the committee, and Drs. Shrivastava and Duhay. 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. Robins 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, and Mr. Robins and Dr. Duhay. 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, and Mr. Robins 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 and Yury Zhivilo serves as Chairman of the board of directors. 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, three 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 and Chief Financial Officer, who report directly to our board of directors and who supervise 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

Except as set forth below, 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, 2018 and 2017. 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, 2018.

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	2018	293,308(1)		507,697(8)			7,692(10)	808,697
Chief Executive Officer	2017	-	-	-	-	-	-	-
Benedict Broennimann, M.D.	2018	120,000(2)	-	-	-	-	120,000-(2)	240,000
Former Co-Chief Executive Officer	2017	360,000(2)	-		-	-	-	360,000
Steven A. Cantor	2018	71,539(3)		-	-	-	4892(11)	76,431
Former Co-Chief Executive Officer	2017	300,000(3)	300,000(4)	-	-	-	274,816(12)	874,816
Robert A. Rankin	2018	110,577(5)		165,000(9)			17,297(13)	292,874
Chief Financial Officer, Secretary and Treasurer	2017	-	-	-	-	-	-	-
William R. Abbott	2018	173,077(6)					150,991(14)	324,068
Former Chief Financial Officer	2017	267,445(6)					38,101(15)	305,546
Marc H. Glickman, M.D.	2018	300,000	-	-	-	-	62,640(16)	362,640
Chief Medical Officer and Senior Vice President	2017	300,000	-	-	-	-	41,717(17)	341,717
Susan Montoya	2018	301,638(7)	-	-	-	-	37,827(18)	339,465
Former Vice President Operations, Quality Assurance/Regulatory Affairs	2017	295,192(7)	-	-	-	-	43,539(19)	338,731

(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) Beginning August 30, 2016, Dr. Broennimann's annual base salary rate under his employment agreement was $360,000. Dr. Broennimann received $90,000 in base salary in 2017. He orally agreed to defer certain amounts of base salary until such time as the Company and Dr. Broennimann agree. As a result, the Company owed Dr. Broennimann $410,000 in base salary as of December 31, 2017. On April 30, 2018, Dr. Broennimann assigned $200,000 of his compensation to Rosewall, which agreed to accept 44,444 shares of our common stock in satisfaction of the deferred compensation. Dr. Broennimann is not a U.S. taxpayer and is not, therefore, subject to U.S. tax laws governing deferred compensation. 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.

(3) 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 and 2017.

(4) Mr. Cantor received a $300,000 incentive payment in 2017 for achieving certain capital raising milestones in accordance with his employment agreement.

(5) 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.

(6) Mr. Abbott's annual base salary rate under his employment agreement was amended on June 1, 2017, where his annual base salary was increased to $300,000 from $225,000. 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 and 2017.

(7) Ms. Montoya resigned her employment with the Company effective November 15, 2018. Amounts in this column for Ms. Montoya reflect base salary earned for 2018 and 2017.

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

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

(12) Includes (i) federal and state income tax payments of $125,180 and $23,149, respectively, made by us on behalf of Mr. Cantor to gross up his $300,000 incentive payment received in 2017 in accordance with his employment agreement, (ii) $12,497 from company paid healthcare, and (iii) relocation and temporary living expenses of $38,408 and the associated federal and state tax payments made by us on Mr. Cantor's behalf of $19,186 and $4,980, respectively, and (iv) $51,415 paid to Mr. Cantor in 2017 under the terms of a retention award that we entered into with him in September 2013.

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

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

(15) Includes company paid healthcare of $25,883 and 401(k) match of $12,218.

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

(17) Includes company paid healthcare of $27,831 and 401(k) match of $13,846

(18) Includes company paid healthcare of $24,779 and 401(k) match of $13,048.

(19) Includes company paid healthcare of $28,779 and 401(k) match of $14,760.

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.

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).

Benedict Broennimann, M.D.

On August 30, 2016, we entered into an employment agreement with Benedict Broennimann, M.D., one of our previous Co-Chief Executive Officers. Pursuant to the terms of his employment agreement, Dr. Broennimann's initial base salary is $360,000, subject to annual review and adjustment at the discretion of our board of directors. Dr. Broennimann has orally agreed to defer certain amounts of cash compensation until such time as we and Dr. Broennimann agree. As a result, we owe Dr. Broennimann $410,000 as of December 31, 2017. On April 30, 2018, Dr. Broennimann assigned $200,000 of his compensation to Rosewall, which agreed to accept 44,444 shares of our common stock in satisfaction of the deferred compensation. Dr. Broennimann is not a U.S. taxpayer and is not, therefore, subject to U.S. tax laws governing deferred compensation.

In connection with his employment, Dr. Broennimann received an initial equity grant of an option to purchase up to 146,500 shares of our common stock with 20% of the shares vesting immediately and 80% vesting on a monthly basis over 24 months thereafter. Dr. Broennimann is an at-will employee and has a full-time commitment. Further, Dr. Broennimann'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.

In April 2018, we entered into an amendment to Dr. Broennimann's employment agreement to appoint him as our Chief Medical Officer, OUS. Other than Dr. Broennimann's title and duties, the remaining terms of his employment agreement were unchanged.

On May 1, 2018, the Company entered into Service Agreement with Rosewall Ventures Ltd ("Rosewall"), which Dr. Broennimann is Chairman and principal owner, for Dr. Broennimann to contract his services through Rosewall as Chief Medical Officer, OUS for a $15,000 fixed fee per month.

Steven A. Cantor

On July 1, 2016, we entered into an employment agreement with Mr. Cantor, who prior to December 1, 2016, was our business development manager and commencing on December 1, 2016 became our Chief Business Development Officer. The employment agreement was amended on December 1, 2016, and again on June 12, 2017. Pursuant to the terms of his employment agreement, as amended to date, Mr. Cantor's base salary was $300,000 and was subjected to annual review and adjustment at the discretion of our board of directors, and in no event was Mr. Cantor's annual salary reduced from the preceding year without his consent. Mr. Cantor was entitled to receive a bonus of $250,000 upon the earlier of (i) a commercial sale of one of our product candidates, or (ii) the entry into a definitive agreement for the distribution or license of one of our product candidates. We also agreed to pay Mr. Cantor's relocation expenses in connection with Mr. Cantor's move to Orange County, California, and, after June 12, 2018 or at such time he no longer spends a substantial portion of his daily working day working on matters that reasonably can be determined at Mr. Cantor's sole discretion to be in Orange County, California, to move Mr. Cantor back to New York when requested by him. In addition, so long as Mr. Cantor was living in Orange County, California, we agreed to pay or reimburse Mr. Cantor for all payments relating to (i) a furnished residence in Orange County, California and (ii) an automobile selected by Mr. Cantor, provided, however, that the amount of payments or reimbursements pursuant to (i) and (ii) would not exceed $5,000 per month. We further agreed to pay Mr. Cantor an amount equal to the aggregate federal, state and local income and employment taxes imposed on Mr. Cantor as a direct result of such payments or reimbursements in advance.

We also agreed to a net of withholdings and deductions lump sum payment to Mr. Cantor in the amount of twelve months' gross salary, which was subjected to claw back if Mr. Cantor's relocation was for less than twelve months. Such lump sum payment and withholdings and deductions were to be paid if we raised at least $3.0 million in one or more financings. We have raised at least $3.0 million since June 12, 2017 through the issuance of the 2017 Notes and the 2018 Notes. As a result, we paid Mr. Cantor $300,000 accordingly.

In connection with his employment, Mr. Cantor received 299,400 shares of our common stock, which we issued to replace shares of our common stock previously earned under Mr. Cantor's prior employment agreement and we ratified the issuance to Mr. Cantor of a warrant to purchase 416,667 shares of our common stock at an exercise price of $12.00 per share. As of December 31, 2017, Mr. Cantor returned to us 250,000 of such warrants and transferred the balance of 166,667 warrants to others.

Mr. Cantor's employment agreement prohibited 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. Cantor was entitled to severance in the event of certain terminations of employment. In the event Mr. Cantor's employment was terminated by us without cause and other than by reason of disability or he resigned for good reason, subjected to his timely executing a release of claims in our favor and in addition to certain other accrued benefits, he was entitled to receive 12 months of continued base salary (or 24 months if such termination occurred within 24 months following a change of control).

On March 20, 2018, we terminated Mr. Cantor's employment with our company.

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.

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.

William Abbott

On July 22, 2016, we entered into an employment agreement with William Abbott, our Senior Vice President, Chief Financial Officer, Secretary and Treasurer. Pursuant to the terms of his employment agreement, Mr. Abbott's base salary is $225,000, 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. On June 1, 2017, Mr. Abbott's employment agreement was amended to change his base salary to $300,000. In connection with his employment, Mr. Abbott received an initial equity grant of an option to purchase up to 293,000 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 Mr.

Abbott's employment agreement ends on December 31, 2018 and will be automatically extended for additional three-year terms, unless either party gives written notice to the other to terminate the agreement or unless sooner terminated under its terms. If we elect not to renew Mr. Abbott's employment agreement, our non-renewal will be deemed a termination without cause or for good reason thereunder.

Mr. Abbott 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. Abbott'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. Abbott is entitled to severance in the event of certain terminations of employment. In the event Mr. Abbott'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 12 months of continued base salary (or 24 months if such termination occurs within 24 months following a change of control).

On July 20, 2018, Mr. Abbott services with the Company were terminated.

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. Pursuant to the terms of his 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 employment, 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 employment agreement ends on December 31, 2018 and will be automatically extended for additional three-year terms, unless either party gives written notice to the other to terminate the agreement or unless sooner terminated under its terms. If we elect not to renew Dr. Glickman's employment agreement, our non-renewal will be deemed a termination without cause or for good reason thereunder.

Dr. Glickman 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. Dr. Glickman'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, Dr. Glickman is entitled to severance in the event of certain terminations of employment. In the event Dr. Glickman'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 12 months of continued base salary (or 24 months if such termination occurs within 24 months following a change of control).

Susan Montoya

On July 22, 2016, we entered into an employment agreement with Susan Montoya, our Senior Vice President of Operations and Quality Assurance/Regulatory Affairs. Pursuant to the terms of her employment agreement, Ms. Montoya's base salary is $295,000, subject to annual review and adjustment at the discretion of our board of directors, and she will be eligible for an annual year-end discretionary bonus of up to 50% of her base salary, subject to the achievement of key performance indicators, as determined by our board of directors. In connection with her employment, Ms. Montoya received an initial equity grant of an option to purchase up to 818,500 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 Ms. Montoya's employment agreement ends on December 31, 2018 and will be automatically extended for additional three-year terms, unless either party gives written notice to the other to terminate the agreement or unless sooner terminated under its terms. If we elect not to renew Ms. Montoya's employment agreement, our non-renewal will be deemed a termination without cause or for good reason thereunder.

Ms. Montoya is entitled to participate in our employee benefit, pension and/or profit sharing plans, and we will pay certain health and dental premiums on her behalf. Ms. Montoya's employment agreement prohibits her 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 her employment agreement, Ms. Montoya is entitled to severance in the event of certain terminations of employment. In the event Ms. Montoya's employment is terminated by us without cause and other than by reason of disability or she resigns for good reason, subject to her timely executing a release of claims in our favor and in addition to certain other accrued benefits, she is entitled to receive 12 months of continued base salary (or 24 months if such termination occurs within 24 months following a change of control).

On November 15, 2018, Ms. Montoya 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, 2018.

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	2018	540,104(1)	540,103(1)	N/A	$ 4.99	September 23, 2028
	2017	-	-	N/A	-	-
Benedict Broennimann, M.D. Former Co-Chief Executive Officer	2018	146,500(2)	-	N/A	$ 10.00	October 1, 2026
	2017	97,669(2)	48,831(2)	N/A	$ 10.00	October 1, 2026
Steven A. Cantor Former Co-Chief Executive Officer	2018	-	-	N/A	-	-
	2017	-	-	N/A	-	-
Robert A. Rankin Chief Financial Officer, Secretary and Treasurer	2018	-	150,000(3)	N/A	$ 2.98	July 15, 2028
	2017	-	-	N/A	-	-
William R. Abbott Former Chief Financial Officer	2018	-(4)	-	N/A	-	-
	2017	97,669(2)	48,831(2)	N/A	$ 10.00	October 1,2026
Marc H. Glickman, M.D. Chief Medical Officer and Senior Vice President	2018	184,500(2)	-	N/A	$ 10.00	October 1, 2026
	2017	123,000(2)	61,500(2)	N/A	$ 10.00	October 1, 2026
Susan Montoya Vice President Operations, Quality Assurance/Regulatory Affair	2018	818,500(5)	-	N/A	$ 10.00	October 1, 2026
	2017	545,669(2)	272,831(2)	N/A	$ 10.00	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 October 1, 2016, and 20% of the shares subject to these options vested immediately upon grant, with the remaining shares subject to these options vesting monthly over twenty-four months.

(3) Options were granted on July 16, 2018, and 50,000 options vest 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.

(4) Mr. Abbott's service with the Company terminated July 20, 2018 and per the Amended and Restated 2016 Omnibus Incentive Plan, he had 90 days to exercise his options after his termination date, which he failed to exercise forfeiting his options.

(5) Ms. Montoya resigned her employment with the Company effective November 15, 2018. Per the Amended and Restated 2016 Omnibus Incentive Plan, she had 90 days to exercise her options after her termination date or until February 13, 2019, which she failed to exercise forfeiting her options.

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 4,500,000 shares of our common stock for issuance under the 2016 Plan, 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), 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, which became effective upon the completion of our initial public offering, will limit 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 will 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-five thousand (25,000) options and restricted stock units ("RSUs") worth up to twenty-five thousand dollars ($25,000) per annum (the "Annual RSUs"). A Non-Employee Director who is newly appointed to the Board other than in connection with an annual meeting of stockholders will generally also receive a grant of sixty-thousand (60,000) options and RSUs worth up to seventy-five thousand dollars ($75,000) upon appointment (an "Initial RSU Award", which together with the "Annual RSUs" are the "Award RSUs"). All Award RSUs 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 2018 and 2017.

Name		Fees earned or paid in cash	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation($)	Total ($)
Yury Zhivilo	2018	-	-	-	-	-	-	-
	2017	-	-	-	-	-	-	-
Francis Duhay, M.D.	2018		$57,491(1)	$33,600(2)				$ 91,091
Marcus W. Robins	2018		$57,491(1)	$33,600(2)				$ 91,091
Sanjay Shrivastava, M.D.	2018		$57,491(1)	$33,600(2)				$ 91,091
Robert A. Anderson, Former Director	2018	-	-	$ 9,960(3)	-	-	-	$ 9,960
	2017	-	-	$86,860(4)	-	-	$ 1,000(5)	$ 87,860
Robert W. Doyle, Former Director	2018	-	-	$ 9,960(3)	-	-		$ 9,960
	2017	-	-	$86,860(4)	-	-	$ 1,000(5)	$ 87,860
Steven Girgenti, Former Director	2018	-	-	$ 9,000(3)	-	-	-	$ 9,000
	2017	-	-	$78,400(4)	-	-	-	$ 78,400

(1) Under the Company's nonemployee director compensation program, Dr. Francis Duhay, Mr. Marcus Robins 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. Francis Duhay, Mr. Marcus Robins 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) 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.

