SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CorMedix Inc.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended: **December 31, 2019**

OR

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

For the transition period from _____ to _____

Commission file number: 001-34673

CORMEDIX INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	20-5894890
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
400 Connell Drive, Suite 5000, Berkeley Heights, NJ	**07922**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (908) 517-9500

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 Par Value	CRMD	NYSE American 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 ☒

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 ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐

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

Large accelerated filer ☐ Accelerated filer ☒

Non-accelerated filer ☐ Smaller reporting company ☒

Emerging growth company ☐

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

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

The aggregate market value of the registrant's voting common equity held by non-affiliates of the registrant, based upon the closing price of the registrant's common stock on the last business day of the registrant's most recently completed second fiscal quarter was approximately $209.3 million. Solely for the purpose of this calculation, shares held by directors and executive officers of the registrant have been excluded.

The number of outstanding shares of the registrant's common stock was 26,126,859, as of March 12, 2020.

DOCUMENTS INCORPORATED BY REFERENCE

None

Neutrolin® is our registered trademark. All other trade names, trademarks and service marks appearing in this report are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this report, appear with the trade name, trademark or service mark notice and then throughout the remainder of this report without trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

PART I

Forward-Looking Statements

This report contains “forward-looking statements” that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements are often identified by the use of words such as, but not limited to, “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “will,” “plan,” “project,” “seek,” “should,” “target,” “will,” “would,” and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below in the section titled “Item 1A. Risk Factors.” Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Item 1. Business

Overview

We are a biopharmaceutical company focused on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases.

Our primary focus is on the development of our lead product candidate, Neutrolin®, for potential commercialization in the United States, or U.S., and other key markets. We have in-licensed the worldwide rights to develop and commercialize Neutrolin. Neutrolin is a novel anti-infective solution (a formulation of taurolidine 1.35%, citrate 3.5%, and heparin 1000 u/ml) intended for the reduction and prevention of catheter-related infections and thrombosis in patients requiring central venous catheters in clinical settings such as hemodialysis, critical/intensive care, and oncology. Infection and thrombosis represent key complications among hemodialysis, critical care/intensive care and cancer patients with central venous catheters. These complications can lead to treatment delays and increased costs to the healthcare system when they occur due to hospitalizations, need for intravenous, or IV, antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the central venous catheter, related treatment costs and increased mortality. We believe Neutrolin addresses a significant unmet medical need and a potential large market opportunity.

Neutrolin – United States

In late 2013, we met with the U.S. Food and Drug Administration, or FDA, to determine the pathway for U.S. marketing approval of Neutrolin. We launched the Phase 3 clinical trial in patients with hemodialysis catheters in the U.S. in December 2015. The clinical trial, named Phase 3 Prospective, Multicenter, Double-blind, Randomized, Active Control Study to Demonstrate Safety and Effectiveness of Neutrolin in Preventing Catheter-related Bloodstream Infection in Subjects on Hemodialysis for End Stage Renal Disease, or LOCK-IT-100, was a prospective, multicenter, randomized, double-blind, active control trial which aimed to demonstrate the efficacy and safety of Neutrolin in preventing catheter-related bloodstream infections, or CRBSI, in subjects receiving hemodialysis therapy as treatment for end stage renal disease. The primary endpoint for the trial was time to CRBSI. The trial evaluated Neutrolin relative to the active control heparin by documenting the incidence of CRBSI and the time until the occurrence of CRBSI for each study subject. Secondary endpoints were catheter patency, which was defined as required use of tissue plasminogen activating factor, or tPA, or removal of catheter due to dysfunction, and removal of catheter for any reason.

During the course of the study, in consultation with the FDA, we established the Clinical Adjudication Committee, or CAC, to critically and independently assess CRBSI while being blinded to treatment assignment. As announced in July 2018, the CAC reviewed potential cases of CRBSI in our LOCK-IT-100 study that occurred through early December 2017 and identified 28 such cases. As previously agreed with the FDA, an interim efficacy analysis was performed when the first 28 CRBSIs were identified. On July 25, 2018, we announced that the independent Data Safety Monitoring Board, or DSMB, had completed its review of the interim analysis of the data from the LOCK-IT-100 study. Based on the first 28 cases, there was a highly statistically significant 72% reduction in CRBSI relative to the control (p=0.0034). Because the pre-specified level of statistical significance was reached for the primary endpoint and efficacy had been demonstrated with no safety concerns, the DSMB recommended the study be terminated early.

Following discussions with the FDA, we proceeded with an orderly termination of LOCK-IT-100. In late January 2019, we announced the topline results of the full data set of the LOCK-IT-100 study. The study continued enrolling and treating subjects until study termination, and the final efficacy analysis was based on a total of 795 subjects.

The primary endpoint of the Phase 3 LOCK-IT-100 study was the reduction of the risk of occurrence of CRBSI by Neutrolin relative to the active control of heparin. In the analysis of the full data set, a total of 41 CRBSI events were determined by the CAC. There was a 71% reduction in the risk of occurrence of CRBSIs compared with the active control of heparin, which was well in excess of the study's assumed treatment effect size of a 55% reduction. In the Neutrolin arm, the CRBSI event rate was 0.13 per 1000 catheter days, which is significantly lower than the event rate of 0.46 per 1000 catheter days in the control arm. The statistical significance of the primary endpoint in the full data set (p=0.0006) was even more impressive than that of the interim analysis (p=0.0034).

There were no statistically significant differences between the results in the Neutrolin arm compared with the control arm in the final analysis for the secondary endpoints. The event rate for one of the secondary endpoints, catheter removal for any reason, was 3.48 per 1000 catheter-days (236 out of 397 subjects) in the Neutrolin arm and 3.23 per 1000 catheter-days (225 out of 398 subjects) in the control arm (p=0.416). The loss of catheter patency, which was defined either as catheter removal due to loss of catheter patency or the administration of tissue plasminogen activating factor (tPA), was also a secondary endpoint. The event rate for loss of catheter patency was 0.99 per 1000 catheter-days (63 out of 397 subjects) in the Neutrolin arm and 0.74 per 1000 catheter-days (48 out of 398 subjects) in the control arm (p=0.12). In the top-line safety analysis, the observed rate of treatment-emergent adverse events was lower in the Neutrolin arm. The rate of adverse events per patient was 5.1 in the Neutrolin arm and 5.8 in the control arm.

Although the FDA usually requires two pivotal clinical trials to provide substantial evidence of safety and effectiveness for approval of an NDA, the FDA will in some cases accept one adequate and well-controlled trial, where it is a large multicenter trial with a broad range of subjects and investigation sites with procedures to include trial quality that has demonstrated a clinically meaningful and statistically very persuasive effect on prevention of a disease with potentially serious outcome.

We have had discussions with the FDA and plan to proceed with submission of the NDA for Neutrolin based on the results of LOCK-IT-100. Whether data from LOCK-IT-100 are sufficient will be a review issue with the FDA.

In January 2015, the FDA designated Neutrolin as a Qualified Infectious Disease Product, or QIDP, for prevention of catheter-related blood stream infections in patients with end stage renal disease receiving hemodialysis through a central venous catheter. Catheter-related blood stream infections and clotting can be life-threatening. The QIDP designation provides five years of market exclusivity in addition to the five years granted for a New Chemical Entity upon approval of a New Drug Application, or NDA. In addition, in January 2015, the FDA granted Fast Track designation to Neutrolin Catheter Lock Solution, a designation intended to facilitate development and expedite review of drugs that treat serious and life-threatening conditions so that the approved drug can reach the market expeditiously. The Fast Track designation of Neutrolin provides us with the opportunity to meet with the FDA on a more frequent basis during the development process, and also ensures eligibility to request priority review of the marketing application.

The FDA has agreed that the Neutrolin NDA is eligible for both priority review and for submission under rolling review. In January 2020, the FDA granted our request for rolling review. A determination on priority review will not be made until the submitted NDA is reviewed by the FDA to determine the acceptance for filing. The FDA informs the applicant of a Priority Review designation within sixty days of the receipt of the complete original application, if it determines the criteria have been met. Priority Review designation would mean the FDA's goal is to take action on an application within six months, compared to a standard review period of ten months.

The FDA also agreed that we could request consideration of Neutrolin for approval under the Limited Population Pathway for Antibacterial and Antifungal Drugs, or LPAD. LPAD, passed as part of the 21st Century Cures Act, is a new program intended to expedite the development and approval of certain antibacterial and antifungal drugs to treat serious or life-threatening infections in limited populations of patients with unmet needs. Given that the LPAD pathway provides for a streamlined clinical development program for a limited population that may involve smaller, shorter, or fewer clinical trials, we believe that LPAD will provide additional flexibility for the FDA to approve Neutrolin to prevent CRBSIs in the limited population of patients with end-stage renal disease receiving hemodialysis through a central venous catheter.

Neutrolin – International

In the European Union, or EU, Neutrolin is regulated as a Class 3 medical device. In July 2013, we received CE Mark approval for Neutrolin. In December 2013, we started commercial sales of Neutrolin in Germany for the prevention of CRBSI, and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in certain European Union and Middle Eastern countries for such treatment.

In September 2014, the TUV-SUD and The Medicines Evaluation Board of the Netherlands, or MEB, granted a label expansion for Neutrolin for these same expanded indications for the EU. In December 2014, we received approval from the Hessian District President in Germany to expand the label to include use in oncology patients receiving chemotherapy, IV hydration and IV medications via central venous catheters. The expansion also adds patients receiving medication and IV fluids via central venous catheters in intensive or critical care units (cardiac care unit, surgical care unit, neonatal critical care unit, and urgent care centers). An indication for use in total parenteral nutrition was also approved.

Additional Development Possibilities

In addition to Neutrolin, we are sponsoring a pre-clinical research collaboration for the use of taurolidine as a possible treatment for rare orphan pediatric tumors. In February 2018, the FDA granted orphan drug designation to taurolidine for the treatment of neuroblastoma in children. We may seek one or more strategic partners or other sources of capital to help us develop and commercialize taurolidine for the treatment of neuroblastoma in children. We are also evaluating opportunities for the possible expansion of taurolidine as a platform compound for use in certain medical devices. Patent applications have been filed in several indications, including wound closure, surgical meshes, and wound management. Based on initial feasibility work, we are advancing pre-clinical studies for taurolidine-infused surgical meshes, suture materials and hydrogels. We will seek to establish development/commercial partnerships as these programs advance.

The FDA regards taurolidine as a new chemical entity and therefore it is currently an unapproved new drug. We might in the future pursue product candidates that would involve devices impregnated with taurolidine, and we believe that at the current time such products would be combination products subject to device premarket submission requirements (while subject also, under review by FDA, to the standards for drug approvability). Consequently, given that there is no appropriate predicate medical device currently marketed in the U.S. on which a 510(k) approval process could be based and that taurolidine is not yet approved in any application, we anticipate that we would be required to submit a premarket approval application, or PMA, for marketing authorization for any medical device indications that we may pursue for devices containing taurolidine. In the event that an NDA for Neutrolin® is approved by the FDA, the regulatory pathway for these medical device product candidates may be revisited with the FDA. Although there may be no appropriate predicate, de novo Class II designation can be proposed, based on a risk assessment and a reasonable assurance of safety and effectiveness.

Neutrolin

Market Opportunity

Central venous catheters and peripherally inserted central catheters (“Central Catheters”) are an important and frequently used method for accessing the vasculature in hemodialysis (a form of dialysis where the patient’s blood is circulated through a dialysis filter), administering chemotherapy and basic fluids (total parenteral nutrition) in cancer patients and for cancer chemotherapy, long term antibiotic therapy, total parenteral nutrition (complete or partial dietary support via intravenous nutrients) and critical care/intensive care patients.

According to the 2015 United States Renal Disease System, there were 660,000 patients on hemodialysis in the U.S. Hemodialysis National Kidney Foundation has reported that patients requiring Central Catheters represent over 63 million catheter/dialysis treatment days per year. In the United States, 5.7 million intensive care patients are admitted annually according to the Society of Critical Care Medicine, which is estimated to represent 28.5 million catheter days associated with Central Catheter use in the ICU alone. As of 2014, there were over 14.5 million patients in the United States living with cancer, with an estimated 7.7 million having had long-term Central Catheters. When stages of disease and types of chemotherapy regime are considered, the number of catheter days per year in cancer patients reaches 90 million.

One of the major and common complications for all patients requiring central venous catheters is CRBSI and the clinical complications associated with them. There are an estimated 250,000 CRBSI each year. The U.S. Centers for Disease Control and Prevention stated in the Journal of American Medicine that the total annual cost in the United States of treating all CRBSI episodes and their complications amounts to approximately $6.0 billion.

Biofilm build up is the pathogenesis of both infections and thrombotic complications in central venous catheters. Prevention of CRBSI and inflammatory complications requires both removal of pathogens from the internal surface of the catheter to prevent the systemic dissemination of organisms contained within the biofilm as well as an anticoagulant to retain blood flow during dialysis. Biofilm forms when bacteria adhere to surfaces in aqueous environments and begin to excrete a slimy, glue-like substance that can anchor them to various types of materials, including intravenous catheters. The presence of biofilm has many adverse effects, including the ability to release bacteria into the blood stream. The current standard of catheter care is to instill a heparin lock solution at a concentration of 1000 u/mL into each catheter lumen immediately following treatment, in order to prevent clotting between dialysis treatments. However, a heparin lock solution provides no protection from the risk of infection.

Currently, there are no pharmacologic agents approved in the U.S. for the prevention of CRBSI in central venous catheters. As noted above, we received the CE Mark approval for Neutrolin from the MEB of the EU in July 2013. We believe there is a significant need for prevention of CRBSI in the hemodialysis patient population as well as for other patient populations utilizing central venous catheters and peripherally inserted central catheters, such as oncology/chemotherapy, total parenteral nutrition and intensive care unit patients.

Neutrolin is a broad-spectrum antimicrobial/antifungal and anticoagulant combination that is active against common microbes including antibiotic-resistant strains and in addition may prevent biofilm formation. We believe that using Neutrolin as an anti-infective solution will significantly reduce the incidence of life-threatening catheter-related blood stream infections, thus reducing the need for local and systemic antibiotics while prolonging catheter life.

Initially, we expect to sell Neutrolin in the U.S. primarily to key operators of dialysis centers. We anticipate that Medicare reimbursement could be available for Neutrolin in hemodialysis and other catheter indications in intensive care, oncology and total parenteral nutrition through relevant hospital inpatient diagnosis-related groups (DRGs) or outpatient ambulatory payment classifications (APCs), the End-Stage Renal Disease Prospective Payment System (ESRD PPS) base payment, or under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule, depending on the setting of care. We also plan to seek separate reimbursement as a drug, where available under Medicare, through mechanisms such as pass-through status under the Hospital Outpatient Prospective Payment System, the transitional drug add-on payment adjustment (TDAPA) under the ESRD PPS, or reimbursement as a drug used with a DMEPOS infusion pump. We have engaged U.S. Centers for Medicare & Medicaid Services (CMS) in preliminary discussions concerning the reimbursement for Neutrolin under TDAPA; however, qualifications cannot be determined until after FDA approval. To be eligible for TDAPA, a new renal drug or biologic must be:

- Approved by FDA
- Commercially available
- Assigned a Healthcare Common Procedure Coding System code
- Identified as having an end action effect that treats or manages a condition or conditions associated with ESRD
- Identified as not fitting into an established ESRD PPS functional category
- Designated by CMS as a renal dialysis service

We cannot fully anticipate changes in reimbursement requirements and mechanisms in the coming years, and we cannot be certain that Neutrolin will be granted separate reimbursement under any of these mechanisms. Furthermore, we anticipate that the CMS, and private payers will increasingly demand that manufacturers demonstrate the cost effectiveness of their product as part of the reimbursement review and approval process. With this in mind, we are performing health economic evaluations to support this review in the context of the prospective use of Neutrolin in dialysis, the ICU and oncology settings. Our studies may not be sufficient to support coverage or reimbursement at levels that allow providers to use Neutrolin.