(4) During 2017, we issued options to purchase shares of our common stock to our former directors Robert Doyle, Robert Anderson, and Steven Girgenti each exercisable for of 40,000 shares of our common stock, at an exercise price of $12.00 per share. The options were valued at $1.96 per share as of the date of the grant. In addition, we issued to each Robert Doyle and Robert Anderson options exercisable to purchase 3,000 shares of our common stock, at an exercise price of $7.00 per share. The options were valued at $2.82 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. These amounts do not reflect actual compensation earned or to be earned by our non-employee directors.

(5) Robert Doyle and Robert Anderson each received $1,000 from us for attending a two day meeting at our headquarters.

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

The following table lists, as of February 28, 2019, 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 14,167,698 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 February 28, 2019. 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]	4,443,569	31.4%
Named Executive Officers and Directors		
Yury Zhivilo[2]	4,478,581	31.6%
Robert A. Berman[3]	648,124	4.4%
Marc Glickman, M.D.[3]	184,500	1.3%
Benedict Broennimann, M.D.[3] [4]	586,283	4.1%
Francis Duhay, M.D. [3]	10,000	*
Marcus W. Robins[3]	10,000	*
Sanjay Shrivastava, M. D. [3]	10,000	*
All directors and executive officers as a group (7 persons)[5]	5,927,488	39.1%

* 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) Mr. Zhivilo is the controlling shareholder, President and director of Biodyne Holding, S.A., or Biodyne, and Leman Cardiovascular S.A., or Leman. Accordingly, Mr. Zhivilo is deemed to be the beneficial owner of the shares of common stock owned by Biodyne (4,443,569 shares) and Leman (35,012 shares). He has voting and dispositive power over the shares held by Biodyne and Leman. The principal business address of Biodyne is 13 Rue de la Gare, 1100 Morges, Switzerland.
(3) Represents shares of common stock issuable upon exercise of options that are currently exercisable or exercisable within 60 days of February 28, 2019.
(4) Dr. Broennimann may be deemed to be the beneficial owner of 439,783 shares of common stock owned by Rosewall and 146,500 shares of common stock issuable upon exercise of options. The principal business address of Rosewall is Route de Lausanne 3, CH-1303 Penthaz, Switzerland.
(5) Excludes shares held by Mr. Cantor, Ms. Montoya, Mr. Doyle, Mr. Anderson and Mr. Girgenti, who were included in our named executive officers and directors for the year ended December 31, 2018, but do not serve as one of our executive officer or directors as of December 31, 2018.

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our directors and executive officers and persons who beneficially own more than 10% of our common stock (referred to herein as the “reporting persons”) file with the SEC various reports as to their ownership of and activities relating to our common stock. Such reporting persons are required by the SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in fiscal year 2018, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons, with exception of Form 3 and 4 by Dr. Francis Duhay.

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

The following is a description of transactions since January 1, 2017 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 June 30, 2015, we entered into a loan agreement with Biodyne. The loan agreement has a maximum borrowing capacity of $2,200,000, available in advances in several installments over a period of 8 months. All advances bore interest at a rate of 3% per annum. On April 1, 2016, the related note was amended such that it was convertible at the option of Biodyne into shares of our common stock at a conversion price of $10.00 per share. The interest was due and payable on an annual basis, the first payment of which was due November 1, 2016. The highest principal balance owed under the loan agreement was approximately $1,200,000 as of August 31, 2016. On August 31, 2016, the entire principal advanced and $36,789 of related interest was converted into 123,481 shares of our common stock. During the year ended on December 31, 2017, we borrowed additional $499,000 in aggregate principal and incurred approximately $13,886 in interest. An additional 197 shares were issued in satisfaction of accrued interest payable.

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, 2018, Biodyne owns 4,443,569 shares of our common stock, representing an ownership interest of approximately 37.6%. Yury Zhivilo, the chairman of our board of directors, is the majority shareholder of Biodyne.

Leman Cardiovascular S.A.

On May 10, 2013, we issued a note payable with a principal balance amount of $1,070,000, or the Leman Note, in connection with the purchase of certain assets from Leman. The Leman Note bears interest at a rate of 6% per annum and originally matured on May 10, 2014, which was later extended to May 10, 2018. During the years ended 2013, 2014, 2015, 2016 and 2017 we repaid principal of $302,000, $30,000, $248,000, $76,000 and $174,734, respectively. As of December 31, 2017 and 2016, the principal balance due on the Leman Note was $270,038 and $444,772, respectively, and the related accrued interest was $6,436 and $15,419, respectively. As of December 31, 2017, the principal balance due is $270,038. The highest principal balance owed under the Leman Note since January 1, 2015 was approximately $768,011.

On April 26, 2018, the Company and Leman agreed to convert the remaining aggregate principal and accrued interests of the Leman Note into shares of our common stock at a conversion price of $4.30 per share. We issued to Leman 35,012 shares of common stock for the conversion of the Leman Note which carried $148,905 in aggregate principal and approximately $1,648 in accrued interests.

Yury Zhivilo, the chairman of our board of directors, is a shareholder of Leman, and Norman Jaffe, our former president, and Sue Montoya, who was our Senior Vice President of Operations, Regulatory Affairs and Quality Assurance until she resigned her employment with the Company, were former officers of Leman.

Rosewall Venture Ltd.

On April 30, 2018, we issued to Rosewall 44,444 shares of our common stock at a value of $4.50 per share in satisfaction of $200,000 in deferred compensation to Mr. Benedict Broennimann, M.D., our Chief Medical Officer, OUS. Dr. Broennimann holds controlling interest in Rosewall and has assigned his compensation to Rosewall.

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. The Company elected to issue 5,339 shares of common stock for the 25% of the monthly fee for the months of October, November and December of 2018.

Indemnification of Officers and Directors

Our amended and restated certificate of incorporation and amended and restated bylaws, which became effective in connection with the completion of our initial public offering, 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, 2018 and 2017 totaled $103,195 and $126,655, 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, 2018 and 2017 were $184,432 and $204,104, 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, 2018 and 2017 were $4,000 and $11,000, 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).
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 *
10.45	Form of Restricted Stock Unit under Amended and Restated 2016 Omnibus Incentive Plan *
10.46	Share Purchase Agreement, dated as March 12, 2019, by and among the Company and the investors signatory thereto *
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**
99.1*	Effect of private placement offering
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 13, 2019

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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, 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 3, the Company has a significant working capital deficiency, has incurred significant losses from operations 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 over the next twelve months from the issuance of this 10-K. Management's plans in regard to these matters are also described in Note 3. 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 13, 2019

HANCOCK JAFFE LABORATORIES, INC.
BALANCE SHEETS

	December 31, 2018	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 2,740,645	$ 77,688
Accounts receivable, net	32,022	35,181
Prepaid expenses and other current assets	64,306	57,544
Total Current Assets	2,836,973	170,413
Property and equipment, net	26,153	23,843
Intangible assets, net	666,467	1,109,410
Deferred offering costs	-	880,679
Security deposits and other assets	29,843	30,543
Total Assets	$ 3,559,436	$ 2,214,888
Liabilities, Temporary Equity and Stockholders' Equity (Deficiency)		
Current Liabilities:		
Accounts payable	$ 1,077,122	$ 1,451,244
Accrued expenses and other current liabilities	412,871	903,594
Accrued interest - related parties	-	20,558
Convertible notes payable, net of debt discount	-	1,574,832
Convertible note payable - related party	-	499,000
Notes payable	-	275,000
Notes payable - related party	-	270,038
Deferred revenue - related party	33,000	103,400
Derivative liabilities	-	3,076,918
Total Liabilities	1,522,993	8,174,584
Redeemable Convertible Series A Preferred Stock, par value $0.00001, 0 and 1,005,700 shares issued and outstanding and liquidation preference of $0 and $10,801,863 at December 31, 2018 and December 31, 2017, respectively	-	3,935,638
Redeemable Convertible Series B Preferred Stock, par value $0.00001, 0 and 253,792 shares issued and outstanding and liquidation preference of $0 and $3,103,416 at December 31, 2018 and December 31, 2017, respectively	-	1,235,117
Commitments and Contingencies		
Stockholders' Equity (Deficiency):		
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, 11,722,647 and 6,133,678 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	117	61
Additional paid-in capital	50,598,854	24,389,307
Accumulated deficit	(48,562,528)	(35,519,819)
Total Stockholders' Equity (Deficiency)	2,036,443	(11,130,451)
Total Liabilities, Temporary Equity and Stockholders' Equity (Deficiency)	$ 3,559,436	$ 2,214,888

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

HANCOCK JAFFE LABORATORIES, INC.
STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2018	**2017**
Revenues:		
Product sales	$ -	$ 184,800
Royalty income	116,152	137,711
Contract research - related party	70,400	99,600
Total Revenues	186,552	422,111
Cost of revenues	-	419,659
Gross Profit	186,552	2,452
Selling, general and administrative expenses	6,482,953	5,455,963
Research and development expenses	1,238,749	649,736
Loss on Impairment of intangible asset	319,635	-
Loss from Operations	(7,854,785)	(6,103,247)
Other Expense (Income):		
Amortization of debt discount	6,562,736	1,710,130
(Gain) on extinguishment of convertible notes payable	(1,481,317)	(257,629)
Interest expense, net	298,161	209,506
Change in fair value of derivative liabilities	(191,656)	26,215
Total Other Expense (Income)	5,187,924	1,688,222
Net Loss	(13,042,709)	(7,791,469)
Deemed dividend to preferred stockholders	(3,310,001)	(459,917)
Net Loss Attributable to Common Stockholders	$ (16,352,710)	$ (8,251,386)
Net Loss Per Basic and Diluted Common Share:	$ (1.75)	$ (1.35)
Weighted Average Number of Common Shares Outstanding:		
Basic and Diluted	9,362,474	6,126,824

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

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

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	(Deficiency)
Balance at January 1, 2017	6,123,481	$ 61	$ 23,508,930	$ (27,728,350)	$ (4,219,359)
Exchange of accrued interest for common stock	197	-	1,973	-	1,973
Stock-based compensation					
Amortization of stock options	-	-	801,624	-	801,624
Common Stock issued to consultants	10,000	-	76,780	-	76,780
Net loss				(7,791,469)	(7,791,469)
Balance at December 31, 2017	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

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,	
	2018	**2017**
Cash Flows from Operating Activities		
Net loss	$ (13,042,709)	$ (7,791,469)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount	6,562,736	1,710,130
Gain on extinguishment of convertible notes payable	(1,481,317)	(257,629)
Stock-based compensation	1,922,455	878,404
Depreciation and amortization	133,419	139,213
Change in fair value of derivatives	(191,656)	26,215
Loss on Impairment	319,635	-
Changes in operating assets and liabilities:		
Accounts receivable, net	3,159	(11,681)
Inventory	-	90,908
Prepaid expenses and other current assets	(6,762)	(11,495)
Security deposit and other assets	700	(700)
Accounts payable	(294,122)	545,385
Accrued expenses	(210,976)	377,079
Deferred revenue - related party	(70,400)	103,400
Total adjustments	6,686,871	3,589,229
Net Cash Used in Operating Activities	(6,355,838)	(4,202,240)
Cash Flows from Investing Activities		
Collection of receivable for sale of assets	-	166,250
Issuance of note receivable to related party	-	(160,000)
Receipts from collections of note receivable to related party	-	160,000
Advances to related party	-	(206,000)
Receipts from repayment of related party advances	-	216,000
Purchase of property and equipment	(12,422)	(10,938)
Net Cash (Used in) Provided by Investing Activities	(12,422)	165,312
Cash Flows from Financing Activities		
Proceeds from initial public offering, net [1]	7,657,427	-
Initial public offering costs paid in cash	(706,596)	(209,964)
Proceeds from issuance of notes payable	-	275,000
Repayments of notes payable	(1,125,000)	-
Proceeds from issuance of note payable to related party	-	311,000
Repayments of notes payable - related party	(120,864)	(174,734)
Proceeds from issuance of notes payable, net of commission	722,500	-
Proceeds from issuance of convertible notes, net [2]	2,603,750	2,564,400
Proceeds from issuance of redeemable Series B preferred stock and warrant, net [3]	-	1,292,400
Net Cash Provided by Financing Activities	9,031,217	4,058,102
Net Increase in Cash and Cash Equivalents	2,662,957	21,174
Cash and cash equivalents - Beginning of year	77,688	56,514
Cash and cash equivalents - End of year	$ 2,740,645	$ 77,688

[1] Net of offering costs paid from escrow of $967,573
[2] Net of cash offering costs of $186,100
[3] Net of cash offering costs of $175,196

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

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

	Year Ended December 31,	
	2018	**2017**
Supplemental Disclosures of Cash Flow Information:		
Cash Paid During the Period For:		
Interest, net	$ 286,551	$ 105,938
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	$ 1,973
Fair value of placement agent warrants issued in connection with preferred stock offering included in derivative liabilities	$ -	$ 57,283
Fair value of warrants issued in connection with convertible debt included in derivative liabilities	$ 1,046,763	$ 870,966
Embedded conversion option in convertible debt included in derivative liabilities	$ 1,239,510	$ 2,349,560
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. ("Hancock Jaffe" or the "Company") is a development stage company developing biologic-based solutions that are designed to be life sustaining or life enhancing for patients with cardiovascular disease, and peripheral arterial and venous disease. HJLI's products are being developed to address large unmet medical needs by either offering treatments where none currently exist or by substantially increasing the type of treatment. 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. Our third product is a Bioprosthetic Heart Valve ("BHV") which has the potential to be used for pediatric heart valve recipients. All of our current products are being developed for approval by the U.S. Food and Drug Administration ("FDA"). 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.

The Company also realizes sub-contract manufacturing and royalty revenue from sales of the ProCol® Vascular Bioprosthesis for hemodialysis patients with end stage renal disease, which has been approved by the FDA, as well as revenue from research and development services performed on behalf of Hancock Jaffe Laboratory Aesthetics, Inc. ("HJLA"), (in which the Company owns a minority interest as described in Note 4 to the Financial Statements – Significant Accounting Policies - *Investments*), pursuant to a Development and Manufacturing Agreement dated April 1, 2016.

Note 2 - Initial Public Offering

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.

Note 3 – 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 $13,042,709 during the year ended December 31, 2018 and had an accumulated deficit of $48,562,528 at December 31, 2018. Cash used in operating activities was $6,355,838 for the year ended December 31, 2018. 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, 2018, the Company had a cash balance of $2,740,645 and working capital of $1,313,980.

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 4 – 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.

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct, incremental professional fees relating to the IPO, have been capitalized within non-current assets and were offset against the IPO proceeds upon the consummation of the IPO. Deferred offering costs of $2,542,555, consisting primarily of legal, accounting and underwriting fees of which $880,679 of the deferred offering costs were incurred in 2017, and the full amount was charged to additional paid in capital upon the consummation of the IPO on June 4, 2018.

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 28.5% 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.

Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on the guidance of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") ASC 820 "Fair Value Measurements and Disclosures" ("ASC 820") which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

FASB ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1	Quoted prices available in active markets for identical assets or liabilities trading in active markets.
Level 2	Observable inputs other than quoted prices included in Level 1, such as quotable prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
Level 3	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

Financial instruments, including accounts receivable and accounts payable are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The Company's other financial instruments include notes payable, the carrying value of which approximates fair value, as the notes bear terms and conditions comparable to market for obligations with similar terms and maturities. Derivative liabilities are accounted for at fair value on a recurring basis.

The fair value of derivative liabilities as of December 31, 2018 and December 31, 2017, by level within the fair value hierarchy appears below:

Description:	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Derivative liabilities - Preferred Stock Series A Warrants			
December 31, 2018	$ -	$ -	$ -
December 31, 2017	$ -	$ -	$ 541,990
Derivative liabilities - Preferred Stock Series B Warrants			
December 31, 2018	$ -	$ -	$ -
December 31, 2017	$ -	$ -	$ 60,551
Derivative liabilities - Convertible Debt Warrants			
December 31, 2018	$ -	$ -	$ -
December 31, 2017	$ -	$ -	$ 1,298,012
Derivative liabilities - Convertible Debt Embedded Conversion Feature			
December 31, 2018	$ -	$ -	$ -
December 31, 2017	$ -	$ -	$ 1,176,365

The following table sets forth a summary of the changes in the fair value of Level 3 derivative liabilities that are measured at fair value on a recurring basis:

	Derivative Liabilities
Balance – January 1, 2017	$ 551,351
Issuance of derivative liabilities - common stock Series B warrants	57,283
Issuance of derivative liabilities - convertible debt warrants	1,268,177
Issuance of derivative liabilities - convertible debt conversion feature	2,349,560
Extinguishment of derivative liabilities - convertible debt conversion feature	(1,175,668)
Change in fair value of derivative liabilities	26,215
Balance - December 31, 2017	3,076,918
Issuance of derivative liabilities - convertible debt warrants	1,942,362
Issuance of derivative liabilities - convertible debt embedded conversion feature	3,652,588
Extinguishment of derivative liabilities upon debt modification	(2,420,390)
Change in fair value of derivative liabilities	(191,656)
Extinguishment of derivative liabilities upon conversion of debt	(2,465,820)
Reclassification of warrant derivatives to equity	(3,594,002)
Balance - December 31, 2018	$ -

Preferred Stock

The Company applies the accounting standards for distinguishing liabilities from equity under U.S. GAAP when determining the classification and measurement of its Series A and Series B Preferred Stock (together, the "Preferred Stock"). Preferred stock subject to mandatory redemption is classified as a liability instrument and is measured at fair value. Conditionally redeemable preferred stock (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) is classified as temporary equity. At all other times, preferred stock is classified as permanent equity. As of the issuance date, the carrying amount of the Preferred Stock was less than the redemption value. If the Company were to determine that redemption was probable, the carrying value would be increased by periodic accretions such that the carrying value would equal the redemption amount at the earliest redemption date. Such accretion would be recorded as a preferred stock dividend (see Note 12 to the Financial Statements – Temporary Equity).

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 (as discussed in Note 8 to the Financial Statements - Convertible Notes and Convertible Note – Related Party), 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 (see Fair Value of Financial Instruments, above).

The Company recorded a gain and a loss on the change in fair value of derivative liabilities of $191,656 and $26,215 during the years ended December 31, 2018 and 2017, respectively.

Convertible Notes

The convertible notes payable discussed in Note 8 to the Financial Statements – Convertible Notes and Convertible Note – Related Party, had a conversion price that could be adjusted based on the Company's stock price, which resulted in the conversion feature being recorded as a derivative liability and a debt discount. The debt discount was amortized to interest expense over the life of the respective note, using the effective interest method.

On June 4, 2018, principal of $10,000 owed on the Convertible Notes was paid in cash, and all of the remaining principal and interest owed pursuant to the Convertible Notes were converted into common stock in connection with the Company's IPO. The conversion of the Convertible Notes was deemed to be a debt extinguishment; accordingly, the warrant and embedded conversion option derivative liabilities were remeasured to fair value on June 4, 2018 and reclassified to additional paid in capital (See Derivative Liabilities, above).

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 and the beneficial conversion feature recorded in connection with the conversion of the Preferred Stock (see Note 12 to the Financial Statements – Temporary Equity).

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,	
	2018	**2017**
Net loss	$ (13,042,709)	$ (7,791,469)
Deemed dividend to Series A and B preferred stockholders	(3,310,001)	(459,917)
Net loss attributable to common stockholders	$ (16,352,710)	$ (8,251,386)

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, 2018 and 2017:

	December 31,	
	2018	**2017**
Shares of common stock issuable upon conversion of preferred stock	-	629,746
Shares of common stock issuable upon exercise of preferred stock warrants and the subsequent conversion of the preferred stock issued therewith	-	50,285
Shares of common stock issuable upon the conversion of convertible debt	-	229,208
Shares of common stock issuable upon exercise of warrants	3,780,571	371,216
Shares of common stock issuable upon exercise of options and restricted stock units	2,883,256	1,422,000
Potentially dilutive common stock equivalents excluded from diluted net loss per share	6,663,827	2,702,455

Revenue Recognition

In March 2016, the FASB issued 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 will be 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 will be 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,	
	2018	**2017**
Product sales	$ -	$ 184,800
Royalty income	116,152	137,711
Contract research - related party	70,400	99,600
Total Revenues	$ 186,552	$ 422,111

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 September 30, 2018.

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 $103,400 as of December 31, 2018 and 2017, respectively, related to cash received in advance for contract research and development services. The Company expects to satisfy its remaining performance obligations for contract research and development services and recognize the deferred revenue over the next twelve months.

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 $2,490,645 at December 31, 2018. There were no cash balances in excess of federally insured amounts at December 31, 2017.

During the year ended December 31, 2017, 44% of the Company’s revenues were from the sub-contract manufacture of product for LeMaitre Vascular, Inc. (“LeMaitre”), and 33% were from royalties earned from the sale of product by LeMaitre, with whom the Company entered a three-year Post-Acquisition Supply Agreement effective March 18, 2016. During the year ended December 31, 2018, 62% 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 earns royalty from the sale of product by LeMaitre ends on March 18, 2019. The Company did not recognize any subcontract manufacturing revenues during the year ended December 31, 2018. During the years ended December 31, 2018 and 2017, 38% and 24%, respectively, of the Company’s revenues were earned from contract research and development services performed for HJLA.

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 other subsequent events that would have required adjustment or disclosure in the financial statements, except as disclosed in Note 17 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 will adopt the standard using the prospective approach. Upon adoption, we expect to record approximately $1.1 million in right-of-use assets and operating lease liabilities in our Balance Sheets.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments (Topic 230)" ("ASU 2016-15"). ASU 2016-15 will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017. ASU 2016-15 requires adoption on a retrospective basis unless it is impracticable to apply, in which case the Company would be required to apply the amendments prospectively as of the earliest date practicable. The adoption of ASU 2016-15 did not have a material impact on the Company's financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718); Scope of Modification Accounting. The amendments in this ASU provide guidance that clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. If the fair value, vesting conditions or classification of the award changes, modification accounting will apply. The guidance is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The adoption of ASU 2017-09 did not have a material impact on the Company's financial statements.

On June 20, 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718) - Improvements to Nonemployee Share-Based Payment Accounting, which simplifies accounting for share-based payment transactions resulting for acquiring goods and services from nonemployees. ASU 2018-07 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The new standard was adopted effective April 1, 2018, using the modified retrospective approach; however, the Company did not identify or record any adjustments to the opening balance of retained earnings on adoption. The new standard did not have a material impact on the Company's financial statements.

Note 5 – Property and Equipment

As of December 31, 2018 and 2017, property and equipment consist of the following:

	December 31,	
	2018	2017
Lab equipment	$ 94,905	$ 120,861
Furniture and fixtures	93,417	93,417
Computer software and equipment	26,830	14,409
Leasehold improvements	158,092	158,092
	373,244	386,779
Less: accumulated depreciation	(347,091)	(362,936)
Property and equipment, net	$ 26,153	$ 23,843

During the year ended December 31, 2017, the Company wrote off $25,956 of fully depreciated lab equipment that was no longer in use. Depreciation and amortization expense amounted to $10,112 and $15,905 for the years ended December 31, 2018 and 2017, respectively. Depreciation and amortization expense is reflected in general and administrative expenses in the accompanying statements of operations.

Note 6 – Intangible Assets

On May 10, 2013, the Company purchased a patent related to heart valve bioprosthesis technology. The patent expires on July 9, 2027.

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. (See Note 11 to the Financial Statements – Commitments and Contingencies - *Development and Manufacturing Agreement*). The right to provide development and manufacturing services to HJLA expires on December 31, 2025. As of December 31, 2018, the Company performed an impairment analysis and determined that it was unlikely that the Company will provide development and manufacturing services to HJLA and recorded an impairment loss of $319,635, equal to the remaining unamortized value as of December 31, 2018.

As of December 31, 2018 and 2017, the Company's intangible assets consisted of the following:

	December 31,	
	2018	2017
Patent	$ 1,100,000	$ 1,100,000
Right to develop and manufacture	-	445,200
	1,100,000	1,545,200
Less: accumulated amortization	(433,533)	(435,790)
Total	$ 666,467	$ 1,109,410

Amortization expense charged to operations for the years ended December 31, 2018 and 2017 was $123,308 and $123,308, respectively, and is reflected in general and administrative expense in the accompanying statements of operations.

The estimated future amortization of Patent is as follows:

For the Years Ended December 31,	Patent
2019	$ 77,647
2020	77,647
2021	77,647
2022	77,647
2023	77,647
Thereafter	278,232
	$ 666,467

The remaining amortization period of the Patent is 8.5 years as of December 31, 2018 and has no residual value.

Note 7 – Accrued Expenses and Accrued Interest – Related Party

As of December 31, 2018 and 2017, accrued expenses consist of the following:

	December 31,	
	2018	2017
Accrued compensation costs	$ 288,549	$ 556,118
Accrued professional fees	55,300	235,654
Deferred rent	22,473	4,978
Accrued interest	-	101,050
Accrued franchise taxes	26,985	-
Accrued research and development	17,064	-
Other accrued expenses	2,500	5,794
Accrued expenses	$ 412,871	$ 903,594

Included in accrued compensation costs in the table above 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.

Accrued interest - related parties consisted of accrued interest on notes payable to the majority stockholder and to Leman Cardiovascular S.A. (see Note 9 to the Financial Statements - Notes Payable and Note Payable – Related Party) totaling, in the aggregate, $0 and $20,558 as of December 31, 2018 and 2017, respectively.

Note 8 - Convertible Notes and Convertible Note – Related Party

Convertible Notes

During the period from June 15, 2017 through December 7, 2017, the Company issued senior secured convertible promissory notes aggregating $2,750,500. The Company incurred cash offering costs of $186,100 (including $129,030 of placement agent fees) resulting in net cash proceeds of $2,564,400. The notes, as amended on December 29, 2017 (the "2017 Convertible Notes"), matured on February 28, 2018, and bore interest at 15% per annum. The 2017 Convertible Notes included warrants exercisable for the number of shares of common stock equal to 75% of the total shares issuable upon the conversion of the related 2017 Convertible Note, at a price equal to the lesser of (i) $14.40 per share or (ii) 120% of the 2017 Conversion Price. In connection with the sale of the 2017 Convertible Notes, the Company issued five-year warrants to the placement agent for the financing for the purchase of 15,339 shares of common stock at an exercise price of $15.84 per share (see Note 14 to the Financial Statements – Warrants). The fair value of the conversion option and warrants issued in connection with the 2017 Convertible Notes had an issuance date fair value of $1,175,668 and $397,211, respectively, and the aggregate of $1,572,879 was recorded as a debt discount and a derivative liability.

From January 5, 2018 through January 16, 2018, the Company issued senior secured convertible notes (the "2018 Convertible Notes") in the aggregate amount of $2,897,500. The Company incurred cash offering costs of $293,750 (including $289,750 of placement agent fees) resulting in net cash proceeds of $2,603,750. The 2018 Convertible Notes bore interest at 15% per annum and were due on February 28, 2018 (the "Maturity Date"). The 2018 Convertible Notes include five-year warrants exercisable for the number of common stock equal to 50% of the total shares issuable upon the conversion of the 2018 Convertible Note, at a price equal to the lesser of (i) $14.40 per share or (ii) 120% of the 2018 Conversion price. In connection with the sale of the 2018 Convertible Notes, the Company agreed to issue a five-year warrant to the placement agent for the financing for the purchase of 24,146 shares of common stock, exercisable at a price equal to the 110% of the greater of (i) the price at which the securities are issued, or (ii) the exercise price of the debt holder warrants. The fair value of the conversion option and the warrants issued in connection with the 2018 Convertible Notes had an issuance date fair value of $1,239,510 and $1,046,763, respectively, and the aggregate of $2,286,273 was recorded as a debt discount and a derivative liability.

The 2017 Convertible Notes and the 2018 Convertible Notes are referred to herein together as the "Convertible Notes".

On February 28, 2018, the Convertible Notes were amended such that the maturity date was extended to May 15, 2018, the 2017 Convertible Note warrants became exercisable for the number of shares of common stock equal to 100% of the total shares issuable upon the conversion of the 2017 Convertible Notes and the 2018 Convertible Note Warrants become exercisable for the number of shares of common stock equal to 75% of the total shares issuable upon the conversion on the 2018 Convertible Notes. The amendment of the Convertible Notes was deemed to be a debt extinguishment and, as a result, during the years ended December 31, 2018, the Company recognized a $1,524,791 gain on extinguishment of convertible notes payable within the accompanying statement of operations consisting of the extinguishment of $2,420,390 of derivative liabilities associated with the embedded conversion option of the extinguished Convertible Notes, partially offset by the issue date fair value of additional warrants issued (deemed to be a derivative liability) in the amount of $895,599. Additionally, the embedded conversion option within the re-issued Convertible Notes was deemed to be a derivative liability and the relative fair value was recorded as a discount in the amount of $2,413,079.

On June 4, 2018, principal and interest of $10,000 and $267, respectively, were paid in cash and all remaining principal and accrued interest balances of the Convertible Notes were automatically converted into 1,650,537 shares of common stock upon the closing of the IPO at a conversion price of $3.50 per share. The conversion of the Convertible Notes was deemed to be a debt extinguishment and, as a result, the Company recognized a $43,474 loss on extinguishment of convertible notes payable within the accompanying statement of operations consisting of the fair value of the common stock issued upon the conversion of the Convertible Notes of $8,252,685, less the extinguishment of $5,743,391 of principal and interest converted and $2,465,820 of derivative liabilities associated with the embedded conversion option of the extinguished Convertible Notes.

Interest expense incurred in connection with the Convertible Notes was $305,452 and $172,800 during the years ended December 31, 2018 and 2017, respectively.

Convertible Note – Related Party

On June 30, 2015, the Company entered into a loan agreement with its then-majority (78%) common stock shareholder, (the "2015 Note"). The 2015 Note had a maximum borrowing capacity of $2,200,000 and bore interest at 3% per annum. On April 1, 2016, the 2015 Note was amended such that the 2015 Note became convertible into shares of common stock at the option of the lender at a conversion price of $10.00 per share. During the years ended December 31, 2018 and 2017, the Company borrowed $0 and $311,000, respectively, under the 2015 Note. On April 26, 2018, the outstanding principal balance and accrued interest of the 2015 Note was converted into 120,405 shares of common stock at a conversion price of $4.30 per share. The Company incurred interest expense related to the 2015 Note of $4,613 and $13,886 during the years ended December 31, 2018 and 2017, respectively.

Note 9 - Notes Payable and Note Payable – Related Party

Notes Payable

During December 2017, the Company borrowed an aggregate of $275,000 pursuant to two promissory notes, which bore interest at 10% per annum. The notes were repaid in full during January 2018. The Company incurred interest expense of $958 and $1,188 during the year ended December 31, 2018 and 2017, respectively in connection with these notes.