Competitive Landscape

The drug and medical device industries are highly competitive and subject to rapid and significant technological change. Neutrolin's current and future competitors include large as well as specialty pharmaceutical and biotechnology companies. Many of our competitors have substantially greater financial, technical and human resources than we do and significantly more experience in the development and commercialization of drugs and medical devices. Further, the development of new treatment methods could render Neutrolin non-competitive or obsolete.

We believe that the key competitive factors that will affect the development and commercial success of Neutrolin are efficacy and safety, as well as pricing and reimbursement. Given that there are no approved catheter lock solutions with anti-microbial properties in the U.S., and that the current standard of care is heparin, we believe there is an opportunity for Neutrolin to become the new standard of care in the U.S. market, if approved.

Drug:

To the best of our knowledge, the following product candidates have been recognized for the prevention and treatment of catheter-related blood stream infections in the U.S. or elsewhere.

- TauroLock, manufactured by Tauro-Implant (Winsen, Germany). TauroLock has received a CE Mark and is distributed in 25 countries. It has anti-microbial and anti-coagulant activity and contains a combination of citrate 4% with (cyclo)-taurolidine and heparin or urokinase. TauroLock has four formulations: TauroLock, Taurolock Heparin 100, TauroLock Heparin 500 and TauroLock Urokinase 25000 IU. None of these formulations is approved for use in the U.S.
- Zuragen by Ash Access Technology (Lafayette, IN), has antimicrobial and anticoagulant activity and contains methylene blue, parabens and 7% citrate. Clinicaltrials.gov most recently reported status as not yet recruiting subjects as of October 2014. As of February 2020, development status is listed as “unknown” in clinicaltrials.gov.
- B-Lock by Great Lakes Pharmaceuticals Inc. (Cleveland, OH). It has anti-microbial, anti-coagulant and anti-fungal activity and contains trimethoprim, EDTA and ethanol combinations. B-Lock initiated a study in 2012 in Poland and Hungary to support CE Mark in European Union. Clinicaltrials.gov reported the study as terminated for failure to meet primary endpoint in February 2017.
- DuraLock-C, manufactured by Medical Components, Inc. (Harleysville, PA). DuraLock-C received a CE Mark and is distributed in a number of European Union countries. It has anti-microbial and anti-thrombosis activity and contains trisodium citrate in 46.7%, 30% and 4% concentrations. No clinical update has been provided for this product on Clinicaltrials.gov since March 2008. This product has not been approved for use in the U.S. market.
- IntraLock, manufactured by Fresenius Medical Care AG & Co. (Bad Homburg, Germany). IntraLock received a CE Mark and is distributed in a number of European Union countries. It is an anticoagulant solution to prevent thrombus formation in catheters. IntraLock contains citrate (4%) for anticoagulation and a small amount of polyhexanide for preservation. This product has not been approved for use in the U.S. market.
- TauroSept, manufactured by Geistlich Pharma (Wolhusen, Switzerland). TauroSept received Class 3 CE Mark and is distributed in a number of European Union countries. TauroSept contains 2% taurolidine solution, 5% polyvinylpyrrolidone and traces of HCl and NaOH to adjust pH. It contains no anticoagulant substances. This product has not been approved for use in the U.S. market.
- Mino-Lok, being developed by Citius Pharmaceutical (Cranford, NJ). Mino-Lok is intended to salvage the central venous catheter obviating the need to remove and replace the catheter. Mino-Lok contains a proprietary combination of minocycline, edetate (disodium EDTA), and ethyl alcohol. This product is in Phase 3 development in the U.S.

Medical Devices:

- Tego® Needlefree Connector, manufactured by ICU Medical Inc. (San Clemente, CA). Tego Needlefree Connector received 510(k) clearance from the FDA. The Tego connector creates a mechanical and microbiology closed system when attached to the hub of the catheter and works with all hemodialysis central venous catheter, or CVC, related applications.
- Curos® (Luer-lock caps twist on, stay on) disinfecting port protectors designed specifically for Tego Needlefree Connectors, manufactured by Ivera Medical Corporation (San Diego, CA). Curos received 510(k) clearance from the FDA. Curos for Tego Needlefree Connectors contains 70% isopropyl alcohol-saturated, sponge-like foam that disinfects ports in three minutes and keeps ports clean for seven days.
- ClearGuard® HD End Caps for Hemodialysis Catheters, manufactured by Pursuit Vascular, Inc. (Maple Grove, MN). ClearGuard HD End Caps received 510(k) clearance from the FDA. The ClearGuard HD End Cap consists of (1) a copolyester polymer plug, which has a rod extending from the tier region that is coated with the antimicrobial agent chlorhexidine acetate (CHA) and (2) a nylon lock ring with threads that are also coated with CHA.
- BioFlo DuraMax Dialysis Catheter with Endexo Technology, manufactured by AngioDynamics (Latham, NY). The product received 510(k) clearance by the FDA. The BioFlo DuraMax chronic dialysis catheter features Endexo Technology, a catheter material more resistant to thrombus accumulation. Endexo technology is permanent, non-eluting polymer “blended” into the polyurethane from which the catheter is made.

Some device companies have launched antibiotic or antimicrobial-coated catheters as short-term prevention of catheter infection. We believe these are not effective for hemodialysis catheters due to the long-term use and high blood flow associated with hemodialysis.

Manufacturing/Supply Chain

We do not own or operate any manufacturing facilities related to the production of our products. All our manufacturing processes currently are, and we expect them to continue, to be outsourced to third parties. We rely on third-party manufacturers to produce sufficient quantities of drug product for use both commercially and in clinical trials. We intend to continue this practice in the future.

With regards to taurolidine, an active drug ingredient, or API, of Neutrolin, we have a Drug Master File filed with the FDA. There is a master commercial supply agreement between the third-party manufacturer, Alcami, and CorMedix in place from August 2018. We have three sources for the other key API, Heparin sodium.

We currently utilize two drug product contract manufacturer organizations, or CMO. One is for the EU and Middle East markets and the other for U.S. production. In order to assure supply, we are in the process of beginning to qualify a second CMO for U.S. vial production. All API and drug products are validated at commercial scale.

We are confident that these CMO's have adequate capacity to produce the volumes needed, and that there exists a sufficient number of potential alternate sources for the drug substances required to produce our products, as well as third-party manufacturers, that we will be able to find alternate suppliers and third-party manufacturers in the event that our relationship with any supplier or third-party manufacturer deteriorates.

United States Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. Our products may be classified by the FDA as a drug or a medical device depending upon the indications for use or claims. Because certain of our product candidates are considered as medical devices and others are considered as drugs for regulatory purposes, we intend to submit applications to regulatory agencies for approval or clearance of both medical devices and pharmaceutical product candidates.

In the United States, the FDA regulates drugs and medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA) and the agency's implementing regulations. If we fail to comply with the applicable United States requirements at any time during the product development process, clinical testing, and during the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution, among other actions. Any agency enforcement action and/or any related impact could have a material adverse effect on us.

Drug Approval Process

The research, development, and approval process in the United States and elsewhere is intensive and rigorous and generally takes many years to complete. The typical process required by the FDA before a therapeutic drug may be marketed in the United States includes:

- Pre-clinical laboratory and animal tests performed under the FDA's Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may commence;
- human clinical studies to evaluate the drug's safety and effectiveness for its intended uses;
- FDA review of whether the facility in which the drug is manufactured, processed, packaged, or held meets standards designed to assure the product's continued quality and FDA review of clinical trial sites to determine whether the clinical trials were conducted in accordance with Good Clinical Practices, or GCPs; and
- submission of a new drug application, or NDA, to the FDA, and approval of the application by the FDA to allow sales of the drug.

During pre-clinical testing, studies are performed with respect to the chemical and physical properties of candidate formulations. These studies are subject to GLP requirements. Biological testing is typically done in animal models to demonstrate the activity of the compound against the targeted disease or condition and to assess the apparent effects of the new product candidate on various organ systems, as well as its relative therapeutic effectiveness and safety. An IND application must be submitted to the FDA and become effective before studies in humans may commence.

Clinical trial programs in humans generally follow a three-phase process. Typically, Phase 1 studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease. Phase 1 studies are conducted to determine the metabolic and pharmacological action of the product candidate in humans and the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In Phase 2, studies are generally conducted in larger groups of patients having the target disease or condition in order to validate clinical endpoints, and to obtain preliminary data on the effectiveness of the product candidate and optimal dosing. This phase also helps determine further the safety profile of the product candidate. In Phase 3, large-scale clinical trials are generally conducted in patients having the target disease or condition to provide sufficient data for the statistical proof of effectiveness and safety of the product candidate as required by United States and foreign regulatory agencies. Typically, two Phase 3 trials are required for marketing approval.

In the case of products for certain serious or life-threatening diseases, the initial human testing may be done in patients with the disease rather than in healthy volunteers. Because these patients are already afflicted with the target disease or condition, it is possible that such studies will also provide results traditionally obtained in Phase 2 studies. These studies are often referred to as “Phase 1/2” studies. However, even if patients participate in initial human testing and a Phase 1/2 study is carried out, the sponsor is still responsible for obtaining all the data usually obtained in both Phase 1 and Phase 2 studies.

Before proceeding with a study, sponsors may seek a written agreement known as a Special Protocol Assessment, or SPA, from the FDA regarding the design, size, and conduct of a clinical trial. Among other things, SPAs can cover clinical studies for pivotal trials whose data will form the primary basis to establish a product’s efficacy. SPAs help establish up-front agreement with the FDA about the adequacy of a clinical trial design to support a regulatory approval, but the agreement is not binding on the FDA if new circumstances arise. An SPA may only be modified with the agreement of the FDA and the trial sponsor or if the director of the FDA reviewing division determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, and the continuing validity and scientific merit of the clinical trial. The data safety monitoring board receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determined there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy. The committee can also stop a clinical trial for an overwhelming demonstration of efficacy, based on pre-defined, stringent statistical parameters and ethical considerations.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to current Good Manufacturing Practice, or cGMP, requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

IND sponsors are required to submit a number of reports to the FDA during the course of a development program. For instance, sponsors are required to make annual reports to the FDA concerning the progress of their clinical trial programs as well as more frequent reports for certain serious adverse events. Sponsors must submit a protocol for each clinical trial, and any subsequent protocol amendments to the FDA. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their clinicaltrials.gov website. Moreover, under the 21st Century Cures Act, manufacturers or distributors of investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must have a publicly available policy concerning expanded access to investigational drugs.

United States law requires that studies conducted to support approval for product marketing be “adequate and well controlled.” In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. The recently passed 21st Century Cures Act, however, provides for FDA acceptance of new kinds of data such as patient experience data, real world evidence, and, for appropriate indications sought through supplemental marketing applications, data summaries. Studies must also be conducted in compliance with good clinical practice requirements, and informed consent must be obtained from all study subjects.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, to ensure that the benefits of the drug outweigh the risks of the drug. The REMS plan could include medication guides, physician communication plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. An assessment of the REMS must also be conducted at set intervals. Following product approval, a REMS may also be required by the FDA if new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks of the drug.

The clinical trial process for a new compound can take ten years or more to complete. The FDA may prevent clinical trials from beginning or may place clinical trials on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. Trials may also be prevented from beginning or may be terminated by institutional review boards, or IRBs, who must review and approve all research involving human subjects and amendments thereto. The IRB must continue to oversee the clinical trial while it is being conducted. This includes the IRB receiving information concerning unanticipated problems involving risk to subjects. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market.

Following the completion of a clinical trial, the data are analyzed by the sponsoring company to determine whether the trial successfully demonstrated safety and effectiveness and whether a product approval application may be submitted. In the United States, if the product is regulated as a new drug, an NDA must be submitted and approved by the FDA before commercial marketing may begin. The NDA must include a substantial amount of data and other information concerning the safety and effectiveness of the compound from laboratory, animal, and human clinical testing, as well as data and information on manufacturing, product quality and stability, and proposed product labeling.

Each domestic and foreign manufacturing establishment, including any contract manufacturers that we may decide to use, must be listed in the NDA and must be registered with the FDA. The application generally will not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug product, and determines that the facility is in compliance with current cGMP requirements. Moreover, FDA will also typically inspect one or more clinical trial sites to confirm that the applicable clinical trials were conducted in accordance with GCPs.

Under the Prescription Drug User Fee Act (PDUFA), as amended, the FDA assesses and receives application user fees for reviewing an NDA, as well as annual program fees for commercial manufacturing establishments and for approved products. These fees can be significant. Fee waivers, reductions or refunds are available in certain circumstances. One basis for a waiver or refund of the application user fee is if the applicant is a "small business" generally defined as employing fewer than 500 employees, including employees of affiliates, no approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application. Product candidates that are designated as orphan drugs, which are further described below, are also not subject to application user fees unless the application includes an indication other than the orphan indication. Under certain circumstances, orphan products may also be exempt from product and establishment fees.

Each NDA submitted for FDA approval is usually reviewed for administrative completeness and reviewability. Following this review, the FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

Once accepted for filing, the FDA's review of an application may involve review and recommendations by an independent FDA advisory committee. The FDA must refer applications for drugs that contain active ingredients, including any ester or salt of the active ingredients that have not previously been approved by the FDA to an advisory committee or provide in an action letter a summary for not referring it to an advisory committee. The FDA may also refer drugs to advisory committees when it is determined that an advisory committee's expertise would be beneficial to the regulatory decision-making process, including the evaluation of novel products and the use of new technology. An advisory committee is typically a panel that includes clinicians and other experts, which review, evaluate, and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter, or CRL. If a CRL is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval and describes all the specific deficiencies that the FDA identified in the NDA. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or pre-clinical testing in order for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes; or major, for example, requiring additional clinical trials. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS or otherwise limit the scope of any approval.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including Fast Track designation, priority review and breakthrough designation, that are intended to expedite or simplify the process for the development and FDA review of certain drug products that are intended for the treatment of serious or life threatening diseases or conditions, and demonstrate the potential to address unmet medical needs or present a significant improvement over existing therapy. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if the product will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy, safety, or public health factors. If Fast Track designation is obtained, drug sponsors may be eligible for more frequent development meetings and correspondence with the FDA. In addition, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. A Fast Track product is also eligible to apply for accelerated approval and priority review.