On May 15, 2018, the Company received aggregate proceeds of $722,500 in exchange for certain promissory notes (the "May Notes") in the aggregate principal amount of $850,000 and 55,000 shares of the Company's common stock, net of commissions of $27,500. The $27,500 commission and the original issue discount of $100,000 were recorded as debt discount, and the relative fair value of the common stock issued in connection with the May Notes of $228,966 was recorded as a debt discount with a corresponding credit to additional paid-in capital. The May Notes bore interest between 0-10% per annum and were repaid in full upon the consummation of the IPO on June 4, 2018. The Company incurred $4,911 of interest expense during the year ended December 31, 2018 in connection with the May Notes.

Note Payable – Related Party

The Company had a note payable to a related party (the "Related Party Note"), of which the Company's Former President and Vice President of Operations were officers, and of which a member of the Company's Board of Directors is a shareholder. The Related Party Note, as amended, bore interest at 6% per annum and matured on May 10, 2018. On April 26, 2018, the outstanding principal balance and accrued interest of the Related Party Note was amended such that the note became convertible into common stock at a conversion price of $4.30, and on the same day, principal and interest in the aggregate of $150,553 due in connection with the Related Party Note was converted into 35,012 shares of common stock. The Company incurred interest expense of $4,078 and $21,283 during the years ended December 31, 2018 and 2017, respectively, in connection with the Related Party Note.

Note 10 – Income Taxes

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

	For the Years Ended December 31,	
	2018	**2017**
Federal:		
Current	$ -	$ -
Deferred	(1,710,997)	(138,931)
State and local:		
Current	-	-
Deferred	(570,332)	(479,833)
	(2,281,329)	(618,764)
Change in valuation allowance	2,281,329	618,764
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, 2018 and 2017 is as follows:

	For the Years Ended December 31,	
	2018	**2017**
Tax benefit at federal statutory rate	(21.0)%	(34.0)%
State taxes, net of federal benefit	(7.0)%	(6.0)%
Permanent differences	11.4%	9.4%
True up adjustments	(0.9)%	1.3%
Effect of change in tax rate	0.0%	21.3%
Change in valuation allowance	17.5%	7.9%
Effective income tax rate	(0.0)%	(0.0)%

Significant components of the Company's deferred tax assets at December 31, 2018 and 2017 are as follows:

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 5,298,599	$ 3,122,308
Research and development credit carryforwards	185,680	185,680
Intangible assets	152,109	48,629
Property and equipment	30,957	34,974
Accrued salaries	-	106,400
Stock-based compensation	526,945	419,868
Deferred rent	6,292	1,394
Impairment loss	136,612	136,612
Total gross deferred tax assets	6,337,194	4,055,865
Less: valuation allowance	(6,337,194)	(4,055,865)
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 net operating loss carry forwards are subject to annual limitations due to a greater than 50% ownership change in 2018.

At December 31, 2018 and 2017, the Company had post-ownership change net operating loss carryforwards for federal and state income tax purposes of approximately $17.4 million and $11.1 million, respectively. Pre-2018 federal and state net operating loss ("NOL") carryovers may be carried forward for twenty years and begin to expire in 2026. Under the Tax Act, post-2017 federal NOLs 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.

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, state and local income taxes for the years beginning in 2015 remain subject to examination. No tax audits were initiated during 2018 or 2017.

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, 2018 and 2017. 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.

New tax legislation, commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act", was enacted on December 22, 2017, which, among things, reduced the United States corporate income tax rate from 35% to 21%. Pursuant to ASC 740, Accounting for Income Taxes, the Company was required to recognize the effect of tax law changes in the period of enactment even though the effective date for most provisions of the Tax Act is for tax years beginning after December 31, 2017. The change in tax law required the Company to remeasure existing net deferred tax assets using the lower rate in the period of enactment, resulting in a reduction of the deferred tax asset balance as of December 31, 2017 by $1.7 million. Due to the Company's full valuation allowance position, there was no net impact on the Company's income tax provision at December 31, 2017 as the reduction in the deferred tax asset balance was fully offset by a corresponding decrease in the valuation allowance.

Note 11 – 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 25, 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 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 tissue delivered. The Company believes it has numerous defenses and rights of setoff including without limitation: that ATSCO had an obligation to mitigate the fees when they were not delivering tissues and not incurring any costs; $173,400 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% as described in Note 4 to the Financial Statements – Significant Accounting Policies - *Investments*) and is not the obligation of HJLI; the Company has a right of setoff against any amounts owed to ATSCO for 120,000 shares of HJLI stock transferred to ATSCO's principal and owner; the yields of the materials delivered by ATSCO to HJLI was inferior; and the Agreement was constructively terminated. The Company recorded the disputed invoices in accounts payable and as of December 31, 2018, the Company has fully accrued for the outstanding claim against the Company. On January 18, 2019, the Superior Court granted a Right to Attach Order and Order for Issuance of Writ of Attachment in the amount of $810,055, which the Company plans on appealing. The attachment order is not a binding ruling on the merits of the case and the Company plans on filing a Cross-Complaint for abuse of process and excessive and wrongful attachment as $173,400 of the claim is to a wholly separate company, and over $500,000 of the claim is attributable to invoices sent without delivery of any tissue. The Company has entered into new supply relationships with two domestic and one international company to supply porcine and bovine tissues. A Mandatory Settlement Conference is scheduled for July 26, 2019 and the Jury Trial is scheduled for September 9, 2019.

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, 2018, the Company has fully accrued for the outstanding claim against the Company.

The Company has been contacted by an individual that claims to be owed a fee for introducing the Company to Alexander Capital. The Company has conducted its own factual investigation and legal analysis and believes that the claim is without merit. The individual has threatened to file a lawsuit, and in the event that a lawsuit is filed, the Company would have numerous defenses including without limitation that the individual was unlicensed to provide the services he alleges he provided.

Property Lease Obligation

On or about July 1, 2010, the Company's seven-year lease for 14,507 square foot industrial building located in Orange County, California became effective. The lease required a $26,113 security deposit and the prepayment of the first month's rent at the inception of the lease. Monthly rent payments under the lease at the inception of the lease were $21,761 and payments increase by 5% every 24 months. Payments under the lease also include real estate taxes not to exceed $7,254 per month. The lease expired on June 30, 2017. The Company rented the building on a month-to-month basis from July 1, 2017 through September 30, 2017. On September 20, 2017, the Company entered into an agreement to renew the lease effective October 1, 2017. The lease renewal has a five-year term. Rent expense pursuant to the lease is $26,838 per month for the first year and increases by 3% on each anniversary of the lease inception date. As of December 31, 2018, remaining future minimum lease payments under the lease are $1,304,847.

On May 1, 2016, the Company's entered into a one-year lease of an apartment located in Irvine, California for the chairman of the Company's board of directors, who resides in Switzerland. The lease required a $3,720 security deposit and the monthly rent payments under the lease were $1,860. The lease expired on April 30, 2017 and the Company is currently renting the apartment on a month-to-month basis at $2,010 per month.

Future minimum lease payments under the Company's operating leases are as follows:

For The Years Ending December 31,	Amount
2019	$ 334,203
2020	344,229
2021	354,561
2022	271,854
Total	1,304,847

The Company recognizes rent expense on a straight-line basis over the term of the respective lease. Differences between the straight-line rent expenses and rent payments are included in accrued expenses on the accompanying balance sheets. Rent expense for the years ended December 31, 2018 and 2017 was $348,227 and $418,358, respectively.

Development and Manufacturing Agreement

On April 1, 2016, the Company entered into a development and manufacturing agreement with HJLA, pursuant to which: (1) the Company paid $445,200 for the exclusive right to provide development and manufacturing services to HJLA for a period of ten years (see Note 6 to the Financial Statements – Intangible Assets), and (2) the Company has the right to purchase up to 484,358 shares of common stock of HJLA at $8.66 per share for an aggregate purchase price of $4,194,540 through April 1, 2021. Through the date these financial statements were available to be issued, no shares were purchased pursuant to this agreement.

Employment Agreements

Chief Executive Officer

On March 20, 2018, the Company entered into an Amendment to Employment Agreement (the "Employment Amendment") with the Company's then Chief Executive Officer (the "Old CEO"), pursuant to which the Old CEO was removed from the position of Chief Executive Officer of the Company and was appointed to serve as the Company's Chief Medical Officer Outside of the United States. The Employment Amendment represented a change in position only; all other terms and conditions of the Old CEO's Employment Agreement with the Company remained in effect. Further, on March 20, 2018, the employment of the Company's then Co-Chief Executive Officer was terminated without cause, and the Company entered into an Employment Agreement (the "New CEO Agreement") with Robert Berman (the "New CEO") under which he serves as the Company's Chief Executive Officer. The New CEO Agreement provides for an annual base salary of $400,000 as well as standard employee insurance and other benefits. Pursuant to the New CEO Agreement, the New CEO is eligible for annual salary increases at the discretion of the Company's Board of Directors as well as annual bonus payments of up to 50% of base salary, as determined by the Compensation Committee of the Board of Directors. The New CEO Agreement provides for severance payments equal to six months of base salary in the event of termination without cause, severance payments equal to one year of base salary if such termination occurs on or after the two-year anniversary of the effective date of the New CEO Agreement and severance payments equal to two years of base salary if such termination occurs within 24 months of a change in control of the Company. In addition, in connection with the New CEO Agreement, the New CEO received an option for the purchase of up to 6.5% of the Company's common stock on a fully-diluted basis as of the date of the IPO. The New CEO'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 the New CEO or the Company.

Chief Financial Officer

On July 16, 2018, the Company entered into an employment agreement with Mr. Robert Rankin (the "CFO Employment Agreement") under which he serves as the Company's Chief Financial Officer. The CFO Employment Agreement provides for an annual base salary of $250,000 as well as standard employee insurance and other benefits. Pursuant to the CFO Employment Agreement, Mr. Rankin is eligible for annual salary increases at the discretion of the Company's 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. The CFO Employment Agreement provides for severance payments in the event of termination without Cause or he resigns for Good Reason, as defined in the CFO 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 CFO Employment Agreement, Mr. Rankin's severance will not be less than six months of his base salary. In addition, in connection with the CFO Employment Agreement, Mr. Rankin received an initial equity grant of an option (the "CFO Option") to purchase up to 150,000 shares of the Company's common stock. 50,000 of the shares will vest on the first anniversary of Mr. Rankin's employment with the Company, and the remaining 100,000 shares will vest on a quarterly basis over the following two-year period, provided that all unvested shares will immediately vest upon a Change of Control. The CFO Option will have an exercise price per share equal to $2.98, the last reported sale price of the Company's common stock on the Nasdaq Capital Market on July 16, 2018, the date of the grant. 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.

R&D Agreement

On October 2, 2018, The Company entered into an Agreement with the Texas Heart Institute for the development of the Company's CoreoGraft product to be used for coronary artery bypass surgery. The Company estimates the initial feasibility study will cost approximately $200,000. The agreement will terminate on August 31, 2019 and may be extended by mutual consent.

Note 12 – Temporary Equity

On March 1, 2017, the Company filed a second amended and restated certificate of incorporation, to increase the number of the Company's authorized shares of preferred stock to 6,000,000, to designate 1,300,000 shares of the Company's authorized preferred stock as Series A preferred Stock, or Series A preferred stock, and set forth the rights, preferences and privileges of the Company's Series A preferred stock. On June 8, 2017, the Company filed a third amended and restated certificate of incorporation to revise certain protective voting provisions afforded to the holders of the Company's preferred stock. On the same date, the Company filed a certificate of designation, preferences, rights and limitations of Series B convertible preferred stock, to designate 2,000,000 shares of the Company's authorized preferred stock as Convertible Series B Preferred Stock, or Series B preferred stock, and set forth the rights, preferences and privileges of the Company's Series B preferred stock.

The Company's Preferred Stock had certain redemption rights that were considered by the Company to be outside of the Company's control. Accordingly, the Series A Preferred Stock and Series B Preferred Stock are presented as temporary equity on the Company's balance sheets for December 31, 2017.

The Series A and Series B Preferred Stock were convertible at the option of the holder at a conversion price of $10.00 and $12.00 per share, respectively, which was reduced to $4.30 and $4.50 per share, respectively, if the conversion resulted from a mandatory IPO conversion. On June 4, 2018, all Series A and Series B Preferred Stock and dividends in arrears of $911,151 and $107,556, respectively, were mandatorily converted into 1,743,231 shares of common stock, upon the completion of the IPO (see Note 2 to the Financial Statements – Initial Public Offering). In connection with the mandatory conversion of the Preferred Stock, the Company recorded a deemed dividend of $3,087,591 equal to the number of additional shares of common stock issued upon conversion of the Preferred Stock resulting from the reduction in the conversion price upon the mandatory IPO conversion, multiplied times the fair value of the common stock on the commitment date.

Note 13 – Common Stock

On October 31, 2017, our Board of Directors approved a 1 for 2 reverse stock split of the Company's common stock, which was effected on December 14, 2017. Per share and share amounts presented herein have been adjusted for all periods presented to give retroactive effect to the aforementioned stock splits.

The Company completed the IPO via an issuance of common stock and warrants on June 4, 2018 (see Note 2 to the Financial Statements - Initial Public Offering).

In connection with the IPO, on June 1, 2018, the Company filed an Amended and Restated Certificate of Incorporation (the "Restated Certificate") with the Secretary of State of the State of Delaware and adopted the Amended and Restated Bylaws (the "Restated Bylaws"). The Company's Board of Directors and stockholders previously approved the Restated Certificate and the Restated Bylaws to be effective immediately prior to the closing of the IPO. Pursuant to the Restated Certificate, the Company is authorized to issue an aggregate of 60,000,000 shares of stock, of which 50,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred 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 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.

Note 14 - Warrants

During the years ended December 31, 2018 and 2017, the Company issued five-year warrants in connection with the issuance of the Convertible Notes (see Note 8 to the Financial Statements – Convertible Notes and Convertible Note – Related Party) for the purchase of 1,441,298 shares of common stock and issued five-year warrants for the purchase of 138,392 shares of common stock to the placement agents. In connection with the IPO, the exercise price of the warrants issued to investors and the placement agent in connection with the Convertible Notes became fixed at $4.20 per share and $4.62 per share, respectively, pursuant to the terms of the warrants.

On June 4, 2018, the Company issued five-year warrants for the purchase of 1,725,000 shares of common stock at an exercise price of $6.00 per share to purchasers of Units in the IPO and issued five-year warrants for the purchase of 75,000 shares of common stock at an exercise price of $6.25 to the underwriter for the IPO. Further, in connection with the IPO, warrants for the purchase of 100,570 shares of Series A Preferred Stock were amended such that they became exercisable for the purchase of 116,912 shares of common stock at an exercise price of $4.30 per share. 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.

On June 18, 2018, the Company issued five-year warrants for the purchase 100,000 shares of common stock to certain consultants. The warrants vested immediately, were exercisable at $4.99 per share and had a grant date fair value of $179,000 using the Black-Scholes pricing model, with the following assumptions used: stock price of $4.93, risk free interest rate of 2.67-2.80%, expected term of 3-5 years, volatility of 42.6% and an annual rate of quarterly dividends of 0%.

A summary of warrant activity during the years ended December 31, 2018 and 2017 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, 2017	100,570	$ 5.00			416,666	12.00		
Issued [1]					204,550	12.00		
Exercised								
Cancelled					(250,000)			
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 [2]	(100,570)	5.00			116,912	4.30		
Outstanding, December 31, 2018	-	$ -	-	$ -	3,780,571	$ 5.48[3]	4.1	$ -
Exercisable, December 31, 2018	-	$ -	-	$ -	3,780,571	$ 5.48	4.1	$ -

[1] Warrants granted in 2017 consist of Series B warrants for purchase of 17,303 shares, convertible note debt holder warrants for purchase of 171,908 shares and convertible note placement agent warrants for purchase of 15,339 shares of common stock.

[2] 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.

[3] Pursuant to the terms of the warrant, the exercise price of the warrants issued to investors and the placement agent in connection with the sale of the Convertible Notes became fixed at $4.20 per share and $4.62 per share, respectively, at the date of the IPO, based upon the price of stock issued in the IPO.

A summary of outstanding and exercisable warrants as of December 31, 2018 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	4.5	183,969
$ 6.25	Common Stock	75,000	4.4	75,000
$ 6.00	Common Stock	1,725,000	4.4	1,725,000
$ 4.99	Common Stock	100,000	4.5	100,000
$ 4.62	Common Stock	138,392	3.9	138,392
$ 4.30	Common Stock	116,912	2.1	116,912
$ 4.20	Common Stock	1,441,298	3.8	1,441,298
		3,780,571		3,780,571

Note 15 – 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 June 18, 2018, the Company granted non-qualified stock options for the purchase of 80,000 shares of common stock at an exercise price of $4.93 to members of its Medical Advisory Board. The options have a ten-year term and vest monthly over two years. The options had grant date fair value of $2.21 per share for an aggregate grant date fair value of $176,800, using the Black Scholes method with the following assumptions used: stock price of $4.93, risk-free interest rate of 2.85%, volatility of 42.6%, annual rate of quarterly dividends of 0%, and a contractual term of six years.

On July 16, 2018, in connection with the CFO Employment Agreement, the Company granted non-qualified stock options for the purchase of 150,000 shares of common stock at an exercise price of $2.98 to its CFO, Mr. Rankin. The options have a ten-year term and 50,000 of the shares will vest on the first anniversary of Mr. Rankin's employment with the Company, and the remaining 100,000 shares will vest on a quarterly basis over the following two-year period. The options had grant date fair value of $1.10 per share for an aggregate grant date fair value of $165,000, using the Black Scholes method with the following assumptions used: stock price of $2.98, risk-free interest rate of 2.76%, volatility of 35.6%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

On September 24, 2018, the Board of Directors of the Company approved the grant of a ten-year option to purchase an aggregate of 1,080,207 shares of the Company's common stock at an exercise price of $4.99 per share (the "Option") to its CEO, Robert Berman, which Option was issued pursuant to the terms of that certain employment agreement, dated March 30, 2018 (the "Effective Date"), between Mr. Berman and the Company (the "Employment Agreement"). The grant of the Option was in fulfillment of the express terms of the previously agreed to Employment Agreement. The Employment Agreement provides that Mr. Berman is entitled to receive an equity grant of an option to purchase up to 6.5% of the Company's common stock outstanding on a fully diluted basis at the closing of the IPO. The shares subject to the Option will vest over a period of 2 years, with 1/5th of the shares subject to the Option having vested on the Effective Date (the "Initial Vesting") and the remaining shares vesting in substantially equal monthly installments during the twenty-four (24) month period following the Effective Date and ending March 30, 2020. The Option had grant date fair value of $0.47 per share for an aggregate grant date fair value of $507,697, using the Black-Scholes method with the following assumptions used: stock price of $4.99, risk-free interest rate of 2.97%, volatility of 35.3%, annual rate of quarterly dividends of 0%, and a contractual term of 5.2 years.

On October 1, 2018, Robert Anderson, Robert Doyle and Steven Girgenti ("Resigning Directors") resigned as Directors of our Board. Effective upon their resignation, each of the Resigning Directors 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. All of these options were vested in full as of the date of grant. The Option had grant date fair value of $0.50 per share for an aggregate grant date fair value of $15,000, using the Black-Scholes method with the following assumptions used: stock price of $1.97, risk-free interest rate of 2.89%, volatility of 36.1%, annual rate of quarterly dividends of 0%, and a contractual term of 5.5 years.

Per the Amended and Restated 2016 Omnibus Incentive Plan, the options that were awarded and had vested to the Resigning Directors prior to their resignation 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 Resigning Directors before their resignation date were modified such that they can be exercised by the Resigning Directors for a 10 year period from their original 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 the Resigning Directors in 2017 at an exercise price of $12.00 per share were valued at $.10 per share as of the date of the modification for an aggregate grant date fair value of $12,000, using the Black-Scholes method with the following assumptions used: stock price of $2.90, risk-free interest rate of 2.96%, volatility of 36.1%, annual rate of quarterly dividends of 0%, and a contractual term of 5.0 years. 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 for an aggregate grant date fair value of $1,920 using the Black-Scholes method with the following assumptions used: stock price of $2.90, risk-free interest rate of 2.96%, volatility of 36.1%, annual rate of quarterly dividends of 0%, and a contractual term of 5.0 years.

Under the Company's nonemployee director compensation program, Dr. Francis Duhay, Mr. Marcus Robins and Dr. Sanjay Shrivastava in connection with their appointment to the Company's Board of Directors 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. All of these options vest in equal quarterly portions over a 3 year period starting from October 2, 2018. The Option had grant date fair value of $0.56 per share for an aggregate grant date fair value of $100,800, using the Black-Scholes method with the following assumptions used: stock price of $1.97, risk-free interest rate of 2.90%, volatility of 36.1%, 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, 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	$ -
Exercisable, December 31, 2018	1,865,604	$ 8.50	8.4	$ -

A summary of outstanding and exercisable options and Restricted Stock units as of December 31, 2018 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	8.7	120,000
$ 10.00	Common Stock	1,149,500	7.8	1,149,500
$ 7.00	Common Stock	6,000	8.9	6,000
$ 4.99	Common Stock	1,080,207	9.7	540,104
$ 4.93	Common Stock	80,000	9.5	20,000
$ 2.98	Common Stock	150,000	9.5	-
$ 2.90	Common Stock	30,000	9.9	30,000
$ 2.57	Common Stock	180,000	9.9	-
	Total	2,795,707		1,865,604

The Company recognized stock-based compensation related to stock options of $864,626 and $801,624 during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, there was $758,012 of unrecognized stock-based compensation expense related to outstanding stock options that will be recognized over the weighted average remaining vesting period of 1.6 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

Under the Company's nonemployee director compensation program, Dr. Francis Duhay, Mr. Marcus Robins and Dr. Sanjay Shrivastava in connection with their appointment to the Company's Board of Directors 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 for an aggregate grant date value of $172,472. These units vest in equal annual portions on the October 2, 2019, October 2, 2020 and October 2, 2021.

Restricted Stock Units Outstanding			Restricted Stock Units Exercisable	
Grant Date Closing Stock Price	Exercisable Into	Outstanding Number of Units	Weighted Average Remaining Life In Years	Exercisable Number of Units
$ 1.97	Common Stock	87,549	9.9	-

Note 16 – Related Party Transactions

Contract & Research Revenue – Related Party

During the years ended December 31, 2018 and 2017, the Company recognized $70,400 and $99,600, respectively of revenue for contract research services provided pursuant to a Development and Manufacturing Agreement with HJLA dated April 1, 2016.

Advances to Related Party

During the year ended December 31, 2017, the Company paid $206,000 as short-term advances to HJLA, and received repayments from HJLA of $216,000. The balance of advances outstanding as of December 31, 2017 was $0.

Loan Receivable - Related Party

On June 15, 2017, the Company entered into a promissory note agreement (the "Note Receivable") with HJLA, pursuant to which the Company loaned $160,000 to HJLA. The Note Receivable bears interest at 15% per annum, and all unpaid principal and interest was due on September 15, 2017. During the year ended December 31, 2017, the note principal, along with $6,685 of accrued interest was repaid in full.

Note 17 – Subsequent Events

On January 2, 2019, H. Chris Sarner began her employment with the Company as our Vice President Regulatory Affairs and Quality Assurances and entered into an employment agreement with the Company which 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 sole discretion of our Chief Executive Officer. Per her employment agreement, Ms. Sarner was granted stock options for the right to purchase 150,000 shares at an exercise price of $1.59, equal to the closing price of our common stock on February 7, 2019, the date that the Board approved the option grant. The options vest quarterly, over a 3 year period, with a 1 year cliff. The stock options were granted in accordance with our Amended and Restated 2016 Omnibus Incentive Plan. 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.

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 is on a month to month basis that can be cancelled by either party with thirty (30) days advance notice. The Company will pay a monthly fee of $7,500 and will issue 35,000 warrants to Alere with a strike 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 warrants shall vest equally monthly over a 12 month period provided that the Alere Agreement remains in effect.

On January 7, 2019, Dr. Peter Pappas agreed to join the Company's Medical Advisory Board for a term of two years. As compensation, Dr Pappas will receive twenty thousand (20,000) options to purchase shares of the Company's common stock at a price equal to the closing share price for the Company's common stock on the day that the Company's board of directors approves the 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.

On January 18, 2019, the Superior Court granted to ATSCO, Inc., who had filed a complaint with the Superior Court on September 25, 2018 (see Note 11 to the Financial Statements – Commitments and Contingencies under *Litigations Claims and Assessments*), a Right to Attach Order and Order for Issuance of Writ of Attachment in the amount of $810,055, which the Company plans on appealing. The attachment order is not a binding ruling on the merits of the case and the Company plans on filing a Cross-Complaint for abuse of process and excessive and wrongful attachment as $173,400 of the claim is to a wholly separate company, and over $500,000 of the claim is attributable to invoices sent without delivery of any tissue.

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, that can be cancelled by either party at the end of six (6) months with thirty (30) day notice. After the full twelve (12) month term, the MZ Agreement will automatically renew every (6) months thereafter unless either party to the other delivers written notice of termination at least thirty (30) days notice prior to the end of the then current MZ Agreement. MZ will receive compensation of $8,000 per month and eight-five thousand (85,000) restricted shares that vest quarterly over a year, with a 6 month cliff, that either party can terminate the agreement after 6 months but if the agreement is terminated by MZ at the end of six months, MZ forfeits the restricted shares.

On February 7, 2019, the Company's board of directors approved the grant of 30,000 stock options 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 the first quarter 2019. The stock options were granted at an exercise price of $1.59, equal to the closing price of our common stock on February 7, 2019, the date that the Board approved the option grant. The options vest monthly, over a one (1) year period.

On March 12, 2019, the Company raised $2,714,000 in gross proceeds a private placement offering of its common stock to certain accredited investors (the "Offering"). The Company sold an aggregate of 2,360,051 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 (the "Purchase Agreement"). Pursuant to the terms of the Purchase Agreement, the Company has agreed to file a registration statement with the Securities and Exchange Commission for the resale of the purchasers' shares on or before March 31, 2019 and to use commercially reasonable efforts to have the registration statement declared effective within ninety days of the filing date. The Purchase Agreement also

contains customary representations, warranties and agreements. The Company engaged Network 1 Financial Securities, Inc., a FINRA-member (the "Placement Agent"), to act as exclusive placement agent for the Offering. The Placement Agent is entitled to a warrant to purchase 188,804 shares of the Company's common stock. Such warrant will be exercisable for a period of five years from the date of issuance and will have an exercise price of $1.50. The Company received $2,326,176 in net proceeds after giving effect to estimated offering fees and expenses of $387,824. For illustration purposes, attached as Exhibit 99.1 of this report are the unaudited cash and stockholders' equity balances that the Company believes are as of March 12, 2019.

HANCOCK JAFFE LABORATORIES, INC.
AMENDED AND RESTATED 2016 OMNIBUS INCENTIVE PLAN

Stock Option Grant

FOR GOOD AND VALUABLE CONSIDERATION, Hancock Jaffe Laboratories, Inc. (the " **Company**") hereby grants, pursuant to the provisions of the Hancock Jaffe Laboratories, Inc. Amended and Restated 2016 Omnibus Incentive Plan (as amended, the "**Plan**"), to the Grantee designated in this Stock Option Grant (the "**Award Agreement**") [an Incentive/a Non-qualified] Stock Option (the "**Option**") to purchase the number of Shares set forth below, subject to certain terms and conditions as outlined herein. Any capitalized term not otherwise defined in the Award Agreement shall have the definition set forth in the Plan.

1. General Terms of Grant.

Grantee:	[Name]
Type of Option:	[Incentive/Non-qualified] Stock Option
Grant Date:	[Date]
Number of Shares Purchasable:	[####]
Option Price per Share:	$[#.##], which is the Fair Market Value as of the Grant Date[1]
Expiration Date:	[Date], which is [10] years from the Grant Date[2]
Exercisability Schedule:	[Insert schedule - time-based or performance-based] [Notwithstanding the foregoing Exercisability Schedule, exercisability of all or some portion of the Option may be accelerated in accordance with the terms and conditions set forth in this Award Agreement and the Plan.]
Exercise after Separation from Service:	*Separation from Service for any reason other than death, Disability or Cause*: any non-exercisable portion of the Option expires immediately and any exercisable portion of the Option remains exercisable for [90 days] following Separation from Service for any reason other than death, Disability or Cause. *Separation from Service due to death or Disability*: any non-exercisable portion of the Option expires immediately and any exercisable portion of the Option remains exercisable for [12 months] following Separation from Service due to death or Disability. *Separation from Service for Cause*: the entire Option, including any exercisable and non-exercisable portion, expires immediately upon Separation from Service for Cause. **IN NO EVENT MAY THE OPTION BE EXERCISED AFTER THE EXPIRATION DATE AS PROVIDED ABOVE.**
Change in Control:	[State the impact of a change in control upon the restricted stock award. The plan provides flexibility to the board to provide for one or more of the following: (i) accelerate vesting of the restricted stock award, (ii) cause for the assumption, continuation or substitution of the restricted stock award or (iii) cash-out the restricted stock award. See Section 15.2 in the plan.]

[1] 110% of FMV if an ISO is granted to a 10% shareholder

[2] 5 year max if an ISO is granted to a 10% shareholder

2. Grant of Option. The Option granted to the Grantee is subject to the terms and conditions of the Plan. The terms and conditions of the Plan are hereby incorporated herein by reference. Except as otherwise expressly set forth herein, the Award Agreement shall be construed in accordance with the terms and conditions of the Plan. [The Committee has approved the grant to the Grantee of the Option, conditioned upon the Grantee's acceptance of the terms and conditions of the Award Agreement within 60 days after the Award Agreement is presented to the Grantee for review.] If designated herein as an Incentive Stock Option, the Option is intended to qualify as an Incentive Stock Option. To the extent that the Option fails to meet the requirements of an Incentive Stock Option or is not designated as an Incentive Stock Option, the Option shall be treated as a Non-qualified Stock Option.