The FDA may give a priority review designation to drugs that are intended to treat serious conditions and, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. A priority review means that the goal for the FDA is to review an application within six months, rather than the standard review of ten months under current PDUFA guidelines, of the 60-day filing date for new molecular entities.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are eligible for the Fast Track designation features as described above, intensive guidance on an efficient drug development program beginning as early as Phase 1 trials, and a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative, cross-disciplinary review.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

A final new program to expedite the development of drug products is the LPAD, which was passed as part of the 21 st Century Cures Act. LPAD allows for the FDA's determination of safety and effectiveness to reflect the risk-benefit profile of the drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection and the availability of alternative treatments in the limited population. Under LPAD, a sponsor may request drug approval for an antibacterial or antifungal drug if the drug is intended to treat a serious life-threatening infection in a limited population of patients with unmet needs. The drug may be approved for the limited population notwithstanding a lack of evidence to fully establish a favorable benefit-risk profile in a broader population. The FDA must provide prompt advice to sponsors seeking approval under LPAD to enable them to plan a development program. If approved under LPAD, certain post-marketing requirements would apply, such as required labeling and advertising statements and pre-distribution submission of promotional materials to FDA. If after approval for a limited population, a product receives a broader approval, the FDA may remove such post-marketing restrictions. While a drug may only be approved for a limited population under this program, the 21st Century Cures Act states that it is not intended to restrict the prescribing of antimicrobial drugs or other products by healthcare professionals.

Exclusivity

For approved drug products, market exclusivity provisions under the FDCA provide periods of regulatory exclusivity, which gives the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug.

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application in which the applicant, in part, relies on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics, and intended use, among other things, to a previously approved product. Limited changes must be pre-approved by the FDA via a suitability petition.

Five years of exclusivity are available to New Chemical Entities, or NCEs. A NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule, that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent derivatives, such as a complex, chelate, or clathrate, of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review and make an ANDA or a 505(b)(2) NDA approval effective for an application submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if the applicant submits a certification stating that the patents listed by the NCE sponsor in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book, are invalid or will not be infringed by the manufacture, use, or sale of the drug product for which approval is sought. Five-year exclusivity will also not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity period described above. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the required time frames, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection cover the drug are extended by six months. Moreover, pediatric exclusivity attaches to all formulations, dosage forms, and indications for products with existing marketing exclusivity or patent life that contain the same active moiety as that which was studied.

The Orphan Drug Act also provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting fewer than 200,000 individuals annually in the United States, or affecting more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making the drug available in the United States will be recovered from sales in the United States. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan designation if there is a drug already approved by the FDA that is intended for the same indication and that is considered by the FDA to be the same drug as the already approved drug. This hypothesis must be demonstrated to obtain orphan drug exclusivity. If granted, prior to product approval, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers. In addition, if a product receives FDA approval for the indication for which it has orphan designation, the product is generally entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

For certain infectious disease products, the above discussed exclusivity periods may be further extended under the FDA's qualified infectious disease product program. A qualified infectious disease product, or QIDP, is an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or qualifying pathogens designated by the FDA that have the potential to pose a serious threat to public health. Subject to the specified statutory limitations, a drug that is designated as a QIDP and is approved for the use for which the QIDP designation was granted will receive a 5-year extension to any exclusivity for which the application qualifies upon approval. For example, if the FDA approves an NDA for a drug designated as a QIDP, the NCE exclusivity period is extended to ten years and the FDA may not accept applications for nine years. Moreover, if a product is designated as a QIDP and an orphan product, the orphan product exclusivity period is extended to twelve years. These extensions are in addition to any extension that an application may be entitled to under the pediatric exclusivity provisions. To receive a QIDP designation, the sponsor must request that the FDA designate the product as such prior to the submission of an NDA. This designation may not be withdrawn except if the FDA finds that the request for designation contained an untrue statement of material fact. QIDPs are also eligible for fast track status and priority review.

Post Approval Requirements

Significant legal and regulatory requirements also apply after FDA approval to market under an NDA. These include, among other things, requirements related to adverse event and other reporting, product tracking and tracing, suspect and illegitimate product investigations and notifications, product advertising and promotion and ongoing adherence to cGMPs, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. The FDA also enforces the requirements of the Prescription Drug Marketing Act which, among other things, imposes various requirements in connection with the distribution of product samples to physicians. The FDA enforces these requirements through, among other ways, periodic announced and unannounced facility inspections.

The FDA also strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product's labeling and that differ from those tested and approved by the FDA. Pharmaceutical companies, however, are allowed to promote their drug products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including, but not limited to, criminal and civil penalties under the FDCA and the civil False Claims Act, or FCA, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment, and refusal of government contracts.

The regulatory framework applicable to the production, distribution, marketing, and/or sale, of our product candidates may change significantly from the current descriptions provided herein in the time that it may take for any of our product candidates to reach a point at which a NDA is approved. Moreover, individual states may have laws and regulations that we must comply with, such as laws and regulations concerning licensing, promotion, sampling, distribution, and reporting.

Overall research, development, and approval times depend on a number of factors, including the period of review at the FDA, the number of questions posed by the FDA during review, how long it takes to respond to the FDA's questions, the severity or life-threatening nature of the disease in question, the availability of alternative treatments, the availability of clinical investigators and eligible patients, the rate of enrollment of patients in clinical trials, and the risks and benefits demonstrated in the clinical trials.

Medical Device Approval Process

In addition to our lead product candidate Neutrolin, which is subject to regulation by the FDA as a drug, we may be developing other products that may be regulated as medical devices in the United States. The FDA considers a product to be a device, and subject to the FDA regulation, if it meets the definition of a medical device in the FDCA, which states that a device is an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

The FDA regulates the design, development, clinical testing, manufacture, labeling, distribution, import and export, sale and promotion of medical devices. Unless an exemption applies or a product is a Class I device, all medical devices must receive either 510(k) clearance or an approved pre-market application (PMA), from the FDA before they may be commercially distributed in the U.S. In addition, certain modifications made to marketed devices also may require 510(k) clearance or approval of a PMA supplement. Unlike approved drug products, there are no market exclusivity provisions under the FDCA for products regulated as medical devices.

To obtain a 510(k) clearance for a device, a pre-market notification to the FDA must be submitted demonstrating that the device is substantially equivalent to a legally marketed predicate device. For a new device to be found “substantially equivalent” to one or other legally marketed predicate devices, the new device must have: 1) the same intended use as a predicate; and 2) either a) the same technological characteristics as the predicate device or b) different technological characteristics, but the information submitted must not raise new questions of safety and effectiveness and must demonstrate substantial equivalence. The FDA attempts to respond to a 510(k) pre-market notification within 90 days of submission, but as a practical matter, pre-market clearance can take significantly longer, potentially up to one year or more.

The PMA process is much more demanding and uncertain than the 510(k) pre-market notification process and must be supported by extensive clinical, laboratory, technical and other information, including at least one adequate and well-controlled clinical investigation conducted under an investigational device exemption (IDE). The FDA has 180 days to review an accepted PMA, although the review generally occurs over a significantly longer period of time and can take up to several years.

The FDA has informed us that it regards taurolidine as a new chemical entity and therefore an unapproved new drug. Consequently, for any other products that we intend to develop as a medical device, there is currently no appropriate predicate device currently marketed in the U.S. on which a 510(k) approval process could be based. As a result, we will be required to submit a premarket approval application for marketing authorization for these indications. In the event that the NDA for Neutrolin is approved by the FDA, the regulatory pathway for these taurolidine product candidates can be revisited with the FDA. Although there will presumably still be no appropriate predicate, *de novo* Class II designation can be proposed, a process that provides a pathway to classify novel medical device for which there is no legally marketed predicate device, based on a risk assessment and a reasonable assurance of safety and effectiveness.

After a device is placed on the market, numerous regulatory requirements apply, including:

- Quality System Regulations, or QSRs, which require manufacturers to have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices;
- labeling regulations, which govern product labels and labeling, prohibit the promotion of products for unapproved, or off-label, uses and impose other restrictions on labeling and promotional activities;
- medical device listing and establishment registration;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance requirements;
- medical device reporting, or MDR, regulations, which require that manufacturers evaluate and investigate potential adverse events and malfunctions, and report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- regulations requiring the reporting of any device corrections or removals if the correction or removal was initiated to reduce a risk to health posed by the device or remedy a violation of the FDCA which may present a risk to health; and
- the FDA’s recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is a risk to health.

Our manufacturing facilities, as well as those of certain of our suppliers, are subject to periodic and for-cause inspections by the FDA and other governmental authorities to verify compliance with the QSR and other regulatory requirements.

Reimbursement and Pricing Controls

In many of the markets where we or the parties we collaborate with have targeted or will target Neutrolin for sale, laws control the prices charged to certain purchasers of pharmaceutical products and the prices paid by drug reimbursement programs through varying price control mechanisms. Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating rebates with the manufacturers, limiting the reimbursement rate paid to providers, and using tiered formularies, co-payment structures that incentivize beneficiaries to request lower cost alternatives, and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Federal and commercial payors use competition for health plan coverage and market share as leverage to obtain rebates on products they reimburse, which impacts the manufacturer's net realization on the sale of the products. These rebates may be paid on drugs sold at a mandatory discount. Additionally, federal and commercial health plans may choose to reimburse dialysis providers for dialysis services and drugs used in the provision of those services through a single bundled payment rate, which tends to make cost a more important factor for providers when making drug purchase decisions than it would otherwise be if the providers were reimbursed for drugs on a stand-alone basis. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA.

Foreign Regulatory Requirements

We and our collaborative partners may be subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, manufacture, product registration and approval, and pharmaceutical sales. Whether or not FDA approval has been obtained, we or our collaboration partners must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in those countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current United States law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. to take advantage of differing regulatory requirements. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

In the European Union, in order for our product candidates to be marketed and sold, we are required to comply with the Medical Devices Directive and obtain CE Mark certification. The CE Mark certification encompasses an extensive review of our quality management system which is inspected by a notified body's auditor as part of a Stage 1 and 2 International Organization for Standardization, or ISO, 13485:2003 audit, in accordance with worldwide recognized ISO standards and applicable European Medical Devices Directives for quality management systems for medical device manufacturers. Once the quality management system and design dossier has been successfully audited by a notified body and reviewed and approved by a competent authority, a CE certificate for the medical device will be issued. We are also required to comply with other foreign regulations such as the requirement that we obtain Ministry of Health, Labor and Welfare approval before we can launch new products in Japan. The time required to obtain these foreign approvals to market our products may vary from U.S. approvals, and requirements for these approvals may differ from those required by the FDA.

Medical device laws and regulations are in effect in many of the countries in which we may do business outside the United States. These laws and regulations range from comprehensive device approval requirements for our medical device product to requests for product data or certifications. The number and scope of these requirements can be complex and could increase. We may not be able to obtain or maintain regulatory approvals in such countries and we may be required to incur significant costs in obtaining or maintaining our foreign regulatory approvals. In addition, the export of certain of our products which have not yet been cleared for domestic commercial distribution may be subject to FDA export restrictions. Any failure to obtain product approvals in a timely fashion or to comply with state or foreign medical device laws and regulations may have a serious adverse effect on our business, financial condition or results of operations.

Intellectual Property

On January 30, 2008, we entered into a License and Assignment Agreement, or the NDP License Agreement, with ND Partners, LLC, or NDP. Pursuant to the NDP License Agreement, NDP granted us exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the "NDP Technology"). We acquired such licenses and patents through our assignment and assumption of NDP's rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann, and Dr. Johannes Reinmueller. NDP also granted us exclusive licenses, with the right to grant sublicenses, to use and display certain trademarks in connection with the NDP Technology. As consideration in part for the rights to the NDP Technology, we paid NDP an initial licensing fee of $325,000 and granted NDP an equity interest in our company consisting of 73,107 shares of common stock as of December 31, 2010. In addition, we are required to make payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The maximum aggregate number of shares issuable upon achievement of milestones and the number of shares held in escrow is 29,109 shares of common stock. The maximum aggregate amount of cash payments upon achievement of milestones is $3,000,000 with $2,500,000 remaining at December 31, 2019. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval processes and certain worldwide net sales amounts.

On April 11, 2013, we entered into an amendment to the NDP License Agreement. Under Article 6 of the NDP License Agreement, we were obligated to make a milestone payment of $500,000 to NDP upon the first issuance of a CE Mark for a licensed product, which payment was payable to NDP within 30 days after such issuance. Pursuant to the terms of the amendment, we and NDP agreed to delay such milestone payment to a time, to be chosen by us, anytime within twelve months after the achievement of such issuance. As consideration for the amendment, we issued NDP a warrant to purchase 25,000 shares of our common stock at an exercise price of $7.50 per share. The warrant was exercisable immediately upon issuance and had a term of five years and expired in April 2018.

During the year ended December 31, 2013, a milestone payment of $500,000 was earned by NDP upon the first issuance of the CE Mark for Neutrolin, which was converted in January 2014 into 10,000 Series C-3 non-voting preferred stock and 50,000 warrants at an exercise price of $7.50 per share. During the year ended December 31, 2014, a certain milestone was achieved resulting in the release of 7,277 shares held in escrow. The number of shares held in escrow as of December 31, 2019 is 21,832 shares of common stock. There were no milestones achieved in 2019 or 2018.

The NDP License Agreement will expire on a country-by-country basis upon the earlier of (i) the expiration of the last patent claim under the NDP License Agreement in a given country, or (ii) the payment of all milestone payments and release of all shares of our common stock held in escrow under the NDP License Agreement. Upon the expiration of the NDP License Agreement in each country, we will have an irrevocable, perpetual, fully paid-up, royalty-free exclusive license to the NDP Technology in such country. The NDP License Agreement also may be terminated by NDP if we materially breach or default under the NDP License Agreement and that breach is not cured within 60 days following the delivery of written notice to us, or by us on a country-by-country basis upon 60 days prior written notice. If the NDP License Agreement is terminated by either party, our rights to the NDP Technology will revert back to NDP.

We believe that the patents and patent applications we have licensed pursuant to the NDP License Agreement cover effective solutions to the various medical problems discussed previously when using taurolidine in clinical applications, and specifically in hemodialysis applications. Our patent portfolio consists of 7 issued U.S. patents and 17 pending U.S. patent applications; 13 issued foreign patents and 46 pending foreign patent applications. Additional patent applications will be filed to cover any additional related subject matter developed. The patents cover additional applications using taurolidine in, among others, sutures, hydrogels, meshes, transdermal and biofilm products.

Employees

As of March 12, 2020, we had 30 full time employees, including our customer service representative and office manager in Germany. We also engage various consultants and contractors for project management and research and development, manufacturing and regulatory development, marketing, financing, sales and marketing and administrative activities.

Corporate Information

We were organized as a Delaware corporation on July 28, 2006 under the name "Picton Holding Company, Inc." and we changed our corporate name to "CorMedix Inc." on January 18, 2007. Our principal executive offices are located at 400 Connell Drive, Suite 5000, Berkeley Heights, New Jersey 07922. Our telephone number is (908) 517-9500.