3. Exercise of Option.

a. Right to Exercise. The Option shall be exercisable, in whole or in part, during its term in accordance with the Exercisability Schedule set forth herein and in accordance with the applicable provisions of the Plan. No Shares shall be issued pursuant to the exercise of the Option unless the issuance and exercise comply with applicable laws. Assuming such compliance, for income tax purposes the Shares shall be considered transferred to the Grantee on the date on which the Option is exercised with respect to such Shares. Until such time as the Option has been duly exercised and Shares have been delivered, the Grantee shall not be entitled to exercise any voting rights with respect to such Shares, shall not be entitled to receive dividends or other distributions with respect thereto and shall not have any other rights of a Stockholder with respect thereto.

b. Method of Exercise. The Grantee may exercise the Option by delivering an exercise notice in a form approved by the Company (the "**Exercise Notice**"), which shall state the election to exercise the Option, the number of Shares with respect to which the Option is being exercised, and such other representations and agreements as may be required by the Company. The Exercise Notice shall be accompanied by payment of the aggregate Option Price as to all Shares exercised. The Option shall be deemed to be exercised upon receipt by the Company of such fully executed Exercise Notice accompanied by the aggregate Option Price (as well as any applicable withholding or other taxes).

c. Acceleration of Exercisability under Certain Circumstances. The exercisability of the Option shall not be accelerated under any circumstances, except as otherwise provided in the Plan; *provided*, *however*, that the Option shall become fully vested and exercisable in the event of disability or death of the optionee [or immediately prior to, and contingent upon, a Change in Control.][3]

4. Method of Payment. If the Grantee elects to exercise the Option by submitting an Exercise Notice in accordance with Section 3(b) above, the aggregate Option Price (as well as any applicable withholding or other taxes) shall be paid by cash or check; *provided, however*, that the Committee may,[4] but is not required to, consent to payment in any of the following forms, or a combination of them:

a. cash or check;

b. a "net exercise" under which the Company reduces the number of Shares issued upon exercise by the largest whole number of Shares with a Fair Market Value that does not exceed the aggregate Option Price and any applicable withholding, or such other consideration received by the Company under a cashless exercise program approved by the Company in connection with the Plan;[5]

---

[3] See change in control above.

[4] Consider whether this determination should be made in advance of issuance.

[5] Consider that the company will not be able to sell the shares directly into market to cover withholding taxes so the company will either have to come out of pocket to pay the taxes or do a separate offering pursuant to which the proceeds will be used to pay the taxes. An alternative is to appoint a plan administrator that can receive the (registered) shares on behalf of the grantee, can sell a sufficient number of shares into the market to pay the exercise price and any withholding, and then send the money back to the company while holding the remaining shares in the account of the grantee. If you go this route, keep in mind that grantee will only be able to exercise and sell during an open trading window or pursuant to a 10b5-1 plan.

c. surrender of other Shares owned by the Grantee that have a Fair Market Value on the date of surrender equal to the aggregate Option Price of the exercised Shares and any applicable withholding; or

d. any other consideration that the Committee deems appropriate and in compliance with applicable law.

5. Restrictions on Exercise. The Option may not be exercised until such time as the Plan has been approved by the Stockholders,[6] or if the issuance of the Shares upon exercise or the method of payment of consideration for those Shares would constitute a violation of any applicable law, regulation or Company policy.

6. Transferability. The Option may not be transferred in any manner other than by will or by the laws of descent or distribution and may be exercised during the lifetime of the Grantee only by the Grantee; *provided*, *however*, that the Grantee may transfer the Option (a) pursuant to a domestic relations order by a court of competent jurisdiction or (b) to any Family Member of the Grantee in accordance with Section 17.11.2 of the Plan (entitled "Family Transfers," or any successor provision thereto) by delivering to the Company a notice of assignment in a form acceptable to the Company. No transfer or assignment of the Option to or on behalf of a Family Member under this Section 6 shall be effective until the Company has acknowledged such transfer or assignment in writing.

7. Withholding.

a. The Committee shall determine the amount of any withholding or other tax required by law to be withheld or paid by the Company with respect to any income recognized by the Grantee with respect to the Option.

b. The Grantee shall be required to meet any applicable tax withholding obligation in accordance with the provisions of Section 17.3 of the Plan (entitled "Tax Withholding," or any successor provision thereto).

c. Subject to any rules prescribed by the Committee, the Grantee shall have the right to elect to meet any withholding requirement (i) by having withheld from the Option at the appropriate time that number of whole Shares whose Fair Market Value is equal to the amount of any taxes required to be withheld with respect to the Option, (ii) by direct payment to the Company in cash of the amount of any taxes required to be withheld with respect to the Option or (iii) by a combination of Shares and cash.

d. If the Grantee makes any disposition of Shares delivered pursuant to the exercise of an Incentive Stock Option under the circumstances described in Code Section 421(b) (relating to certain disqualifying dispositions), the Grantee shall notify the Company of such disposition within 10 days of such disposition.

8. Adjustment. Upon any event described in Section 15 of the Plan (entitled "Effect of Changes in Capitalization," or any successor provision thereto) occurring after the Grant Date, the adjustment provisions as provided for under Section 15 of the Plan shall apply to the Option.

9. Bound by Plan and Committee Decisions. By accepting the Option, the Grantee acknowledges that the Grantee has received a copy of the Plan, has had an opportunity to review the Plan, and agrees to be bound by all of the terms and conditions of the Plan. In the event of any conflict between the provisions of the Award Agreement and the Plan, the provisions of the Plan shall control. The authority to manage and control the operation and administration of the Award Agreement and the Plan shall be vested in the Committee, and the Committee shall have all powers with respect to the Award Agreement as it has with respect to the Plan. Any interpretation of the Award Agreement or the Plan by the Committee and any decision made by the Committee with respect to the Award Agreement or the Plan shall be final and binding on all persons.

---

[6] Has the plan been approved by shareholders?

10. Grantee Representations. The Grantee hereby represents to the Company that the Grantee has read and fully understands the provisions of the Award Agreement and the Plan and that the Grantee's decision to participate in the Plan is completely voluntary. Further, the Grantee acknowledges that the Grantee is relying solely on his or her own advisors with respect to the tax consequences of the Option.

11. Regulatory Limitations on Exercises. Notwithstanding the other provisions of the Award Agreement, the Committee may impose such conditions, restrictions, and limitations (including suspending the exercise of the Option and the tolling of any applicable exercise period during such suspension) on the issuance of Common Stock with respect to the Option unless and until the Committee determines that such issuance complies with (a) any applicable registration requirements under the Securities Act or the Committee has determined that an exemption therefrom is available, (b) any applicable listing requirement of any stock exchange on which the Common Stock is listed, (c) any applicable Company policy or administrative rules, and (d) any other applicable provision of state, federal, or foreign law, including foreign securities laws where applicable.

12. Miscellaneous.

a. Notices. Any notice that either party hereto may be required or permitted to give to the other shall be in writing and may be delivered personally, by intraoffice mail, by fax, by electronic mail or other electronic means, or via a postal service, postage prepaid, to such electronic mail or postal address and directed to such person as the Company may notify the Grantee from time to time; and to the Grantee at the Grantee's electronic mail or postal address as shown on the records of the Company from time to time, or at such other electronic mail or postal address as the Grantee, by notice to the Company, may designate in writing from time to time.

b. Waiver. The waiver by any party hereto of a breach of any provision of the Award Agreement shall not operate or be construed as a waiver of any other or subsequent breach.

c. Entire Agreement. The Award Agreement and the Plan constitute the entire agreement between the parties with respect to the Option. Any prior agreements, commitments, or negotiations concerning the Option are superseded.

d. Binding Effect; Successors. The obligations and rights of the Company under the Award Agreement shall be binding upon and inure to the benefit of the Company and any successor corporation or organization resulting from the merger, consolidation, sale, or other reorganization of the Company, or upon any successor corporation or organization succeeding to substantially all of the assets and business of the Company. The obligations and rights of the Grantee under the Award Agreement shall be binding upon and inure to the benefit of the Grantee and the beneficiaries, executors, administrators, heirs, and successors of the Grantee.

e. Governing Law; Consent to Jurisdiction; Consent to Venue. The Award Agreement shall be construed and interpreted in accordance with the internal laws of the State of Delaware without regard to principles of conflicts of law thereof, or principles of conflicts of laws of any other jurisdiction that could cause the application of the laws of any jurisdiction other than the State of Delaware. For purposes of resolving any dispute that arises directly or indirectly from the relationship of the parties evidenced by the Option or the Award Agreement, the parties hereto hereby submit to and consent to the exclusive jurisdiction of the State of California and agree that any related litigation shall be conducted solely in the courts of Orange County, California or the federal courts for the United States for the Central District of California where the Award Agreement is made and/or to be performed, and no other courts.

f. Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of the Award Agreement.

g. Amendment. The Award Agreement may be amended at any time by the Committee, *provided* that no amendment may, without the consent of the Grantee, materially impair the Grantee's rights with respect to the Option.

h. Severability. The invalidity or unenforceability of any provision of the Award Agreement shall not affect the validity or enforceability of any other provision of the Award Agreement, and each other provision of the Award Agreement shall be severable and enforceable to the extent permitted by law.

i. No Rights to Service. Nothing contained in the Award Agreement shall be construed as giving the Grantee any right to be retained, in any position, as a director, officer, employee, or consultant of the Company or its Affiliates, or shall interfere with or restrict in any way the rights of the Company or its Affiliates, which are hereby expressly reserved, to remove, terminate, or discharge the Grantee at any time for any reason whatsoever or for no reason, subject to the Company's articles of incorporation, bylaws, and other similar governing documents and applicable law.

j. Section 409A. It is intended that the Award Agreement and the Option will be exempt from (or in the alternative will comply with) Code Section 409A, and the Award Agreement shall be administered accordingly and interpreted and construed on a basis consistent with such intent. This Section 12(j) shall not be construed as a guarantee of any particular tax effect for the Grantee's benefits under the Award Agreement and the Company does not guarantee that any such benefits will satisfy the provisions of Code Section 409A or any other provision of the Code.

k. Further Assurances. The Grantee agrees, upon demand of the Company or the Committee, to do all acts and execute, deliver, and perform all additional documents, instruments, and agreements that may be reasonably required by the Company or the Committee, as the case may be, to implement the provisions and purposes of the Award Agreement and the Plan.

l. Confidentiality. The Grantee agrees that the terms and conditions of the Option award reflected in the Award Agreement are strictly confidential and, with the exception of the Grantee's counsel, tax advisor, immediate family, or as required by applicable law, have not and shall not be disclosed, discussed, or revealed to any other persons, entities, or organizations, whether within or outside Company, without prior written approval of Company. The Grantee shall take all reasonable steps necessary to ensure that confidentiality is maintained by any of the individuals or entities referenced above to whom disclosure is authorized.

By signing below, the Grantee agrees that the Option is granted under and governed by the terms and conditions of the Plan and the Award Agreement, as of the Grant Date.

GRANTEE	**HANCOCK JAFFE LABORATORIES, INC.**
Sign Name: _____	Sign Name: _____
Print Name: _____	Print Name: _____
	Title: _____

HANCOCK JAFFE LABORATORIES, INC
AMENDED AND RESTATED 2016 OMNIBUS INCENTIVE PLAN

Award Agreement

This Award Agreement evidences an Award of Restricted Stock Units (the "RSUs") pursuant to the provisions of the Hancock Jaffe Laboratories, Inc.'s Amended and Restated 2016 Omnibus Incentive Plan (the "Plan") to the individual whose name appears below (the "Grantee"), on the following express terms and conditions (capitalized terms not otherwise defined herein shall have the meaning ascribed thereto in the Plan):

1. Name of Participant:

2. Number of RSUs:

3. Purchase Price / Consideration: [1]

4. Grant Date:

5. Commencement Date for Vesting:

6. Restricted Period / Risk of Forfeiture:[2]

7. Change in Control:[3]

8. Settlement of RSUs:[4]

9. Additional Terms:[5]

The Grantee hereby acknowledges receipt of a copy of the Plan as presently in effect. The text and all of the terms and provisions of the Plan are incorporated herein by reference, and this RSU is subject to these terms and provisions in all respects. The Grantee shall remit to the Company an amount sufficient to satisfy the required withholding tax obligation of the Company that arises upon settlement of the RSUs.

HANCOCK JAFFE LABORATORIES, INC.

By: _____ _____
Name: Robert A. Berman Dated
Title: Chief Executive Officer

Agreed to and Accepted by:

_____ _____
Dated

1 If a purchase price is required, provide it here. If the grant is in consideration for services rendered, say so here. If payment in cash is required, you may include any alternatives other than cash payment that the board will accept (for example, shares, keep in mind withholding for employees).
2 Consideration needs to be given here as to what happens in the event there is a termination of service.
3 State the impact of a change in control upon the RSU. The plan provides flexibility to the board to provide for one or more of the following: (i) accelerate vesting of the RSU, (ii) cause for the assumption, continuation or substitution of the RSU or (iii) cash-out the RSU. See Section 15.2 in the plan.
4 Indicate here whether RSUs will be settled for short term deferrals. If not, specify upon which events the RSUs will be settled.
5 The plan provides that RSU holders may have voting rights / dividend rights if provided for in the agreement. You would indicate if there are voting rights / dividend rights here.

SHARE PURCHASE AGREEMENT

This Share Purchase Agreement (this "Agreement") is dated as of March 11, 2019, between Hancock Jaffe Laboratories, Inc., a Delaware corporation (the "Company"), and each purchaser identified on the signature pages hereto (each, including its successors and assigns, a "Purchaser" and collectively, the "Purchasers").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Rule 506 promulgated thereunder, the Company desires to issue and sell to each Purchaser, and each Purchaser, severally and not jointly, desires to purchase from the Company, securities of the Company as more fully described in this Agreement.

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

ARTICLE I.
DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Action" shall have the meaning ascribed to such term in Section 3.1(pp).

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person as such terms are used in and construed under Rule 405 under the Securities Act.

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Closing" means the closing of the purchase and sale of the Securities pursuant to Section 2.1.

"Closing Date" means the Trading Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) the Purchasers' obligations to pay the Subscription Amount and (ii) the Company's obligations to deliver the Securities, in each case, have been satisfied or waived.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.00001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Company Counsel" means Ellenoff Grossman & Schole LLP, with offices located at 1345 Avenue of the Americas, New York, New York 10105-0302.

"Disclosure Time" means, (i) if this Agreement is signed on a day that is not a Trading Day or after 9:00 a.m. (New York City time) and before midnight (New York City time) on any Trading Day, 9:01 a.m. (New York City time) on the Trading Day immediately following the date hereof and (ii) if this Agreement is signed between midnight (New York City time) and 9:00 a.m. (New York City time) on any Trading Day, no later than 9:01 a.m. (New York City time) on the date hereof.

"Escrow Agent" means Signature Bank, a New York State chartered bank, having an office at 565 Fifth Avenue, 12th floor, New York, NY 10017.

"Escrow Agreement" means the escrow agreement entered into prior to the date hereof, by and among the Company, the Escrow Agent and the Placement Agent pursuant to which the Purchasers shall deposit Subscription Amounts with the Escrow Agent to be applied to the transactions contemplated hereunder.

"Evaluation Date" shall have the meaning ascribed to such term in Section 3.1(r).

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Exempt Issuance" means the issuance of (a) shares of Common Stock or options to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company, (b) securities upon the exercise or exchange of or conversion of any Shares issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with stock splits or combinations) or to extend the term of such securities, and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

"FCPA" means the Foreign Corrupt Practices Act of 1977, as amended.

"FDA" shall have the meaning ascribed to such term in Section 3.1(gg).

"FDCA" shall have the meaning ascribed to such term in Section 3.1(gg).

"GAAP" shall have the meaning ascribed to such term in Section 3.1(h).

"Indebtedness" shall have the meaning ascribed to such term in Section 3.1(x).

"Intellectual Property Rights" shall have the meaning ascribed to such term in Section 3.1(o).

"Liens" means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"Material Adverse Effect" shall have the meaning assigned to such term in Section 3.1(b).

"Material Permits" shall have the meaning ascribed to such term in Section 3.1(m).

"Per Share Purchase Price" equals $1.15, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Pharmaceutical Product" shall have the meaning ascribed to such term in Section 3.1(gg).

"Placement Agent" means Network 1 Financial Securities.

"Proceeding" means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

"Purchaser Party" shall have the meaning ascribed to such term in Section 4.7.

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e).

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"SEC Reports" shall have the meaning ascribed to such term in Section 3.1(h).

"Securities" means the Shares.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Shares" means the shares of Common Stock issued pursuant to this Agreement.

"Short Sales" means all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include locating and/or borrowing shares of Common Stock).

"Subscription Amount" means, as to each Purchaser, the aggregate amount to be paid for Shares purchased hereunder as specified below such Purchaser's name on the signature page of this Agreement and next to the heading "Subscription Amount," in United States dollars and in immediately available funds.

"Subsidiary" means any subsidiary of the Company as set forth in the SEC Reports, and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, OTCQB or OTCQX (or any successors to any of the foregoing).

"Transaction Documents" means this Agreement, all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer Agent" means VStock Transfer, LLC, the current transfer agent of the Company, with a mailing address of 18 Lafayette Place, Woodmere, New York 11598 and a facsimile number of (646) 536-3179, and any successor transfer agent of the Company.

ARTICLE II.
PURCHASE AND SALE

2.1 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and the Purchasers, severally and not jointly, agree to purchase, up to an aggregate of $2,714,000 of Shares. Each Purchaser shall deliver to the Escrow Agent, via wire transfer or a certified check, immediately available funds equal to such Purchaser's Subscription Amount as set forth on the signature page hereto executed by such Purchaser. The Company shall deliver to each Purchaser its respective Shares as determined pursuant to Section 2.2(a), and the Company and each Purchaser shall deliver the other items set forth in Section 2.2 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.2 and 2.3, the Closing shall occur at the offices of Company Counsel or such other location as the parties shall mutually agree.

2.2 Deliveries.

(a) On or prior to the Closing Date, the Company shall deliver or cause to be delivered to each Purchaser the following:

(i) this Agreement duly executed by the Company;

(ii) a legal opinion of Company Counsel, in a form reasonably satisfactory to Placement Agent counsel; and

(iii) a copy of the irrevocable instructions to the Transfer Agent instructing the Transfer Agent to deliver on an expedited basis, a certificate evidencing a number of Shares equal to such Purchaser's Subscription Amount divided by the Per Share Purchase Price, registered in the name of such Purchaser.

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company or the Escrow Agent, as applicable, the following:

(i) this Agreement duly executed by such Purchaser; and

(ii) to the Escrow Agent, such Purchaser's Subscription Amount.

2.3 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) on the Closing Date of the representations and warranties of the Purchasers contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of each Purchaser required to be performed at or prior to the Closing Date shall have been performed; and

(iii) the delivery by each Purchaser of the items set forth in Section 2.2(b) of this Agreement.

(b) The respective obligations of the Purchasers hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.2(a) of this Agreement;

(iv) there shall have been no Material Adverse Effect with respect to the Company since the date hereof; and

(v) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market, and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of such Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. Except as set forth in the SEC Reports, the Company hereby makes the following representations and warranties to each Purchaser:

(a) Subsidiaries. All of the direct and indirect subsidiaries of the Company are set forth in the SEC Reports. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non- assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "Material Adverse Effect") and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.4 of this Agreement, (ii) the filing with the Commission of a registration statement for the resale of the Shares by the Purchasers, (iii) the notice and/or application(s) to each applicable Trading Market for the issuance and sale of the Shares and the listing of the Shares for trading thereon in the time and manner required thereby, and (iv) the filing of Form D with the Commission and such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals"). No Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(f) Issuance of the Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company other than restrictions on transfer provided for in the Transaction Documents. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement.

(g) Capitalization. The capitalization of the Company is as set forth in the SEC Reports. Other than as described on Schedule 3.1(g), the Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options under the Company's stock option plans, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans and pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents. Except as a result of the purchase and sale of the Securities and as disclosed in the SEC Reports, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or capital stock of any Subsidiary. The issuance and sale of the Securities will not obligate the Company or any Subsidiary to issue shares of Common Stock or other securities to any Person (other than the Purchasers). There are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(h) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(i) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as set forth on in the SEC Reports, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Securities contemplated by this Agreement or as set forth in the SEC Reports, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition, that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made.

(j) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(k) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree, or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(l) Environmental Laws. The Company and its Subsidiaries (i) are in compliance with all federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata), including laws relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, or toxic or hazardous substances or wastes (collectively, "Hazardous Materials") into the environment, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, as well as all authorizations, codes, decrees, demands, or demand letters, injunctions, judgments, licenses, notices or notice letters, orders, permits, plans or regulations, issued, entered, promulgated or approved thereunder ("Environmental Laws"); (ii) have received all permits licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) are in compliance with all terms and conditions of any such permit, license or approval where in each clause (i), (ii) and (iii), the failure to so comply could be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

(m) Regulatory Permits. Except as disclosed in the SEC Reports, the Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(n) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance.

(o) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). None of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(p) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage at least equal to the aggregate Subscription Amount. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(q) Transactions with Affiliates and Employees. Except as set forth in the SEC Reports, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of $120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

(r) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(s) Certain Fees. Other than to the Placement Agent, no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiary to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchasers shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(t) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(u) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. The Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(v) Disclosure. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, the Company confirms that neither it nor any other Person acting on its behalf has provided any of the Purchasers or their agents or counsel with any information that it believes constitutes or might constitute material, non-public information. The Company understands and confirms that the Purchasers will rely on the foregoing representation in effecting transactions in securities of the Company. All of the disclosure furnished by or on behalf of the Company to the Purchasers regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. The press releases disseminated by the Company during the twelve months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made and when made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(w) No Integrated Offering. Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of (i) the Securities Act which would require the registration of any such securities under the Securities Act, or (ii) any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(x) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances outside of the ordinary course of business which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. The SEC Reports sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. For the purposes of this Agreement, "Indebtedness" means (x) any liabilities for borrowed money or amounts owed in excess of $50,000 (other than trade accounts payable incurred in the ordinary course of business), (y) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (z) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(y) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

(z) No General Solicitation. Neither the Company nor any Person acting on behalf of the Company has offered or sold any of the Securities by any form of general solicitation or general advertising. The Company has offered the Securities for sale only to the Purchasers and certain other "accredited investors" within the meaning of Rule 501 under the Securities Act.

(aa) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of FCPA.

(bb) Accountants. The Company's accounting firm is set forth in the SEC Reports. To the knowledge and belief of the Company, such accounting firm (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending December 31, 2018.

(cc) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Placement Agent.

(dd) Private Placement. Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, no registration under the Securities Act is required for the offer and sale of the Securities by the Company to the Purchasers as contemplated hereby. The issuance and sale of the Securities hereunder does not contravene the rules and regulations of the Trading Market.

(ee) Registration Rights. Other than each of the Purchasers, no Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(ff) No Disagreements with Accountants and Lawyers. There are no disagreements of any kind presently existing, or reasonably anticipated by the Company to arise, between the Company and the accountants and lawyers formerly or presently employed by the Company and the Company is current with respect to any fees owed to its accountants and lawyers which could affect the Company's ability to perform any of its obligations under any of the Transaction Documents.

(gg) FDA. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration (" FDA") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("FDCA") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its Subsidiaries (each such product, a "Pharmaceutical Product"), such Pharmaceutical Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Effect. There is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its Subsidiaries, and none of the Company or any of its Subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Pharmaceutical Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Pharmaceutical Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company.

(hh) Stock Option Plans. Each stock option granted by the Company under the Company's stock option plan was granted (i) in accordance with the terms of the Company's stock option plan and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company's stock option plan has been backdated. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their financial results or prospects.

(ii) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC").

(jj) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(kk) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(ll) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no Action or Proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(mm) No Disqualification Events. With respect to the Securities to be offered and sold hereunder in reliance on Rule 506 under the Securities Act, none of the Company, any of its predecessors, any affiliated issuer, any director, executive officer, other officer of the Company participating in the offering hereunder, any beneficial owner of 20% or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, nor any promoter (as that term is defined in Rule 405 under the Securities Act) connected with the Company in any capacity at the time of sale (each, an "Issuer Covered Person" and, together, "Issuer Covered Persons") is subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act (a "Disqualification Event"), except for a Disqualification Event covered by Rule 506(d)(2) or (d)(3). The Company has exercised reasonable care to determine whether any Issuer Covered Person is subject to a Disqualification Event. The Company has complied, to the extent applicable, with its disclosure obligations under Rule 506(e), and has furnished to the Purchasers a copy of any disclosures provided thereunder.

(nn) Notice of Disqualification Events. The Company will notify the Purchasers and the Placement Agent in writing, prior to the Closing Date of (i) any Disqualification Event relating to any Issuer Covered Person and (ii) any event that would, with the passage of time, become a Disqualification Event relating to any Issuer Covered Person.

(oo) Other Covered Persons. Other than the Placement Agent, the Company is not aware of any person (other than any Issuer Covered Person) that has been or will be paid (directly or indirectly) remuneration for solicitation of purchasers in connection with the sale of any Securities.

(pp) Litigation. Except as disclosed in the SEC Reports and on Schedule 3.1(pp), there is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary, nor, to the Company's knowledge, any current director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

3.2 Representations and Warranties of the Purchasers. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein, in which case they shall be accurate as of such date):

(a) Organization; Authority. Such Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by such Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of such Purchaser. Each Transaction Document to which it is a party has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of such Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Own Account. Such Purchaser understands that the Securities are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Securities as principal for its own account and not with a view to or for distributing or reselling such Securities or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Securities in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting such Purchaser's right to sell the Securities pursuant to the Registration Statement or otherwise in compliance with applicable federal and state securities laws). Such Purchaser is acquiring the Securities hereunder in the ordinary course of its business.

(c) Purchaser Status. At the time such Purchaser was offered the Securities, it was, and as of the date hereof it is, will be either: (i) an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act or (ii) a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act.

(d) Experience of Such Purchaser. Such Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. Such Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) General Solicitation. Such Purchaser is not, to such Purchaser's knowledge, purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or, to the knowledge of such Purchaser, any other general solicitation or general advertisement.

(f) Access to Information. Such Purchaser acknowledges that it has had the opportunity to review the Transaction Documents (including all exhibits and schedules thereto) and the SEC Reports and has been afforded, (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Securities and the merits and risks of investing in the Securities; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment. Such Purchaser acknowledges and agrees that neither the Placement Agent nor any Affiliate of the Placement Agent has provided such Purchaser with any information or advice with respect to the Securities nor is such information or advice necessary or desired. Neither the Placement Agent nor any Affiliate has made or makes any representation as to the Company or the quality of the Securities and the Placement Agent and any Affiliate may have acquired non- public information with respect to the Company which such Purchaser agrees need not be provided to it. In connection with the issuance of the Securities to such Purchaser, neither the Placement Agent nor any of its Affiliates has acted as a financial advisor or fiduciary to such Purchaser.

(g) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that such Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement or to such Purchaser's representatives, including, without limitation, its officers, directors, partners, legal and other advisors, employees, agents and Affiliates, such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to locating or borrowing shares in order to effect Short Sales or similar transactions in the future.

The Company acknowledges and agrees that the representations contained in this Section 3.2 shall not modify, amend or affect such Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transactions contemplated hereby.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4.1 Transfer Restrictions.

(a) The Securities may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of Securities other than pursuant to an effective registration statement or Rule 144, to the Company or to an Affiliate of a Purchaser or in connection with a pledge as contemplated in Section 4.1(b), the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of such transferred Securities under the Securities Act. As a condition of transfer, any such transferee shall agree in writing to be bound by the terms of this Agreement and shall have the rights and obligations of a Purchaser under this Agreement.

(b) The Purchasers agree to the imprinting, so long as is required by this Section 4.1, of a legend on any of the Securities in the following form:

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT WITH A REGISTERED BROKER-DEALER OR OTHER LOAN WITH A FINANCIAL INSTITUTION THAT IS AN "ACCREDITED INVESTOR" AS DEFINED IN RULE 501(a) UNDER THE SECURITIES ACT OR OTHER LOAN SECURED BY SUCH SECURITIES.

The Company acknowledges and agrees that a Purchaser may from time to time pledge pursuant to a bona fide margin agreement with a registered broker-dealer or grant a security interest in some or all of the Securities to a financial institution that is an "accredited investor" as defined in Rule 501(a) under the Securities Act and, if required under the terms of such arrangement, such Purchaser may transfer pledged or secured Securities to the pledgees or secured parties. Such a pledge or transfer would not be subject to approval of the Company and no legal opinion of legal counsel of the pledgee, secured party or pledgor shall be required in connection therewith. Further, no notice shall be required of such pledge. At the appropriate Purchaser's expense, the Company will execute and deliver such reasonable documentation as a pledgee or secured party of Securities may reasonably request in connection with a pledge or transfer of the Securities, including, if the Securities are subject to registration pursuant to Section 4.12 hereof, the preparation and filing of any required prospectus supplement under Rule 424(b)(3) under the Securities Act or other applicable provision of the Securities Act to appropriately amend the list of "selling stockholders" listed in the resale registration statement.

(c) Each Purchaser, severally and not jointly with the other Purchasers, agrees with the Company that such Purchaser will sell any Securities pursuant to either the registration requirements of the Securities Act, including any applicable prospectus delivery requirements, or an exemption therefrom, and that if Securities are sold pursuant to a registration statement, they will be sold in compliance with the plan of distribution set forth therein, and acknowledges that the removal of the restrictive legend from certificates representing Securities as set forth in this Section 4.1 is predicated upon the Company's reliance upon this understanding.

4.2 Furnishing of Information. Until the earliest time that no Purchaser owns Securities, the Company covenants to maintain the registration of the Common Stock under Section 12(b) or 12(g) of the Exchange Act and to timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Exchange Act even if the Company is not then subject to the reporting requirements of the Exchange Act.

4.3 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities in a manner that would require the registration under the Securities Act of the sale of the Securities or that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.4 Securities Laws Disclosure; Publicity. The Company shall (a) by the Disclosure Time, issue a press release disclosing the material terms of the transactions contemplated hereby, and (b) file a Current Report on Form 8-K, including the Transaction Documents as exhibits thereto, with the Commission within the time required by the Exchange Act. From and after the issuance of such press release, the Company represents to the Purchasers that it shall have publicly disclosed all material, non- public information delivered to any of the Purchasers by the Company or any of its Subsidiaries, or any of their respective officers, directors, employees or agents in connection with the transactions contemplated by the Transaction Documents. In addition, effective upon the issuance of such press release, the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement, whether written or oral, between the Company, any of its Subsidiaries or any of their respective officers, directors, agents, employees or Affiliates on the one hand, and any of the Purchasers or any of their Affiliates on the other hand, shall terminate. The Company and each Purchaser shall consult with each other in issuing any other press releases with respect to the transactions contemplated hereby, and neither the Company nor any Purchaser shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of any Purchaser, or without the prior consent of the Placement Agent, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. Notwithstanding the foregoing, the Company shall not publicly disclose the name of any Purchaser, or include the name of any Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of such Purchaser, except (a) as required by federal securities law in connection with the filing of final Transaction Documents with the Commission, (b) in any resale registration statement filed pursuant to the terms hereto and (c) to the extent such disclosure is required by law or Trading Market regulations, in which case the Company shall provide the Purchasers with prior notice of such disclosure permitted under this clause (c).