On March 26, 2019, we effected a 1-for-5 reverse stock split of our issued and outstanding shares of common stock, par value $0.001, per share ("Common Stock"), by combining, reclassifying and changing each authorized and outstanding five shares of "old" common stock into one share of "new" common stock. No fractional shares were issued, and, in lieu thereof, where applicable, one whole share was issued. To reflect the reverse stock split, reclassification, combination and change, proportional adjustments were also made to the number of shares of our common stock issuable upon conversion of outstanding preferred shares and the convertible note payable, warrants and options and other equity awards. The reverse stock split did not affect the par value per share of our common stock (which remains at $0.001 per share) or the total number of shares of common stock that are authorized to be issued pursuant to our Amended and Restated Certificate of Incorporation, as amended, which remains at 160 million shares. All issued and outstanding share and per share amounts included in the accompanying consolidated financial statements and in this report have been adjusted to reflect the reverse stock split, reclassification, combination and change for all periods presented.

In April 2019, we received approximately $5.1 million, net of expenses, from the sale of a portion of our unused net operating losses, or NOL. The NOL was sold through the State of New Jersey's Economic Development Authority, or NJEDA, Technology Business Tax Certificate Transfer program, which allowed us to sell approximately $5.4 million of our total $6.1 million in available NOL tax benefits for the state fiscal year 2018 to two unrelated, profitable New Jersey corporations.

In February 2020, we announced that we were approved by the NJEDA to transfer approximately $5.5 million of the total $6.0 million of our available tax benefits to an unrelated, profitable New Jersey corporation pursuant to our application to participate in the NOL program for state fiscal year 2019. We anticipate receiving approximately $5.2 million in cash proceeds from the sale of our NOLs before the final expiration date. Closing is subject to NJEDA's typical closing conditions, which are in process.

On August 14, 2019, we entered into an exchange agreement (the "Exchange Agreement") with Manchester Securities Corp. ("Manchester"), a wholly owned subsidiary of Elliott Associates, L.P. (together with Manchester, "Elliott"), who collectively beneficially own the largest portion of our common stock pursuant to which Elliott agreed to exchange all of its outstanding warrants, its 10% senior secured convertible note and its shares of Series C-2 Preferred Stock, Series D Preferred Stock and Series F Preferred Stock, and make a cash payment of $2.0 million to us, for 100,000 shares of Series G Preferred Stock.

On September 25, 2019, we entered into a letter agreement with several holders, each referred to as a Holder, of several Series B Warrants, that we had issued on May 3, 2017, and amended on September 20, 2019, referred to as a Letter Agreement. Pursuant to each Letter Agreement, we agreed to reduce the exercise price of each Holder's Series B Warrants from $5.25 to $4.00, provided that the Holder exercised its Series B Warrants for cash at the time of entry into such Letter Agreement. Each Holder exercised its Series B Warrants in full and we issued an aggregate of 1,224,263 shares of our common stock to them. We received net proceeds of approximately $4.9 million. As a result of the modification of the exercise price of these warrants, we recognized a deemed dividend of $369,500 on our consolidated statement of operations and comprehensive loss (see Note 8).

We maintain a website at www.cormedix.com; however, the information on, or that can be accessed through, our website or certain information in our website is not part of this report. This report and all of our filings under the Exchange Act, including copies of annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, are available free of charge through our website on the date we file those materials with, or furnish them to, the Securities and Exchange Commission (the "SEC"). Such filings are also available to the public on the internet at the SEC's website at www.sec.gov. The public may also read and copy any document that we file at the SEC's Public Reference Room located at 100 F Street, NE, Washington, DC 20549 on official business days during the hours of 10 a.m. to 3 p.m. For further information on the Public Reference Room, the public is instructed to call the SEC at 1-800-SEC-0300.

Item 1A. Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital

We have a history of operating losses, expect to incur additional operating losses in the future and may never be profitable.

Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in the early stages of operation. We incurred net losses of approximately $16.4 million and $26.8 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of approximately $195.4 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trial and commercialization activities increase as we develop and commercialize Neutrolin and our other product candidates. As a result, we expect to experience negative cash flow as we fund our operating losses and capital expenditures. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Neutrolin was launched in December 2013 and is currently available for distribution in certain European Union and Middle East countries. We have not generated any significant commercial revenue and do not expect to generate substantial revenues from Neutrolin unless and until it is approved by the United States Food and Drug Administration ("FDA") and launched in the United States ("U.S.") market, and we might never generate significant revenues from the sale of Neutrolin or any other products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following: obtaining FDA approval of Neutrolin for the prevention of catheter-related bloodstream infections ("CRBSIs") in patients with end-stage renal disease receiving hemodialysis through a central venous catheter; successfully launching and marketing Neutrolin in the U.S., if approved by the FDA; successfully marketing Neutrolin in foreign countries in which it is approved for sale; obtaining necessary regulatory approvals for our other product candidates from the FDA and, if sought, international regulatory agencies; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

Our cost of operations could increase significantly more than what we expect depending on the costs to complete our development program for Neutrolin.

Our operations are subject to a number of factors that can affect our operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of our product candidates; the ability to obtain regulatory approval to market our products; ability to manufacture successfully; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, our products; our ability to negotiate favorable licensing or other manufacturing and marketing agreements for our products; and our ability to raise capital to support our operations.

To date, our commercial operations have not generated sufficient revenues to enable profitability. As of December 31, 2019, we had an accumulated deficit of $195.4 million, and incurred net losses of $16.4 million for the year then ended. Based on the current development plans for Neutrolin in both the U.S. and foreign markets (including the concluded hemodialysis Phase 3 clinical trial in the U.S.) and our other operating requirements, management believes that the existing cash at December 31, 2019 plus funding raised through March 12, 2020, will be sufficient to fund operations into the second quarter of 2021. We will need additional funding for a second Phase 3 clinical trial, if required by the FDA, and funding for the commercialization of Neutrolin upon FDA approval.

Our continued operations will ultimately depend on our ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, potential strategic transactions or out-licensing of our products in order to complete the development of Neutrolin and until we achieve profitability, if ever. We can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. Without this funding, we could be required to delay, scale back or eliminate some or all of our research and development programs which would likely have a material adverse effect on our business.

We will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Any additional funds that we obtain may not be on terms favorable to us or our stockholders and may require us to relinquish valuable rights.

We have launched Neutrolin in certain European Union and Middle East countries, but to date have no other approved product on the market and have not generated significant product revenue from Neutrolin to date. Unless and until we receive applicable regulatory approval for Neutrolin in the U.S., we cannot sell Neutrolin in the U.S. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from Neutrolin sales in Europe and other foreign markets, if approved, cash on hand, additional financings, licensing fees and grants.

We believe that our cash resources as of December 31, 2019 plus funding raised through March 12, 2020 will be sufficient to fund operations into the second quarter of 2021. Nevertheless, we may need to raise additional funds through financings or strategic relationships if our costs exceed our expectations, as well as funds for our operations beyond the first quarter of 2021. We can provide no assurances that any financing or strategic relationships will be available to us on acceptable terms, or at all. We expect to continue to use significant cash to fund our operations as we seek FDA approval of Neutrolin in the U.S., commercialize Neutrolin in Europe and other markets, pursue development of our medical devices and other business development activities, and incur additional legal costs to defend our intellectual property.

To raise needed capital, we may sell additional equity or debt securities, obtain a bank credit facility, or enter into a corporate collaboration or licensing arrangement. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in fixed obligations and could also result in covenants that would restrict our operations. Raising additional funds through collaboration or licensing arrangements with third parties may require us to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders.

Risks Related to the Development and Commercialization of Our Product Candidates

Neutrolin®, our lead product candidate, has received Fast Track designation and Qualified Infectious Disease Product designation from FDA, but we cannot provide assurances that these designations will not be rescinded.

Neutrolin is being developed as a catheter lock solution for the prevention of CRBSIs in patients with end-stage renal disease receiving hemodialysis through a central venous catheter. FDA has determined that Neutrolin will be regulated as a New Drug, because it contains the new chemical entity taurolidine as a novel antimicrobial agent. After we filed the Investigational New Drug Application ("IND"), FDA granted designations as Fast Track and a Qualified Infectious Disease Product ("QIDP") in January 2015. Fast Track is designed to facilitate development of a drug that is intended to treat a serious or life-threatening condition and address an unmet medical need. Fast Track confers eligibility to request priority review of an NDA, with FDA's decision regarding potential priority review to be made after receipt of a complete application. QIDP was established pursuant to the Generating Antibiotic Incentives Now ("GAIN") Act and creates incentives for the development of antibacterial and antifungal drug products that treat serious or life-threatening infections. Subject to the specified statutory limitations, a drug that is designated as QIDP and is approved for the use for which the QIDP designation was granted will receive a 5-year extension to any exclusivity for which the application qualifies upon approval, such as the 5 year exclusivity for a new chemical entity. We cannot provide assurances that Neutrolin will retain these designations and continue to receive the benefits conferred, or that it will receive priority review. If we do not receive priority review, we would be subject to the standard FDA review goal of ten months.

If the FDA requires a second clinical trial for Neutrolin to approve the New Drug Application, the development of Neutrolin will take longer and cost more to complete and we will need significant additional funds to undertake a second trial.

Although two pivotal clinical trials to demonstrate safety and effectiveness of Neutrolin are generally required by the FDA to secure marketing approval in the U.S., FDA will in some cases accept one adequate and well-controlled trial, where it is a large multicenter trial with a broad range of subjects and investigation sites with procedures to include trial quality that has demonstrated a clinically meaningful and statistically very persuasive effect on prevention of a disease with potentially serious outcome.

In light of the interim and full analysis results, and the Data Safety Monitoring Board ("DSMB") recommendation, we have discussed with the FDA the appropriate next steps for the development of Neutrolin based on the results of our Phase 3 clinical trial, LOCK-IT-100. We plan to proceed with submission of the NDA for Neutrolin based on the results of LOCK-IT-100. Whether data from LOCK-IT-100 are sufficient will be a review issue with the FDA.

FDA has granted our request for rolling submission and review of the NDA for Neutrolin® as a catheter lock solution for the prevention of CRBSIs in patients with end stage renal disease receiving hemodialysis through a central venous catheter. We also may elect to request review of the NDA pursuant to the Limited Population Pathway for Antibacterial and Antifungal Drugs ("LPAD") pathway, in addition to the standard approval process. LPAD, passed as part of the 21st Century Cures Act, is a new program intended to expedite the development and approval of certain antibacterial and antifungal drugs which meet three criteria: intended to treat serious or life-threatening infections; in limited populations of patients; and with unmet needs. The LPAD pathway provides for a streamlined clinical development program for a limited population that may involve smaller, shorter or fewer clinical trials. Even if an applicant requests for review pursuant to the LPAD pathway, such a review is not guaranteed. FDA has the flexibility to grant full approval of a drug regardless of a request for review under LPAD. Approval under the LPAD pathway is for a limited population, and if we were to obtain approval under this pathway it would be for the limited population of patients with end stage renal disease receiving hemodialysis through a central venous catheter, which is the intended indication for use. Labeling of an LPAD approved product will specify the use in the limited population. FDA could deny the request for consideration under LPAD and require additional information or studies to be collected prior to a drug approval, as LPAD is not a substitution for demonstrating the safety and effectiveness of a drug as required under the Sections 505(c) and (d) of the Federal Food D&C Act. We can provide no assurances that the FDA will not require a second clinical trial prior to approving the NDA for Neutrolin. Were the FDA to require a second clinical trial, the clinical development program for Neutrolin will be more expensive and will take longer to complete. We may need to raise significant additional funds to undertake and complete a second trial. Whether or not and how quickly we complete a second Phase 3 clinical trial would be dependent in part upon the size and scope of the trial, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze the clinical trial database. For example, to facilitate expanding the label, we may choose to pursue a clinical trial in a different catheter population, such as oncology or total parenteral nutrition. We could be required to incur additional costs and extend the anticipated time for completion of the trial. If we experience issues related to the clinical trial results, we may incur additional costs and delays in the trial, and may not be able to complete the clinical trial in a cost-effective or timely manner, which would have an adverse effect on our development program for Neutrolin® as a treatment for catheter-related bloodstream infections.

Our only product Neutrolin is only approved in Europe and is still in development in the United States.

Neutrolin currently and for at least the near future is our only current product as well as product candidate. Neutrolin has received CE Mark approval in Europe, and we started sales in Germany in December 2013. We also are pursuing development of Neutrolin in the U.S. Our product commercialization and development efforts may not lead to commercially viable products for any of several reasons. For example, our product candidates may fail to be proven safe and effective in clinical trials, or we may have inadequate financial or other resources to pursue development efforts for our product candidates. Even if approved, our product may not be accepted in the marketplace. Neutrolin will require significant additional development, including the preparation and filing of an NDA, possibly a second clinical trial, and/or investment by us or our collaborators as we continue its commercialization, as will any other product candidates.

In April 2017, we entered into a commercial collaboration with Hemotech SAS covering France and certain overseas territories. We have entered into agreements with a Saudi Arabian company to market and sell Neutrolin in Saudi Arabia, and with a South Korean company to market, sell and distribute Neutrolin in South Korea upon receipt of regulatory approval in that country. We also have commercial sales in Germany and a distributor agreement for the United Arab Emirates. Consequently, we will be dependent on these companies and individuals for the success of sales in those countries and any other countries in which we receive regulatory approval and in which we contract with third parties for the marketing, sale and/or distribution of Neutrolin. If these companies or individuals do not perform for whatever reason, our business, prospects and results of operations will be adversely affected. Finding a suitable replacement organization or individual for these or any other companies or individuals with whom we might contract could be difficult, which would further harm our business, prospects and results of operations. The negotiation and consummation of collaboration agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well as the collaborators' own internal product opportunities. We may not be able to consummate collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements

Successful development and commercialization of our products is uncertain.

Our development and commercialization of current and future product candidates is subject to the risks of failure and delay inherent in the development of new pharmaceutical products, including but not limited to the following:

- inability to produce positive data in pre-clinical and clinical trials;
- delays in product development, pre-clinical and clinical testing, or manufacturing;
- unplanned expenditures in product development, clinical testing, or manufacturing;
- challenges with securing the heparin supply chain;
- uncertainties relating to, or changes in FDA view of, the appropriate product approval pathway;
- failure to obtain treatment of a drug or application under expedited development and review programs or to obtain marketing exclusivities;
- failure to receive or maintain regulatory approvals;
- emergence of superior or equivalent products;
- inability to manufacture our product candidates on a commercial scale on our own, or in collaboration with third parties;
- failure to comply with a broad range of post-marketing requirements including those related to labeling, promotion and advertising, manufacturing and quality, pharmacovigilance and adverse event reporting, commercial distribution and supply chain requirements, and drug sample distribution requirements; and
- failure to achieve market acceptance.

Because of these risks, our development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained or any approved products are not commercialized successfully, our business, financial condition, and results of operations will be materially harmed.

Final approval by regulatory authorities of our product candidates for commercial use may be delayed, limited or prevented, any of which would adversely affect our ability to generate operating revenues.

Our ability to generate operating revenue will be severely limited until we, a licensee, or a potential collaborator successfully commercializes Neutrolin in the United States. We may need to successfully complete additional clinical trials and obtain regulatory approval before potential commercialization. We may experience unforeseen events during product development that may substantially delay or prevent product approval. For example, were the FDA to require a second clinical trial for our product candidate Neutrolin, in the course of our conduct of such a study, the FDA could order the temporary, or permanent, discontinuation of a clinical trial at any time if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An Institutional Review Board ("IRB") may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to clinical trial patients. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to clinical trial patients, a lack of favorable results, or changing business priorities.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, export, marketing, promotion and distribution, and other possible activities relating to our product candidates are subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions that may negatively impact the approval of one or more of our product candidates or otherwise negatively impact our business. Compliance with such regulations may consume substantial financial and management resources and expose us and our collaborators to the potential for other adverse circumstances. For example, a regulatory authority can place restrictions on the sale or marketing of a drug in order to manage the risks identified during initial clinical trials or after the drug is on the market. A regulatory authority can condition the approval for a drug on costly post-marketing follow-up studies. Based on these studies, if a regulatory authority does not believe that the drug demonstrates a clinical benefit to patients or an acceptable safety profile, it could limit the indications for which a drug may be sold or revoke the drug's marketing approval. In addition, identification of certain side effects either during clinical trials or after a drug is on the market may result in reformulation of a drug, additional pre-clinical and clinical trials, labeling changes, termination of ongoing clinical trials or withdrawal of approval. Any of these events could delay or prevent us from generating revenue from the commercialization of these drugs and cause us to incur significant additional costs.

Neither collaborators, licensees nor we are permitted to market a product candidate in the United States until the particular product candidate is approved for marketing by the FDA. Specific pre-clinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an IND application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and pre-clinical data, as well as extensive information regarding chemistry, manufacturing and controls, to demonstrate the safety and effectiveness of the product candidate, and the FDA will also assess whether the manufacturing processes and facilities are suitable to support the application.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. Despite our grants of Fast Track status, QIDP status, and rolling review of the NDA, these do not provide a guarantee that our application will receive an expedited review. Review time can be impacted by the quality of the information included in the application, FDA's internal resources such as the availability of reviewers, or requests from the FDA for additional information. Regulatory approval of an NDA is not guaranteed. The number and types of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense exerted in pre-clinical and clinical studies, failure can occur at any stage, and we could encounter problems that delay our product candidate development or that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The FDA can delay, limit or deny approval of a product candidate for many reasons, and product candidate development programs may be delayed or may not be successful for many reasons including but not limited to, the following:

- The FDA or IRBs may not authorize us to commence, amend, or continue clinical studies;
- we may not be able to enroll a sufficient number of qualified patients for clinical trials in a timely manner or at all, patients may drop out of our clinical trials or be lost to follow-up at a higher rate than we anticipate, patients may not follow the clinical trial procedures, or the number of patients required for clinical trials may be larger than we anticipate;
- the FDA may not accept an NDA or other submission due to, among other reasons, the content or formatting of the submission;
- a product candidate may not be deemed adequately safe or effective for an intended use;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient;
- the FDA may require that we conduct additional pre-clinical or clinical studies, change our manufacturing process, or gather additional manufacturing information above what we currently have planned for;
- the FDA's interpretation and our interpretation of data from pre-clinical studies and clinical trials or chemistry, manufacturing and controls data may differ significantly;
- the FDA may not agree with our intended indications, the design of our clinical or pre-clinical studies, or there may be a flaw in the design that does not become apparent until the studies are well advanced;
- we may not be able to establish agreements with contractors or collaborators or they or we may fail to comply with applicable FDA and other regulatory requirements, including those identified in other risk factors;
- the FDA may not accept aspects of our proposed labeling, or may impose specific limitations in the labeling and require post-marking commitments or Phase 4 clinical trials before the labeling can be expanded;
- the FDA may determine that the manufacturing processes and facilities for our product candidate do not have sufficient good manufacturing practice (GMP) controls in place to support approval; or
- the FDA may change its approval policies or adopt new regulations.

Our pre-clinical and clinical data, other information and procedures relating to a product candidate may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. Failure to conduct required post-approval studies, or confirm a clinical benefit, will allow the FDA to withdraw the drug from the market on an expedited basis. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our product candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

Additionally, other factors may serve to delay, limit or prevent the final approval by regulatory authorities of our product candidates for commercial use, including, but not limited to:

- we or our licensees will need to conduct significant clinical testing and development work to demonstrate the quality, safety, and efficacy of these product candidates before applications for marketing can be filed with the FDA, or with the regulatory authorities of other countries;
- development and testing of product formulation, including identification of suitable excipients, or chemical additives intended to facilitate delivery of our product candidates;
- it may take us many years to complete the testing of our product candidates, and failure can occur at any stage of this process; and
- negative or inconclusive results or adverse medical events during a clinical trial could cause us to delay or terminate our development efforts.

The successful development of any of these product candidates is uncertain and, accordingly, we may never commercialize any of these product candidates or generate significant revenue.

Changes in funding for the FDA and other government agencies or future government shutdowns or disruptions could cause delays in the submission and regulatory review of marketing applications, which could negatively impact our business or prospects.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept submission, applications, and the payment of user fees, and statutory, regulatory, and policy changes. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. The impact of global events, including terrorism, natural disasters and pandemics or other health emergencies, may also cause disruptions in the normal functioning of the FDA or other government agencies.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, had to furlough critical FDA employees and stop critical activities. In addition, in March 2020, the FDA announced the postponement of most foreign inspections due to the global impact of COVID-19. If a prolonged government shutdown or other disruption to the normal functioning of government agencies occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business or prospects.

Clinical trials required for our product candidates may be expensive and time-consuming, and their outcome is uncertain.

In order to obtain FDA or foreign approval to market a new drug or device product, we must demonstrate proof of safety and effectiveness in humans. Foreign regulations and requirements are similar to those of the FDA. To meet FDA requirements, we must conduct “adequate and well-controlled” clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. The length of time may vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with the Neutrolin development program or the development plans for any other product candidates may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

- inability to manufacture sufficient quantities of qualified materials under the FDA’s cGMP requirements for use in clinical trials;
- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of patients;
- modification of clinical trial protocols;
- changes in regulatory requirements for clinical trials;
- lack of effectiveness during clinical trials;
- emergence of unforeseen safety issues;
- delays, suspension, or termination of clinical trials due to the IRB responsible for overseeing the study at a particular study site; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of the trials.

Further, the results from early pre-clinical and clinical trials are not necessarily predictive of results to be obtained in later clinical trials. Accordingly, even if we obtain positive results from early pre-clinical or clinical trials, we may not achieve the same success in later clinical trials. Moreover, comparisons of results across different studies should be viewed with caution as such comparisons are limited by a number of factors, including differences in study designs and populations. Such comparisons also will not provide a sufficient basis for any comparative claims following product approval. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

Our clinical trials may be conducted in patients with serious or life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product is expected to be used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. We cannot ensure that safety issues will not arise with respect to our products in clinical development.

Clinical trials may not demonstrate statistically significant safety and effectiveness to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of our product candidates. Such a failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay the filing of any NDA or any Premarket Approval Application, or PMA, with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operations.

If we fail to comply with international regulatory requirements, we could be subject to regulatory delays, fines or other penalties.

Regulatory requirements in foreign countries for international sales of medical devices often vary from country to country. The occurrence and related impact of the following factors would harm our business:

- delays in receipt of, or failure to receive, foreign regulatory approvals or clearances;
- the loss of previously obtained approvals or clearances; or
- the failure to comply with existing or future regulatory requirements.

The CE Mark is a mandatory conformity mark for products to be sold in the European Economic Area. Currently, 28 countries in Europe require products to bear CE Marking. To market in Europe, a product must first obtain the certifications necessary to affix the CE Mark. The CE Mark is an international symbol of adherence to the Medical Device Regulations, previously the Medical Device Directives, and the manufacturer's declaration that the product complies with essential requirements. Compliance with these requirements is ascertained within a certified Quality Management System (QMS) pursuant to ISO 13485. In order to obtain and to maintain a CE Mark, a product must be in compliance with the applicable quality assurance provisions of the aforementioned ISO and obtain certification of its quality assurance systems by a recognized European Union notified body. We received CE Mark approval for Neutrolin on July 5, 2013. However, certain individual countries within the European Union require further approval by their national regulatory agencies. Additionally, implementation of the new European Union Medical Device Regulations may pose challenges in demonstrating continued conformity to the new medical device regulatory paradigm. Failure to receive or maintain these other requisite approvals could prohibit us from marketing and selling Neutrolin in the entire European Economic Area or elsewhere.

We do not have, and may never obtain, the regulatory approvals we need to market our product candidates outside of the European Union.

While we have received the CE Mark approval for Neutrolin in Europe, certain individual countries within the European Union require further approval by their national regulatory agencies. Failure to receive or maintain these other requisite approvals could prohibit us from marketing and selling Neutrolin in the entire European Economic Area. In addition, we will need regulatory approval to market and sell Neutrolin in foreign countries outside of Europe.

In the United States, we have not received the regulatory approvals required for the commercial sale of any of our product candidates. We are preparing an NDA for Neutrolin in hemodialysis catheters based on our recently completed Phase 3 trial, LOCK-IT-100. Financing will be required to conduct a second Phase 3 trial, if required by FDA to secure marketing authorization. However, we might not obtain any financing necessary to complete the development of Neutrolin for use in hemodialysis catheters.

We also are pursuing development of taurolidine-based devices for several indications, including wound closure, surgical meshes, and wound management. The FDA regards taurolidine as a new chemical entity and therefore an unapproved new drug. Consequently, there is no appropriate predicate device currently marketed in the U.S. on which a 510(k) approval process for these devices could be based. As a result, we will be required to submit a premarket approval application for marketing authorization for these indications. In the event that the NDA for Neutrolin is approved by the FDA, the regulatory pathway for these devices can be revisited with the FDA. Although there will presumably still be no appropriate predicate, *de novo* Class II designation can be proposed, based on a risk assessment and a reasonable assurance of safety and effectiveness.

It is possible that Neutrolin will not receive any further approval or that any of our other product candidates will be approved for marketing. Failure to obtain regulatory approvals, or delays in obtaining regulatory approvals, would adversely affect the successful commercialization of Neutrolin or any other drugs or products that we or our partners develop, impose additional costs on us or our collaborators, diminish any competitive advantages that we or our partners may attain, and/or adversely affect our cash flow, financial condition and results of operations.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply in the United States and abroad. These include, among other things, requirements related to pharmacovigilance and adverse event and other reporting, supply chain security requirements, suspect and illegitimate product investigations and notifications, limitations on product advertising and promotion and on the distribution of product samples, and ongoing adherence to cGMPs, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Establishing and maintaining systems and procedures for compliance with these requirements, and for training and monitoring personnel relative to their compliance, is expensive, time consuming, and an ongoing effort. Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA, foreign and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA or a foreign regulatory body to modify or withdraw product approval.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste. Even if we contract with third parties for the disposal of these materials and waste, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

The successful commercialization of Neutrolin will depend on obtaining coverage and reimbursement for use of Neutrolin from third-party payors.

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and/or private health insurers, both in the U.S. and abroad. Further, significant uncertainty exists as to the reimbursement status of newly approved health care products. We initially expect to sell Neutrolin directly to hospitals and key dialysis center operators, but also plan to expand its usage into intensive care, oncology and total parenteral nutrition patients needing catheters. All of these potential customers are healthcare providers who depend upon reimbursement by government and commercial insurance payors for dialysis and other treatments. Depending on the treatment setting, we believe that Neutrolin would be eligible for coverage under various reimbursement programs, such as the End Stage Renal Disease ("ESRD") Prospective Payment System and ESRD Quality Incentive Program; however, coverage by any of these reimbursement programs is not assured, and even if coverage is granted, it could later be revoked or modified under future regulations. Further, the U.S. Centers for Medicare & Medicaid Services ("CMS"), which administers Medicare, and works with states to administer Medicaid, has adopted and will continue to adopt and/or amend rules governing reimbursement for specific treatments. We anticipate that CMS and private insurers will increasingly demand that manufacturers demonstrate the cost effectiveness of their products as part of the reimbursement review and approval process. Rising healthcare costs have also led many European and other foreign countries to adopt healthcare reform proposals and medical cost containment measures. Similar legislation could be introduced in the U.S. Any measures affecting the reimbursement programs of these governmental and private insurance payors, including any uncertainty in the medical community regarding their nature and effect on reimbursement programs, could have an adverse effect on purchasing decisions regarding Neutrolin, as well as limit the prices we may charge for Neutrolin. The failure to obtain or maintain reimbursement coverage for Neutrolin or any other products could materially harm our operations.

In anticipation that the CMS and private payers will demand that we demonstrate the cost effectiveness of Neutrolin as part of the reimbursement review and approval process, we will incorporate health economic evaluations into our clinical studies to support this review in the context of the prospective use of Neutrolin in dialysis, the intensive care unit ("ICU") and oncology settings. However, our studies might not be sufficient to support coverage or reimbursement at levels that allow providers to use Neutrolin.

Physicians and patients may not accept and use our products.

Even with the CE Mark approval of Neutrolin, and even if we receive FDA or other foreign regulatory approval for Neutrolin or other product candidates, physicians and patients may not accept and use our products. Acceptance and use of our products will depend upon a number of factors including the following:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product;
- prevalence of the disease to be treated;
- prevalence and severity of any side effects;
- cost-effectiveness of our product relative to competing products;
- availability of coverage and reimbursement from government and other third-party payers;
- timing of market introduction of our drugs and competitive drugs;
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any;
- potential or perceived advantages or disadvantages over alternative treatments;
- potential post-marketing commitments imposed by regulatory authorities, such as patient registries;
- price of our future products, both in absolute terms and relative to alternative treatments; and
- the effect of current and future healthcare laws and regulations on our product candidates.

Because we expect sales of Neutrolin to generate substantially all of our product revenues for the foreseeable future, the failure of Neutrolin to find market acceptance would harm our business and would require us to seek additional financing.

Risks Related to Our Business and Industry

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and medical device companies that are pursuing other forms of prevention or treatment for the same or similar indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than we do, obtaining FDA or any other regulatory agency approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in processes, treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

There can be no assurance that Neutrolin or any other product candidate will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA or any other regulatory agency. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept any of our products as a treatment of choice.

Furthermore, the pharmaceutical and medical device industry is diverse, complex, and rapidly changing. By its nature, the business risks associated with the industry are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA or other regulatory agency regulations preclude us from forecasting regulatory approval, product acceptance, revenues or income with certainty or even confidence.

Healthcare policy changes, including reimbursement policies for drugs and medical devices, may have an adverse effect on our business, financial condition and results of operations.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payors to manage, contain or reduce the costs of health care through various means, such as capping prices, limiting price increases, reducing reimbursement, and requiring rebates. Market acceptance and sales of Neutrolin or any other product candidates that we develop will depend on reimbursement policies and may be affected by health care reform measures in the U.S. and abroad. Government authorities and other third-party payors, such as private health insurers, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for Neutrolin or any other product candidates that we develop. Also, we cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize Neutrolin or any other product candidates that we develop.