4.5 Non-Public Information. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, which shall be disclosed pursuant to Section 4.4, the Company covenants and agrees that neither it, nor any other Person acting on its behalf will provide any Purchaser or its agents or counsel with any information that constitutes, or the Company reasonably believes constitutes, material non-public information, unless prior thereto such Purchaser shall have consented to the receipt of such information and agreed with the Company to keep such information confidential. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company. To the extent that the Company delivers any material, non-public information to a Purchaser without such Purchaser's consent, the Company hereby covenants and agrees that such Purchaser shall not have any duty of confidentiality to the Company, any of its Subsidiaries, or any of their respective officers, directors, agents, employees or Affiliates, or a duty to the Company, any of its Subsidiaries or any of their respective officers, directors, agents, employees or Affiliates not to trade on the basis of, such material, non-public information, provided that the Purchaser shall remain subject to applicable law. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company.

4.6 Use of Proceeds. The Company shall use the net proceeds from the sale of the Securities hereunder for working capital purposes, including, potentially, for the settlement of outstanding litigation, and shall not use such proceeds: (a) for the satisfaction of any portion of the Company's debt (other than payment of trade payables in the ordinary course of the Company's business and prior practices), (b) for the redemption of any Common Stock or Common Stock Equivalents or (c) in violation of FCPA or OFAC regulations.

4.7 Indemnification of Purchasers. Subject to the provisions of this Section 4.7, the Company will indemnify and hold each Purchaser and its directors, officers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls such Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "Purchaser Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents, (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of such Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is solely based upon a material breach of such Purchaser Party's representations, warranties or covenants under the Transaction Documents or any agreements or understandings such Purchaser Party may have with any such stockholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by such Purchaser Party which is finally judicially determined to constitute fraud, gross negligence or willful misconduct) or (c) in connection with any registration statement of the Company providing for the resale by the Purchasers of the Shares, the Company will indemnify each Purchaser Party, to the fullest extent permitted by applicable law, from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable attorneys' fees) and expenses, as incurred, arising out of or relating to (i) any untrue or alleged untrue statement of a material fact contained in such registration statement, any prospectus or any form of prospectus or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any prospectus or supplement thereto, in the light of the circumstances under which they were made) not misleading, except to the extent, but only to the extent, that such untrue statements or omissions are based solely upon information regarding such Purchaser Party furnished in writing to the Company by such Purchaser Party expressly for use therein, or (ii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act or any state securities law, or any rule or regulation thereunder in connection therewith. If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (y) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (z) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by such Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.7 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.8 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue Shares pursuant to this Agreement.

4.9 Listing of Common Stock. The Company hereby agrees to use best efforts to maintain the listing or quotation of the Common Stock on the Trading Market on which it is currently listed, and concurrently with the Closing, the Company shall apply to list or quote all of the Shares on such Trading Market and promptly secure the listing of all of the Shares on such Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other Trading Market, it will then include in such application all of the Shares, and will take such other action as is necessary to cause all of the Shares to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its Common Stock on a Trading Market and will comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of the Trading Market. The Company agrees to maintain the eligibility of the Common Stock for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer.

4.10 Certain Transactions and Confidentiality. Each Purchaser, severally and not jointly with the other Purchasers, covenants that neither it nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales, including Short Sales of any of the Company's securities during the period commencing with the execution of this Agreement and ending at such time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4. Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company pursuant to the initial press release as described in Section 4.4, such Purchaser will maintain the confidentiality of the existence and terms of this transaction. Notwithstanding the foregoing and notwithstanding anything contained in this Agreement to the contrary, the Company expressly acknowledges and agrees that (i) no Purchaser makes any representation, warranty or covenant hereby that it will not engage in effecting transactions in any securities of the Company after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4, (ii) no Purchaser shall be restricted or prohibited from effecting any transactions in any securities of the Company in accordance with applicable securities laws from and after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4 and (iii) no Purchaser shall have any duty of confidentiality or duty not to trade in the securities of the Company to the Company or its Subsidiaries after the issuance of the initial press release as described in Section 4.4. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the covenant set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement.

4.11 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Securities as required under Regulation D and to provide a copy thereof, promptly upon request of any Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Securities for, sale to the Purchasers at the Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of any Purchaser.

4.12 Registration Rights.

(a) As soon as practicable, and in any event on or before March 31, 2019 (the "Filing Date"), the Company shall file a registration statement on Form S-1 (the "Registration Statement") providing for the resale by the Purchasers of the Shares. The Company shall use commercially reasonable efforts to (i) cause such registration to become effective within 90 days following the Filing Date, (ii) prior to the effective date of the Registration Statement, file a pre- effective amendment and otherwise respond in writing to comments made by the Commission in respect of such Registration Statement within ten Business Days after the receipt of comments from the Commission or (iii) file with the Commission a request for acceleration of the Registration Statement within five Business Days of the date that the Company is notified in writing by the Commission that such Registration Statement will not be "reviewed" or will not be subject to further review and to keep such registration statement effective for two (2) years following the date such registration statement is declared effective by the Commission.

(b) The Company shall notify the Purchasers of the effectiveness of the Registration Statement and shall furnish to the Purchasers, without charge, such number of copies of the Registration Statement (including any amendments, supplements and exhibits), the prospectus contained therein (including each preliminary prospectus and all related amendments and supplements) and any documents incorporated by reference in the Registration Statement as the Purchaser may reasonably request in order to facilitate the sale of the Shares in the manner described in the Registration Statement.

(c) The Company shall as promptly as reasonably practicable notify the Purchasers of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement with respect to the Purchasers Shares or the receipt of notice of the initiation of any proceedings for that purpose. The Company shall respond promptly, but no later than five (5) days after its receipt of an issuance from the Commission with respect of any issued stop order suspending the effectiveness of the Registration Statement. The Company shall use its best efforts to obtain the withdrawal of any order suspending the effectiveness of the Registration Statement at the earliest possible moment. The Company shall promptly notify the Purchasers of any request by the Commission for any amendment or supplement to, or additional information in connection with, the Registration Statement (or prospectus relating thereto). The Company shall promptly, but no later than five (5) days after the respective filing date, notify the Purchasers of the filing of the Registration Statement or any prospectus, amendment or supplement related thereto or any post-effective amendment to the Registration Statement and the effectiveness of any post-effective amendment.

(d) Subject to the terms of this Section 4.12, the Company shall promptly prepare and file with the Commission from time to time such amendments and supplements to the Registration Statement and prospectus used in connection therewith as may be necessary to keep the Registration Statement effective for two (2) years following the date such registration statement is declared effective by the Commission and to comply with the provisions of the Securities Act with respect to the disposition of all of the Shares for such period. The Company shall include or incorporate by reference in the Registration Statement a customary plan of distribution.

(e) If the Company has delivered a prospectus to a Purchaser and after having done so the prospectus is amended or supplemented to comply with the requirements of the Securities Act, the Company shall promptly notify such Purchaser and such Purchaser shall immediately cease making offers or sales of Shares under the previously delivered prospectus. The Company shall promptly provide such Purchaser with revised or supplemented prospectuses and, following receipt of the revised or supplemented prospectuses, if a prospectus related to the Registration Statement is required at that time to be delivered under the Securities Act, the Purchaser shall be free, subject to the terms of this Section 4.12, to resume making offers and sales under the Registration Statement.

(f) The Company shall, in connection with the filing of the Registration Statement hereunder, file such documents as may be necessary to register or qualify the Shares under the securities or "blue sky" laws of such states as the Purchasers may reasonably request, and the Company shall use its best efforts to cause such filings to become effective in a timely manner; provided, however, that the Company shall not be obligated to qualify as a foreign corporation to do business under the laws of any such state in which it is not then qualified or to file any general consent to service of process in any such state or subject itself to general taxation in any such jurisdiction or provide any undertakings that cause the Company undue expense or burden.

(g) The Company shall pay all expenses incurred by it in complying with its obligations under this Section 4.12, including registration and filing fees, listing fees, printing expenses, messenger and delivery expenses. The Purchasers shall pay all expenses incurred by the Purchasers in connection with the disposition of their Shares, including any broker's fees or commissions, selling expenses, messenger and delivery expenses, and fees and expenses of any counsel retained by the Purchasers.

(h) Unless and until the Registration Statement has been declared effective, the Company hereby covenants not to register (including, for this purpose, a registration effected by the Company for stockholders other than the Purchasers) any of its Common Stock under the Securities Act.

4.13 Subsequent Equity Sales. From the date hereof until 90 days after the Closing Date, neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents. Notwithstanding the foregoing, this Section 4.13 shall not apply in respect of an Exempt Issuance.

4.14 Equal Treatment of Purchasers. No consideration (including any modification of any Transaction Document) shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of this Agreement unless the same consideration is also offered to all of the parties to this Agreement. For clarification purposes, this provision constitutes a separate right granted to each Purchaser by the Company and negotiated separately by each Purchaser, and is intended for the Company to treat the Purchasers as a class with respect to this Agreement and shall not in any way be construed as the Purchasers acting in concert or as a group with respect to the purchase, disposition or voting of Securities or otherwise.

ARTICLE V.
MISCELLANEOUS

5.1 Termination. This Agreement may be terminated by any Purchaser, as to such Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before the fifth (5th) Trading Day following the date hereof; provided, however, that no such termination will affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. Except as expressly set forth in the Transaction Documents to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall pay all Transfer Agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company and any exercise notice delivered by a Purchaser), stamp taxes and other taxes and duties levied in connection with the delivery of any Securities to the Purchasers.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or email attachment at the email address as set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or email attachment at the email address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers which purchased at least 50.1% in interest of the Shares based on the initial Subscription Amounts hereunder or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, provided that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or group of Purchasers), the consent of such disproportionately impacted Purchaser (or group of Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of each Purchaser (other than by merger). Any Purchaser may assign any or all of its rights under this Agreement to any Person to whom such Purchaser assigns or transfers any Securities, provided that such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions of the Transaction Documents that apply to the "Purchasers."

5.8 No Third-Party Beneficiaries. The Placement Agent shall be the third party beneficiary of the representations and warranties of the Company in Section 3.1 and the representations and warranties of the Purchasers in Section 3.2. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Section 4.7 and this Section 5.8.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal Proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any Action or Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Action or Proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Action or Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If any party shall commence an Action or Proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.7, the prevailing party in such Action or Proceeding shall be reimbursed by the non-prevailing party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Action or Proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever any Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then such Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights.

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchasers and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any Action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to any Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under any Transaction Document are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance or non-performance of the obligations of any other Purchaser under any Transaction Document. Nothing contained herein or in any other Transaction Document, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by the Transaction Documents. Each Purchaser shall be entitled to independently protect and enforce its rights including, without limitation, the rights arising out of this Agreement or out of the other Transaction Documents, and it shall not be necessary for any other Purchaser to be joined as an additional party in any Proceeding for such purpose. Each Purchaser has been represented by its own separate legal counsel in its review and negotiation of the Transaction Documents. The Company has elected to provide all Purchasers with the same terms and Transaction Documents for the convenience of the Company and not because it was required or requested to do so by any of the Purchasers. It is expressly understood and agreed that each provision contained in this Agreement and in each other Transaction Document is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers.

5.18 Liquidated Damages. The Company's obligations to pay any partial liquidated damages or other amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid partial liquidated damages and other amounts have been paid notwithstanding the fact that the instrument or security pursuant to which such partial liquidated damages or other amounts are due and payable shall have been canceled.

5.19 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.20 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.21 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

(Signature Pages Follow)

IN WITNESS WHEREOF, the parties hereto have caused this Share Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

HANCOCK JAFFE LABORATORIES, INC.

By: _____
Name: Robert A. Berman
Title: Chief Executive Officer

Address for Notice:

70 Doppler
Irvine, California 92618
E-Mail: rberman@hancockjaffe.com

With a copy to (which shall not constitute notice):

Barry I. Grossman, Esq.
Ellenoff Grossman & Schole LLP
1345 Avenue of the Americas, 11th Floor
New York, New York 10105

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK
SIGNATURE PAGE FOR PURCHASER FOLLOWS]

[PURCHASER SIGNATURE PAGES TO HJLI SHARE PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the undersigned have caused this Share Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: _____

Signature of Authorized Signatory of Purchaser: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Email Address of Authorized Signatory: _____

Facsimile Number of Authorized Signatory: _____

Address for Notice to Purchaser:

Address for Delivery of Securities to Purchaser (if not same as address for notice):

Subscription Amount: $ _____

Shares: _____

EIN Number: _____

[ ] Notwithstanding anything contained in this Agreement to the contrary, by checking this box (i) the obligations of the above-signed to purchase the securities set forth in this Agreement to be purchased from the Company by the above-signed, and the obligations of the Company to sell such securities to the above-signed, shall be unconditional and all conditions to Closing shall be disregarded, (ii) the Closing shall occur on the second (2nd) Trading Day following the date of this Agreement and (iii) any condition to Closing contemplated by this Agreement (but prior to being disregarded by clause (i) above) that required delivery by the Company or the above-signed of any agreement, instrument, certificate or the like or purchase price (as applicable) shall no longer be a condition and shall instead be an unconditional obligation of the Company or the above-signed (as applicable) to deliver such agreement, instrument, certificate or the like or purchase price (as applicable) to such other party on the Closing Date.

[SIGNATURE PAGES CONTINUE]

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Hancock Jaffe Laboratories, Inc. on Form S-8 [FILE NO. 333-225569] of our report, which includes an explanatory paragraph as to the Company's ability to continue as a going concern dated March 13, 2019, with respect to our audits of the financial statements of Hancock Jaffe Laboratories, Inc. as of December 31, 2018 and 2017 and for the years ended December 31, 2018 and 2017, which report is included in this Annual Report on Form 10-K of Hancock Jaffe Laboratories, Inc. for the year ended December 31, 2018.

/s/ Marcum LLP

Marcum llp
New York NY
March 13, 2019

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Robert Berman, certify that:

1. I have reviewed this Annual Report on Form 10-K of Hancock Jaffe Laboratories, Inc.;

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

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

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

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

   (b) [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313];

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

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

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

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

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

March 13, 2019

/s/ Robert Berman

Name: Robert Berman
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Robert Rankin, certify that:

1. I have reviewed this Annual Report on Form 10-K of Hancock Jaffe Laboratories, Inc.;

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

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

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

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

   (b) [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-493313];

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

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

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

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

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

March 13, 2019

/s/ Robert Rankin

Name: Robert Rankin
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

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

In connection with the Annual Report of Hancock Jaffe Laboratories, Inc. (the "Company's Annual Report") on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Robert Berman, as Chief Executive Officer and principal executive officer and Robert Rankin, as Chief Financial Officer and principal financial officer of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of the undersigned's knowledge and belief, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

/s/ Robert Berman
Robert Berman
Chief Executive Officer and Principal Executive Officer

Dated: March 13, 2019

/s/ Robert Rankin
Robert Rankin
Chief Financial Officer and Principal Financial Officer

Dated: March 13, 2019

This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Exhibit 99.1

HANCOCK JAFFE LABORATORIES, INC.

On March 12, 2019, Hancock Jaffe Laboratories, Inc. (the "Company") completed a private placement offering ("Offering") of the Company's common stock to accredited investors selling 2,360,051 shares at a price per share of $1.15 raising $2,714,000 of gross proceeds and $2,326,176 of net proceeds after giving effect to estimated offering fees and expenses of $387,824. In taking account the net proceeds received by the Company from this Offering, the Company believes that the unaudited Company's cash and stockholders' equity as of March 12, 2019 are as follows:

Cash and cash equivalents	$	3,282,919
Restricted cash		810,055
Total Stockholders' Equity		3,330,775