In both the U.S. and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could affect our ability to sell our approved products profitably. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under the Medicare program in the United States. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act"), was enacted. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers. Such government-adopted reform measures may adversely affect the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

In recent years, the U.S. Congress has sought to repeal and has significantly amended the Affordable Care Act. We expect that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Certain of these changes could impose limitations on the prices we will be able to charge for any products that are approved or the amounts of reimbursement available for these products from governmental agencies or other third-party payors or may increase the tax requirements for life sciences companies such as ours. Any such legislation could have an adverse effect on our business, financial condition and results of operations.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills by Congress and the states designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the U.S. government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a "Blueprint", or plan, to reduce the cost of drugs. The current administration's Blueprint contains certain measures that the U.S. Department of Health and Human Services is already working to implement. Individual states in the United States have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Health administration authorities in countries other than the U.S. may not provide reimbursement for Neutrolin or any of our other product candidates at rates sufficient for us to achieve profitability, or at all. Like the U.S., these countries could adopt health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates.

Any reduction in reimbursement rates under Medicare or private insurers or foreign health care programs could negatively affect the pricing of our products. If we are not able to charge a sufficient amount for our products, then our margins and our profitability will be adversely affected.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in compensation costs, our business may materially suffer.

We are highly dependent on the principal members of our management and scientific staff, specifically, Khoso Baluch, a director and our Chief Executive Officer, Phoebe Mounts, our Executive Vice President and General Counsel, Paul Chew, our Acting Chief Medical Officer, Elizabeth Masson-Hurlburt, our Executive Vice President and Head of Clinical Operations, and John Armstrong, our Executive Vice President for Technical Operations. Our future success will depend in part on our ability to identify, hire, and retain current and additional personnel. We experience intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of our business. Moreover, our work force is located in the New York metropolitan area, where competition for personnel with the scientific and technical skills that we seek is extremely high and is likely to remain high. Because of this competition, our compensation costs may increase significantly. In addition, we have only limited ability to prevent former employees from competing with us.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

Over time, we expect to hire additional qualified personnel with expertise in government regulation, formulation and manufacturing, and sales and marketing, among others. We compete for qualified individuals with numerous pharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. We are currently in the process of hiring a Chief Financial Officer. Attracting and retaining such qualified personnel will be critical to our success.

We may not successfully manage our growth.

Our success will depend upon the expansion of our operations to commercialize Neutrolin and the effective management of any growth, which could place a significant strain on our management and our administrative, operational and financial resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business may be materially harmed.

We face the risk of product liability claims and the amount of insurance coverage we hold now or in the future may not be adequate to cover all liabilities we might incur.

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs. If the use of one or more of our or our collaborators' drugs or devices harms people, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products.

We currently carry product liability insurance. We cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage we hold may not be adequate to cover all liabilities we might incur. Our insurance covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions and exclusions. Our coverage also includes the sale of commercial products. We have expanded our insurance coverage to include the sale of commercial products due to the receipt of the CE Mark approval, but we may be unable to maintain such coverage or obtain commercially reasonable product liability insurance for any other products approved for marketing.

If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we may be exposed to significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our or our collaborators' products and do not have sufficient insurance coverage, our liability could exceed our total assets and our ability to pay the liability. A successful product liability claim or series of claims brought against us would decrease our cash and could cause the value of our capital stock to decrease.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third-party contractors may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local, as well as foreign, laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we and the third-party could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local, as well as foreign, laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators.

Negative conditions in the U.S. or global economy, including financial markets, may adversely affect our business and the business of current and prospective vendors, licensees and collaborators, and others with whom we do or may conduct business. The U.S. or global economy may experience disruptions as the result of international hostilities, natural disasters, pandemics, other international health emergencies, or weather-related or similar events (such as fires, hurricanes, earthquakes, floods, landslides and other natural conditions including the effects of climate change), political instability, labor strikes or turmoil, or terrorist attacks. In particular, countries around the world have experienced the spread of the COVID-19 pandemic, resulting in quarantines, supply chain disruptions, reduction in travel, increased demand for medical services and a general decline in economic activity and market confidence. Similar potential disruptions may occur in the future in any of the locations in which we or our collaborators do business. We continue to assess the potential impact on our counterparties and customers of such events, and what impact, if any, these events could have on our business.

The duration and severity of these conditions is uncertain. If negative economic conditions occur, we may be unable to secure funding on terms satisfactory to us to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our drug development programs.

Risks Related to Our Intellectual Property

If we materially breach or default under any of our license agreements, the licensor party to such agreement will have the right to terminate the license agreement, which termination may materially harm our business.

Our commercial success will depend in part on the maintenance of our license agreements. Each of our license agreements provides the licensor with a right to terminate the license agreement for our material breach or default under the agreement, including the failure to make any required milestone or other payments. Should the licensor under any of our license agreements exercise such a termination right, we would lose our right to the intellectual property under the respective license agreement, which loss may materially harm our business.

If we and our licensors do not obtain protection for and successfully defend our respective intellectual property rights, competitors may be able to take advantage of our research and development efforts to develop competing products.

Our commercial success will depend in part on obtaining further patent protection for our products, product candidates and other technologies and successfully defending any patents that we currently have or will obtain against third-party challenges. The patents which we currently believe are most material to our business are as follows:

- U.S. Patent No. 8,541,393 (expiring November 2, 2024) (the “Prosl Patent”) - use of Neutrolin for preventing infection and maintenance of catheter patency in hemodialysis catheters;
- U.S. Patent No. 9,339,036 (expiring November 2, 2024);
- U.S. Patent No. 7,696,182 (expiring May 16, 2025); and
- European Patent EP 1 814 562 B1 (expiring October 12, 2025) (the “Prosl European Patent”) - a low heparin catheter lock solution for maintaining and preventing infection in a hemodialysis catheter. The European Patent Office has found the Prosl European Patent to be invalid and has revoked it. An appeal to that decision is pending.

We are currently seeking further patent protection for our compounds and methods of treating diseases. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following:

- patents that may be issued or licensed may be challenged, invalidated, or circumvented, or otherwise may not provide any competitive advantage;
- our competitors, many of which have substantially greater resources than we have and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets;
- there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

In addition, the United States Patent and Trademark Office (“PTO”), and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated. Additionally, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that, should any patents issue, we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that should patents issue, they will be of commercial value to us, or that private parties, including competitors, will not successfully challenge our patents or circumvent our patent position in the U.S. or abroad.

The above-mentioned patents are exclusively licensed to us. To support our patent strategy, we have engaged in a review of patentability and certain freedom to operate issues, including performing certain searches. However, patentability and certain freedom to operate issues are inherently complex, and we cannot provide assurances that a relevant patent office and/or relevant court will agree with our conclusions regarding patentability issues or with our conclusions regarding freedom to operate issues, which can involve subtle issues of claim interpretation and/or claim liability. Furthermore, we may not be aware of all patents, published applications or published literature that may affect our business either by blocking our ability to commercialize our product candidates, preventing the patentability of our product candidates to us or our licensors, or covering the same or similar technologies that may invalidate our patents, limit the scope of our future patent claims or adversely affect our ability to market our product candidates. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administration panel to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such loss of patent protection could have a material adverse impact on our business. Additionally, since patent applications in the United States are maintained in secrecy until published or issued and as publication of discoveries in the scientific or patent literature often lag behind the actual discoveries, we cannot be certain that we were the first to make the inventions covered by the pending patent applications or issued patents referred to above or that we were the first to file patent applications for such inventions.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we take measures to protect this information by entering into confidentiality and inventions agreements with our employees, and some but not all of our scientific advisors, consultants, and collaborators, we cannot provide any assurances that these agreements will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure or dispute ownership if they are breached, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may also be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of our intellectual property may be greatly reduced. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

Ongoing and future intellectual property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights.

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may initiate or become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or we may become subject to proceedings initiated by our competitors or other third parties or the PTO or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. In addition, litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. If we are required to defend patent infringement actions brought by third parties, or if we sue to protect our own patent rights, we may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is not adverse to us. In addition, any legal action that seeks damages or an injunction to stop us from carrying on our commercial activities relating to the affected technologies could subject us to monetary liability and require us or any third party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms or at all. Furthermore, to the extent that we or our consultants or research collaborators use intellectual property owned by others in work performed for us, disputes may also arise as to the rights in such intellectual property or in resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties.

We initiated court proceedings in Germany for patent infringement and unfair use of our proprietary information related to Neutrolin (as described below). We also have had opposition proceedings brought against the European Patent and the German utility model patent which are the basis of our infringement proceedings (as described below). The defense and prosecution of these ongoing and any future intellectual property suits, PTO or foreign proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. An adverse determination in litigation or PTO or foreign proceedings to which we may become a party could subject us to significant liabilities, including damages, require us to obtain licenses from third parties, restrict or prevent us from selling our products in certain markets, or invalidate or render unenforceable our licensed or owned patents. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

On September 9, 2014, we filed in the District Court of Mannheim, Germany a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of our European Patent EP 1 814 562 B1, which was granted by the European Patent Office (the "EPO") on January 8, 2014 (the "Prosl European Patent"). The Prosl European Patent covers a low dose heparin catheter lock solution for maintaining patency and preventing infection in a hemodialysis catheter. In this action, we claim that the Defendants infringe on the Prosl European Patent by manufacturing and distributing catheter locking solutions to the extent they are covered by the claims of the Prosl European Patent. We believe that our patent is sound and are seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. Separately, TauroPharm has filed an opposition with the EPO against the Prosl European Patent alleging that it lacks novelty and inventive step. We cannot predict what other defenses the Defendants may raise, or the ultimate outcome of either of these related matters. At present, the EPO has revoked the Prosl European Patent as invalid, and we have filed an appeal, which is currently pending.

In the same complaint against the same Defendants, we also alleged an infringement (requesting the same remedies) of NDP's utility model DE 20 2005 022 124 U1 (the "Utility Model"), which we believe is fundamentally identical to the Prosl European Patent in its main aspects and claims. The Court separated the two proceedings and the Prosl European Patent and the Utility Model claims are now being tried separately. TauroPharm has filed a cancellation action against the Utility Model before the German Patent and Trademark Office (the "German PTO") based on the similar arguments as those in the opposition against the Prosl European Patent.

On March 27, 2015, the District Court held a hearing to evaluate whether the Utility Model has been infringed by TauroPharm in connection with the manufacture, sale and distribution of its TauroLock-HEP100TM and TauroLock-HEP500TM products. A hearing before the same court was held on January 30, 2015 on the separate, but related, question of infringement of the Prosl European Patent by TauroPharm.

The Court issued its decisions on May 8, 2015 staying both proceedings. In its decisions, the Court found that the commercialization by TauroPharm in Germany of its TauroLock catheter lock solutions Hep100 and Hep500 infringes both the Prosl European Patent and the Utility Model and further that there is no prior use right that would allow TauroPharm to continue to make, use or sell its product in Germany. However, the Court declined to issue an injunction in favor of us that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the EPO, in the case of the Prosl European Patent, or the German PTO, in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by us for injunctive and other relief until such time as the EPO or the German PTO has ruled on the underlying validity of the Prosl European Patent and the Utility Model. It is safe to assume that the complaint regarding the infringement of the Utility Model will be dismissed now that the German PTO has voided the Utility Model (see below). This does not, however, have a direct effect on the infringement proceedings concerning the Prosl European Patent.

The opposition proceeding against the Prosl European Patent before the EPO is ongoing. In its preliminary consideration of the matter, the EPO (and the German PTO) regarded the patent as not inventive or novel due to publication of prior art. Oral proceedings before the Opposition Division at the EPO were held on November 25, 2015, at which the three-judge patent examiner panel considered arguments related to the validity of the Prosl European Patent. The hearing was adjourned due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in a further hearing in order to close some gaps in the documentation presented by TauroPharm as regards the publication of prior art.

The German PTO held a hearing in the validity proceedings relating to the Utility Model on June 29, 2016, at which the panel affirmed its preliminary finding that the Utility Model was invalid based upon prior publication of a reference to the benefits that may be associated with adding heparin to a taurolidine based solution. The Company filed an appeal against the ruling on September 7, 2016. An oral hearing was held on September 17, 2019 in which the German Federal Patent affirmed the first instance decision that the Utility Model was invalid. The decision has only a declaratory effect, as the Utility Model had expired in November 2015.

In October 2016, TauroPharm submitted a further writ to the EPO requesting a date for the hearing and bringing forward further arguments, in particular in view of the June 2016 decision of the German PTO on the invalidity of the utility model. On November 22, 2017, the EPO in Munich, Germany held a further oral hearing in this matter. At the hearing, the panel held that the Prosl European Patent would be invalidated because it did not meet the requirements of novelty based on a technical aspect of the European intellectual property law. We disagree with this decision and, after the written opinion was issued by the Opposition Division in September 2018, have appealed the decision. We continue to believe that the Prosl European Patent is indeed novel and that its validity should be maintained. There can be no assurance that we will prevail in this matter. In addition, the ongoing Unfair Competition litigation against TauroPharm is not affected and will continue.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider our claims. The judge made no decision on the merits of our complaint. On January 14, 2016, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. We have prepared the requested reply and produced the respective documentation. TauroPharm has also filed another writ within the same deadline and both parties have filed further writs at the end of April setting out their respective argumentation in more detail. A further oral hearing in this matter was held on November 15, 2016. In this hearing, the court heard arguments from us and TauroPharm concerning the allegations of unfair competition. The court made no rulings from the bench and indicated that it is prepared to further examine the underlying facts of our allegations. On March 7, 2017, the court issued another interim decision in the form of a court order outlining again several issues relating to the argumentation of both sides in the proceedings. In particular the court requested us to further specify our requests and to further substantiate in even more detail which know-how was provided by Biolink to TauroPharm by whom and when. The court also raised the question whether the know-how provided at the time to TauroPharm could still be considered to be secret know-how or may have become public in the meantime. The court granted both sides the opportunity to reply to this court order and provide additional facts and evidence until May 15, 2017. Both parties submitted further writs in this matter and the court scheduled a further hearing for May 8, 2018. After having been rescheduled several times, the hearing took place on November 20, 2018. A decision was rendered by the court on December 11, 2018, dismissing the complaint in its entirety. However, we intend to continue to pursue this matter, and still believe that our claims are well-founded. We have therefore appealed in January 2019 and filed our grounds of appeal in March 2019. An oral hearing was held on September 6, 2019 in which our legal counsel brought forward further arguments for the fact that the manufacturing process of the respective catheter locking solution is indeed protectable as a trade secret. In view of these new arguments, the court issued an evidentiary order on September 27, 2019 ordering an expert opinion. Next steps will be taken after the receipt of the expert opinion.

The decisions by the European and German patent offices may affect patent rights in other jurisdictions.

The prior art on the basis of which the Prosl European Patent and the German Utility Model have been found to be invalid may be used to challenge the validity of issued United States and/or other foreign patents that are directed to the same or similar subject matter, in a court action or in an administrative proceeding before the USPTO. Pending United States and/or foreign patent applications may be denied on that basis of that prior art as well. Such patents and patent applications include: US 7,696,182; US 8,541,393; US 9,339,036; US 16/691,073; and EP 14150248.4.

If we infringe the rights of third parties we could be prevented from selling products and forced to pay damages and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to do one or more of the following:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Risks Related to Dependence on Third Parties

We currently have no internal marketing and sales organization and currently rely and intend to continue to rely on third parties to market, sell, and distribute Neutrolin outside of the U.S. We may seek a sales partner in the U.S. if Neutrolin receives FDA approval or we may undertake marketing and sales of Neutrolin in the U.S. on our own. If we are unable to enter into or maintain agreements with third parties to market and sell Neutrolin or any other product after approval or are unable to find a sales partner or establish our own marketing and sales capabilities, we may not be able to generate significant or any product revenues.

We currently have no sales, marketing, or distribution infrastructure. Our business strategy for Neutrolin relies on collaborating with larger firms with experience in marketing and selling medical devices and pharmaceutical products; for other products we may also rely on such marketing collaborations or out-licensing of our product candidates. Specifically, for Neutrolin, we have a distributor agreement with each of a Saudi Arabian, an Emirati, and a South Korean company for sales and marketing (upon receipt of approval to market in South Korea). In April 2017, we announced a commercial collaboration with Hemotech SAS covering France and certain overseas territories. Assuming we receive applicable regulatory approval for other markets, we plan to enter into distribution agreements with one or more third parties for the sale of Neutrolin in various European, Middle East and other markets. We will be dependent on the firms and individuals with whom we contract for the success of sales in the countries in which they operate. However, there can be no assurance that we will be able to successfully maintain those relationships or establish and maintain additional marketing, sales, or distribution relationships, nor can there be assurance that such relationships will be successful, or that we will be successful in gaining market acceptance for our products. If these firms or individuals do not perform for whatever reason, our business, prospects and results of operations may be materially adversely affected. Finding a new or replacement organization for sales and marketing could be difficult, which would further harm our business, prospects and results of operations. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third parties.

If we are unable to establish and maintain such third-party sales and marketing relationships, or choose not to do so, we will have to establish our own in-house capabilities. To market any of our products directly, we would need to develop a marketing, sales, and distribution force that has both technical expertise and the ability to support a distribution capability. The establishment of a marketing, sales, and distribution capability would take time and significantly increase our costs, possibly requiring substantial additional capital. In addition, there is intense competition for proficient sales and marketing personnel, and we may not be able to attract individuals who have the qualifications necessary to market, sell, and distribute our products. There can be no assurance that we will be able to establish internal marketing, sales, or distribution capabilities. If we are unable to, or choose not to establish these capabilities, or if the capabilities we establish are not sufficient to meet our needs, we will be required to establish collaborative marketing, sales, or distribution relationships with third parties, which we might not be able to do on acceptable terms or at all. The failure to successfully develop our own marketing and sales infrastructure would have a negative adverse effect on our business and results of operations.

If we or our collaborators are unable to manufacture our products in sufficient quantities or are unable to obtain regulatory approvals for a manufacturing facility, we may be unable to meet demand for our products and we may lose potential revenues.

Completion of our clinical trials and commercialization of Neutrolin and any other product candidate require access to, or development of, facilities to manufacture sufficient supplies. All of our manufacturing processes currently are, and we expect them to continue to be, outsourced to third parties. Specifically, we will rely on one or more manufacturers to supply us and/or our distribution partners with commercial quantities of Neutrolin. If, for any reason, we become unable to rely on our current sources for the manufacture of Neutrolin or any other product candidates or for active pharmaceutical ingredient (“API”), either for clinical trials or for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for pre-clinical, clinical, and commercial purposes. We may not be successful in identifying such additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. Such third-party manufacturers must receive FDA or applicable foreign approval before they can produce clinical material or commercial product, and any that are identified may not receive such approval or may fail to maintain such approval. In addition, we may be in competition with other companies for access to these manufacturers’ facilities and may be subject to delays in manufacturing if the manufacturers give other clients higher priority than they give to us. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance may be materially affected.

Before we could begin to commercially manufacture Neutrolin or any other product candidate on our own, we must obtain regulatory approval of the manufacturing facility and process. The manufacture of drugs for clinical and commercial purposes must comply with cGMP and applicable non-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements would require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. We would also have to pass a pre-approval inspection prior to FDA or non-U.S. regulatory agency approval. Failure to pass a pre-approval inspection may significantly delay regulatory approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products. As a result, our business, financial condition, and results of operations could be materially adversely affected.

Corporate and academic collaborators may take actions that delay, prevent, or undermine the success of our products.

Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of our product candidates is heavily dependent on our entering into collaborations with corporations, academic institutions, licensors, licensees, and other parties. Our current strategy assumes that we will successfully establish and maintain these collaborations or similar relationships. However, there can be no assurance that we will be successful establishing or maintaining such collaborations. Some of our existing collaborations, such as our licensing agreements, are, and future collaborations may be, terminable at the sole discretion of the collaborator in certain circumstances. Replacement collaborators might not be available on attractive terms, or at all.

In addition, the activities of any collaborator will not be within our control and may not be within our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all, that we will derive any revenue or profits from such collaborations, or that any collaborator will not compete with us. If any collaboration is not pursued, we may require substantially greater capital to undertake on our own the development and marketing of our product candidates and may not be able to develop and market such products successfully, if at all. In addition, a lack of development and marketing collaborations may lead to significant delays in introducing product candidates into certain markets and/or reduced sales of products in such markets.

Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete.

We rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. If such third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.

We rely on third parties to conduct our clinical trials and pre-clinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our product candidates may not advance in a timely manner or at all.

In the course of our pre-clinical testing and clinical trials, we rely on third parties, including laboratories, investigators, clinical contract research organizations (“CROs”), and manufacturers, to perform critical services for us. For example, we rely on third parties to conduct our clinical trials and many of our pre-clinical studies, which are required to be conducted consistent with regulations on Good Laboratory Practice (“GLP”). CROs and study sites are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our pre-clinical and clinical trials, we are responsible for ensuring that each of our trials is conducted in accordance with its investigational plan and protocol and that the integrity of the studies and resulting data is protected. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as Good Clinical Practices (“GCPs”), for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, if such third parties fail to perform their obligations in compliance with our protocols or the applicable regulatory requirements, our trials may not meet regulatory requirements or may need to be repeated, we may not receive marketing approvals, or we or such third parties may face regulatory enforcement. As a result of our dependence on third parties, we may face delays, failures or cost increases outside of our direct control. These risks also apply to the development activities of collaborators, and we do not control their research and development, clinical trial or regulatory activities.

We will depend on third party suppliers and contract manufacturers for the manufacturing of our product candidates and have no direct control over the cost of manufacturing our product candidates. Increases in the cost of manufacturing our product candidates would increase our costs of conducting clinical trials and could adversely affect our future profitability.

We do not intend to manufacture our product candidates ourselves, and we will rely on third parties for our drug supplies both for clinical trials and for commercial quantities in the future. We have taken the strategic decision not to manufacture API for our product candidates, as these can be more economically supplied by third parties with particular expertise in this area. We have identified contract facilities that are registered with the FDA, have a track record of large-scale API manufacture, and have already invested in capital and equipment. We have no direct control over the manufacturing of our product candidates, or the cost thereof. If the contract manufacturers are unable to produce sufficient quantities of our product candidates, as a result of a lack of available materials or otherwise, our ability to complete product candidate development and our future profitability would be adversely affected. If the cost of manufacturing increases, or if the cost of the materials used increases, these costs will be passed on to us, making the cost of conducting clinical trials more expensive. For example, there could be issues securing the API heparin for our product as a result of the outbreak of African swine fever in China in 2019, which threatened the global heparin supply. The United States is largely dependent on China for its heparin, because almost half of the global pig supply, the main animal source for heparin, is in China. Increases in manufacturing costs could adversely affect our future profitability if we are unable to pass all of the increased costs along to our customers.

Further, we, along with our contract manufacturers, are required to comply with FDA requirements for cGMPs, related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers may not be able to comply with the applicable FDA regulatory requirements, which could result in delays to our product development programs, could result in adverse regulatory actions against them or us, and could prevent us from ultimately receiving product marketing approval. They also generally must pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our product candidates and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP, we may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. Not complying with FDA requirements could result in a product recall or prevent commercialization of our product candidates and delay our business development activities. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter.

Risks Related to our Common Stock

We will need additional financing to fund our activities in the future, which likely will dilute our stockholders.

To date, our commercial operations have not generated sufficient revenues to enable profitability. As of December 31, 2019, we had an accumulated deficit of $195.4 million, and incurred net losses of $16.4 million for the year then ended. Based on the current development plans for Neutrolin in both the U.S. and foreign markets (including the preparation of an NDA for Neutrolin in hemodialysis catheters) and our other operating requirements, management believes that the existing cash at December 31, 2019 plus funding raised through March 12, 2020, will be sufficient to fund operations into the second quarter of 2021. Further, we will need additional funding for Neutrolin's commercial launch. We anticipate that we will incur operating losses for the foreseeable future. Additionally, we will require substantial funds in the future to support our operations. Accordingly, we will need to obtain additional financing, including through issuances of equity securities.

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may, as we have in the past, sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be further diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders.

Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price.

Sales of our common stock by our executive officers and directors, or the perception that such sales may occur, could adversely affect the market price of our common stock. Our executive officers and directors may sell stock in the future, either as part, or outside, of trading plans under Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Our common stock price has fluctuated considerably and is likely to remain volatile, in part due to the limited market for our common stock and you could lose all or a part of your investment.

During the period from the completion of our initial public offering ("IPO"), on March 30, 2010 through December 31, 2019, the high and low sales prices for our common stock were $52.00 and $0.75, respectively. There is a limited public market for our common stock and we cannot provide assurances that an active trading market will develop or continue. As a result of low trading volume in our common stock, the purchase or sale of a relatively small number of shares could result in significant share price fluctuations.

Additionally, the market price of our common stock may continue to fluctuate significantly in response to a number of factors, some of which are beyond our control, including the following:

- the receipt of or failure to obtain additional regulatory approvals for Neutrolin, including FDA approval in the U.S.;
- market acceptance of Neutrolin in those markets in which it is approved for sale;
- our need for additional capital;
- results of clinical trials of our product candidates, including any other Phase 3 trial for Neutrolin in the U.S., if required, or those of our competitors;
- our entry into or the loss of a significant collaboration, or expiration or termination of licenses;
- regulatory or legal developments in the United States and other countries, including changes in the healthcare payment systems;
- changes in financial estimates or investment recommendations by securities analysts relating to our common stock;
- future sales or anticipated sales of our securities by us or our stockholders;
- announcements by our competitors of significant developments, technological innovations, strategic partnerships, joint ventures or capital commitments;
- changes in key personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- actual or anticipated variations in operating results;
- market conditions in the pharmaceutical and medical device sectors and issuance of new or changed securities analysts' reports or recommendations;
- instability in the stock market as a result of current or future domestic and global events;
- liquidity of any market for our securities;
- threatened or actual delisting of our common stock from a national stock exchange;
- general economic, industry and market conditions;
- developments or disputes concerning patents or other proprietary rights; and
- any other factors described in this "Risk Factors" section.

In addition, the stock markets in general, and the stock of pharmaceutical and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In addition, changes in economic conditions in the U.S., the European Union or globally, particularly in the context of current global events, could impact upon our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or our results of operations. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

For these reasons and others, an investment in our securities is risky and you should invest only if you can withstand wide fluctuations in and a significant or complete loss of the value of your investment.

A significant number of additional shares of our common stock may be issued at a later date, and their sale could depress the market price of our common stock.

As of December 31, 2019, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

- options to purchase an aggregate of 19,334 shares of our common stock issued to our officers, directors, employees and non-employee consultants under our 2006 Stock Plan, with a weighted average exercise price of $8.13 per share;
- options to purchase an aggregate of 1,357,060 shares of our common stock issued to our officers, directors and non-employee consultants under our 2013 Stock Plan, with a weighted average exercise price of $8.98 per share;
- 52,000 shares of Series C-3 Preferred Stock, which are convertible into 104,000 shares of common stock;
- 89,623 shares of Series E Preferred Stock, which are convertible into 391,953 shares of common stock;
- 100,000 shares of Series G Preferred Stock, which are convertible into 5,560,137 shares of common stock;
- warrants to purchase an aggregate of 341,328 shares of common stock with a weighted average exercise price of $6.24 per share; and
- 2,490 shares of common stock issuable upon vesting of restricted stock units with a weighted average grant date fair value of $8.49 per share.

Additionally, there are 3,562,196 shares of common stock available for grants under the 2019 Stock Plan (adopted on November 26, 2019).

The possibility of the issuance of these shares, as well as the actual sale of such shares, could substantially reduce the market price for our common stock and impede our ability to obtain future financing.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions in our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated Bylaws, as well as provisions of the General Corporation Law of the State of Delaware, or DGCL, may discourage, delay or prevent a merger, acquisition or other change in control of our company, even if such a change in control would be beneficial to our stockholders. These provisions include the following:

- authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting our stockholders from fixing the number of our directors; and
- establishing advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board of Directors.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by the board of directors. This provision could have the effect of discouraging, delaying or preventing someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. Any provision of our Amended and Restated Certificate of Incorporation, as amended, or Amended and Restated Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

If we fail to comply with the continued listing standards of the NYSE American, it may result in a delisting of our common stock from the exchange.

Our common stock is currently listed for trading on the NYSE American, and the continued listing of our common stock on the NYSE American is subject to our compliance with a number of listing standards. These listing standards include the requirement for avoiding sustained losses and maintaining a minimum level of stockholders' equity. In June 2018, we received a notice from the NYSE American that we did not meet continued listing standards of the NYSE American as set forth in Part 10 of the Company Guide. Specifically, we were not in compliance with Section 1003(a)(i) (requiring stockholders' equity of $2.0 million or more if the issuer has reported losses from continuing operations and/or net losses in two of its three most recent fiscal years), Section 1003(a)(ii) (requiring stockholders' equity of $4.0 million or more if the issuer has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years); and Section 1003(a)(iii) (requiring stockholders' equity of $6.0 million or more if the issuer has reported losses from continuing operations and/or net losses in its five most recent fiscal years). As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide. We submitted a plan of compliance to the NYSE American to address regaining compliance with Section 1003(a)(i), Section 1003(a)(ii) or Section 1003(a)(iii) of the Company Guide. The plan was accepted by the NYSE American and we subsequently regained compliance. However, if, in the future, we fail to maintain compliance with the requirements of the Company Guide, we may be required to take further actions to regain compliance and, if such actions are unsuccessful, our common stock could be delisted.

If our common stock were no longer listed on the NYSE American, investors might only be able to trade on one of the over-the-counter markets, including the OTC Bulletin Board ® or in the Pink Sheets ® (a quotation medium operated by Pink Sheets LLC). This would impair the liquidity of our common stock not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers.

Laws and regulations affecting public companies, including rules adopted by the Securities and Exchange Commission ("SEC") and by the NYSE American, may result in increased costs to us. These laws, rules and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as executive officers. We cannot estimate accurately the amount or timing of additional costs we may incur to respond to these laws, rules and regulations.

Our internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause the trading price of our common stock to fall dramatically.

A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be satisfied. Internal control over financial reporting and disclosure controls and procedures are designed to give a reasonable assurance that they are effective to achieve their objectives. We cannot provide absolute assurance that all of our possible future control issues will be detected. These inherent limitations include the possibility that judgments in our decision making can be faulty, and that isolated breakdowns can occur because of simple human error or mistake. The design of our system of controls is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed absolutely in achieving our stated goals under all potential future or unforeseeable conditions. Because of the inherent limitations in a cost-effective control system, misstatements due to error could occur and not be detected. This and any future failures could cause investors to lose confidence in our reported financial information, which could have a negative impact on our financial condition and stock price.

In future periods, if the process required by Section 404 of the Sarbanes-Oxley Act reveals any material weaknesses or significant deficiencies, the correction of any such material weaknesses or significant deficiencies could require remedial measures which could be costly and time-consuming. In addition, in such a case, we may be unable to produce accurate financial statements on a timely basis. Any associated accounting restatement could create a significant strain on our internal resources and cause delays in our release of quarterly or annual financial results and the filing of related reports, increase our costs and cause management distraction. Any of the foregoing could cause investors to lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable information of clinical trial participants and employees. Similarly, our third-party providers possess certain of our sensitive protected health data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated, and such systems, controls and processes may not be successful in preventing a breach. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including compliance with the Health Insurance Portability and Accountability Act of 1996 and recently enacted laws in a majority of states requiring security breach notification. The collection and use of personal health data of individuals in the European Union is also governed by strict data protection laws. In addition to existing laws, since May 25, 2018, the General Data Protection Regulation ("GDPR") has imposed new obligations with respect to European Union data and substantial fines for breaches of the data protection rules. It will increase our responsibility and potential liability in relation to personal data that we process, and we will be required to put in place additional mechanisms ensuring compliance with the new European Union data protection rules. There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the European Union, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, operating results, prospects and financial condition.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act ("CCPA"), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA, which went into effect on January 1, 2020, requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. The CCPA may significantly impact our business activities and require substantial compliance costs that adversely affect business, operating results, prospects and financial condition.

Thus, any access, disclosure or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt our operations and damage our reputation, which could adversely affect our business.

We do not intend to pay dividends on our common stock so any returns on our common stock will be limited to the value of our common stock.

We have never declared dividends on our common stock, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. Pursuant to the terms of our Series C-3, E and G Convertible Preferred Stock, we may not declare or pay any dividends or make any distributions on any of our shares or other equity securities as long as any of those preferred shares remain outstanding. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business. The payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board of Directors. Any return to holders of our common stock will be limited to the value of their common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located in approximately 6,960 square feet of office space in Berkeley Heights, New Jersey. We sublease this office pursuant to a sublease agreement dated September 2017 which runs from September 15, 2017 to June 29, 2020. This sublease is rent-free to us. A notice of an intention not to renew our current lease has been received and as a result, we are actively seeking a new space to lease that will meet our current needs.

Our subsidiary leases its offices in Fulda, Germany pursuant to a three-month lease agreement which commenced in June 2017, renewable every three months for a base monthly payment of €400.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

On September 9, 2014, we filed in the District Court of Mannheim, Germany a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs, referred to as the Defendants claiming infringement of our European Patent EP 1 814 562 B1, which was granted by the EPO on January 8, 2014, or the Prosl European Patent. The Prosl European Patent covers a low dose heparin catheter lock solution for maintaining patency and preventing infection in a hemodialysis catheter. In this action, we claim that the Defendants infringe on the Prosl European Patent by manufacturing and distributing catheter locking solutions to the extent they are covered by the claims of the Prosl European Patent. We believe that our patent is sound and are seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. Separately, TauroPharm has filed an opposition with the EPO against the Prosl European Patent alleging that it lacks novelty and inventive step. We cannot predict what other defenses the Defendants may raise, or the ultimate outcome of either of these related matters. At present, the EPO has revoked the Prosl European Patent as invalid, and we have filed an appeal, which is currently pending.

In the same complaint against the same Defendants, we also alleged an infringement (requesting the same remedies) of NDP's utility model DE 20 2005 022 124 U1, referred to as the Utility Model, which we believe is fundamentally identical to the Prosl European Patent in its main aspects and claims. The Court separated the two proceedings and the Prosl European Patent and the Utility Model claims are now being tried separately. TauroPharm has filed a cancellation action against the Utility Model before the German Patent and Trademark Office, or German PTO based on the similar arguments as those in the opposition against the Prosl European Patent.

On March 27, 2015, the District Court held a hearing to evaluate whether the Utility Model has been infringed by TauroPharm in connection with the manufacture, sale and distribution of its TauroLock-HEP100TM and TauroLock-HEP500TM products. A hearing before the same court was held on January 30, 2015 on the separate, but related, question of infringement of the Prosl European Patent by TauroPharm.

The Court issued its decisions on May 8, 2015, staying both proceedings. In its decisions, the Court found that the commercialization by TauroPharm in Germany of its TauroLock catheter lock solutions Hep100 and Hep500 infringes both the Prosl European Patent and the Utility Model and further that there is no prior use right that would allow TauroPharm to continue to make, use or sell its product in Germany. However, the Court declined to issue an injunction in favor of us that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the EPO, in the case of the Prosl European Patent, or the German PTO, in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by us for injunctive and other relief until such time as the EPO or the German PTO made a final decision on the underlying validity of the Prosl European Patent and the Utility Model. It is safe to assume that the complaint regarding the infringement of the Utility Model will be dismissed now that the German PTO has voided the Utility Model (see below). This does, however, not have a direct effect on the infringement proceedings concerning the Prosl European Patent.

The opposition proceeding against the Prosl European Patent before the EPO is ongoing. In its preliminary consideration of the matter, the EPO (and the German PTO) regarded the patent as not inventive or novel due to publication of prior art. Oral proceedings before the Opposition Division at the EPO were held on November 25, 2015, at which the three-judge patent examiner panel considered arguments related to the validity of the Prosl European Patent. The hearing was adjourned due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in a further hearing in order to close some gaps in the documentation presented by TauroPharm as regards the publication of prior art.

The German PTO held a hearing in the validity proceedings relating to the Utility Model on June 29, 2016, at which the panel affirmed its preliminary finding that the Utility Model was invalid based upon prior publication of a reference to the benefits that may be associated with adding heparin to a taurolidine based solution. We filed an appeal against the ruling on September 7, 2016. An oral hearing was held on September 17, 2019 in which the German Federal Patent affirmed the first instance decision that the Utility Model was invalid. The decision has only a declaratory effect, as the Utility Model had expired in November 2015.

In October 2016, TauroPharm submitted a further writ to the EPO requesting a date for the hearing and bringing forward further arguments, in particular in view of the June 2016 decision of the German PTO on the invalidity of the utility model. On November 22, 2017, the EPO in Munich, Germany held a further oral hearing in this matter. At the hearing, the panel held that the Prosl European Patent would be invalidated because it did not meet the requirements of novelty based on a technical aspect of the European intellectual property law. We disagree with this decision and, after the written opinion was issued by the Opposition Division in September 2018, have appealed the decision. We continue to believe that the Prosl European Patent is indeed novel and that its validity should be maintained. There can be no assurance that we will prevail in this matter. In addition, the ongoing Unfair Competition litigation against TauroPharm is not affected and will continue.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of our proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using our proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the API of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider our claims. The judge made no decision on the merits of our complaint. On January 14, 2016, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to the court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. We have prepared the requested reply and produced the respective documentation. TauroPharm has also filed another writ within the same deadline and both parties have filed further writs at the end of April 2016 setting out their respective argumentation in more detail. A further oral hearing in this matter was held on November 15, 2016. In this hearing, the court heard arguments from CorMedix and TauroPharm concerning the allegations of unfair competition. The court made no rulings from the bench and indicated that it is prepared to further examine the underlying facts of our allegations. On March 7, 2017, the court issued another interim decision in the form of a court order outlining again several issues relating to the argumentation of both sides in the proceedings. In particular the court requested us to further specify our requests and to further substantiate in even more detail which know-how was provided by Biolink (the company who developed Neutrolin that was acquired by ND Partners) to TauroPharm by whom and when. The court also raised the question whether the know-how provided at the time to TauroPharm could still be considered to be secret know-how or may have become public in the meantime. The court granted both sides the opportunity to reply to this court order and provide additional facts and evidence until May 15, 2017. Both parties have submitted further writs in this matter and the court had scheduled a further hearing for May 8, 2018. After having been rescheduled several times, the hearing took place on November 20, 2018. A decision was rendered by the court on December 11, 2018, dismissing the complaint in its entirety. However, we intend to continue to pursue this matter, and still believe firmly that our claims are well-founded. We have therefore appealed in January 2019 and filed our grounds of appeal in March 2019. An oral hearing was held on September 6, 2019 in which our legal counsel brought forward further arguments for the fact that the manufacturing process of the respective catheter locking solution is indeed protectable as a trade secret. In view of these new arguments, the court issued an evidentiary order on September 27, 2019 ordering an expert opinion. Next steps will be taken after the receipt of the expert opinion.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market for Common Equity

Our common stock trades on the NYSE American under the symbol "CRMD."

Based upon information furnished by our transfer agent, at March 12, 2020, we had approximately 63 holders of record of our common stock.

A comparison of the performance of our common stock is found in Item 12 of the Report under the heading "Stock Performance Graph."

Dividend Policy

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Further, pursuant to the terms of our Series C-3, E and G Non-Voting Convertible Preferred Stock, we may not declare or pay any dividends or make any distributions on any of our shares or other equity securities as long as any of those preferred shares remain outstanding. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board of Directors.

Equity Compensation Plan Information

The following table provides information as of December 31, 2019 about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing equity compensation plans (including individual arrangements):

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by security holders [1]	1,378,884 [2]	$ 8.98 [3]	3,562,196

(1) Our Amended and Restated 2006 Stock Incentive Plan was approved by our stockholders on February 19, 2010. Our 2013 Stock Incentive Plan was approved by our stockholders on July 30, 2013. Our 2019 Omnibus Stock Incentive Plan was approved by our stockholders on November 26, 2019.
(2) Consist of 1,376,394 shares underlying stock options and 2,490 shares of unvested restricted stock units.
(3) Applicable to shares underlying outstanding stock options only.

Item 6. Selected Financial Data

Not applicable.

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

You should read the following discussion and analysis together with our audited financial statements and the accompanying notes contained elsewhere in this report. This discussion contains forward-looking statements, within the meaning of Section 27A of Securities Act, Section 21E of the Exchange Act, and the Private Securities Litigation Reform Act of 1995, including statements regarding *our expected financial condition, business and financing plans. These statements involve risks and uncertainties. Our actual results could differ materially from the results described in or implied by these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this report, particularly under the heading "Risk Factors."*

Overview

CorMedix Inc. and our wholly owned German subsidiary, CorMedix Europe GmbH (collectively referred to herein as "we," "us," "our" and the "Company"), is a biopharmaceutical company focused on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases.

Our primary focus is on the development of our lead product candidate, Neutrolin®, for potential commercialization in the United States, or U.S., and other key markets. We have in-licensed the worldwide rights to develop and commercialize Neutrolin. Neutrolin is a novel anti-infective solution (a formulation of taurolidine 1.35%, citrate 3.5%, and heparin 1000 u/ml) intended for the reduction and prevention of catheter-related infections and thrombosis in patients requiring central venous catheters in clinical settings such as hemodialysis, critical/intensive care, and oncology. Infection and thrombosis represent key complications among hemodialysis, critical care/intensive care and cancer patients with central venous catheters. These complications can lead to treatment delays and increased costs to the healthcare system when they occur due to hospitalizations, need for IV antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the central venous catheter, related treatment costs and increased mortality. We believe Neutrolin addresses a significant unmet medical need and a potential large market opportunity.

In January 2015, the U.S. Food and Drug Administration, or FDA, designated Neutrolin as a Qualified Infectious Disease Product, or QIDP, for prevention of catheter related blood stream infections in patients with end stage renal disease receiving hemodialysis through a central venous catheter. Catheter-related blood stream infections and clotting can be life-threatening. The QIDP designation provides five years of market exclusivity in addition to the five years granted for a New Chemical Entity upon approval of a New Drug Application, or NDA. In addition, in January 2015, the FDA granted Fast Track designation to Neutrolin Catheter Lock Solution, a designation intended to facilitate development and expedite review of drugs that treat serious and life-threatening conditions so that the approved drug can reach the market expeditiously. The Fast Track designation of Neutrolin provides us with the opportunity to meet with the FDA on a more frequent basis during the development process, and also ensures eligibility to request priority review of the marketing application.

In December 2015, we initiated a prospective, multicenter, double-blind, randomized, active control Phase 3 clinical trial in the U.S. which aimed to demonstrate the efficacy and safety of Neutrolin in preventing catheter-related bloodstream infections, or CRBSI, in subjects receiving hemodialysis therapy as a treatment for end stage renal disease, referred to as LOCK-IT-100. The primary endpoint for the trial was time to CRBSI. The trial evaluated Neutrolin relative to the active control heparin by documenting the incidence of CRBSI and the time until the occurrence of CRBSI for each study subject. Secondary endpoints were catheter patency, which was defined as required use of tissue plasminogen activating factor, or tPA, or removal of catheter due to dysfunction, and removal of catheter for any reason.

In consultation with the FDA, we established the Clinical Adjudication Committee, or CAC, to critically and independently assess CRBSI. As announced in July 2018, the CAC, while remaining blinded to treatment assignment, reviewed potential cases of CRBSI in our LOCK-IT-100 study that occurred through early December 2017 and identified 28 such cases. As previously agreed with the FDA, an interim efficacy analysis was performed when the first 28 CRBSIs were identified. On July 25, 2018, we announced that the independent Data Safety Monitoring Board, or DSMB, had completed its review of the interim analysis of the data from the LOCK-IT-100 study. Because the pre-specified level of statistical significance was reached for the primary endpoint and efficacy had been demonstrated with no safety concerns, the DSMB recommended the study be terminated early.

Following discussions with the FDA, we proceeded with an orderly termination of LOCK-IT-100. In late January 2019, we announced the topline results of the full data set of the LOCK-IT-100 study. The study continued enrolling and treating subjects until study termination, and the final efficacy analysis was based on a total of 795 subjects.

Although the FDA usually requires two pivotal clinical trials to provide substantial evidence of safety and effectiveness for approval of a New Drug Application, or the NDA, we have had discussions with the FDA and plan to proceed with the submission of the NDA for Neutrolin based on the results of LOCK-IT-100 study. The FDA has agreed that the Neutrolin NDA is eligible for both priority review and for submission under rolling review. In January 2020, the FDA granted the request for rolling review. A determination on priority review will not be made until the submitted NDA is reviewed by the FDA to determine the acceptance for filing.

The FDA also agreed that we could request consideration of Neutrolin for approval under the Limited Population Pathway for Antibacterial and Antifungal Drugs, or LPAD. LPAD, passed as part of the 21st Century Cures Act, is a new program intended to expedite the development and approval of certain antibacterial and antifungal drugs to treat serious or life-threatening infections in limited populations of patients with unmet needs. We believe that LPAD will provide additional flexibility for the FDA to approve Neutrolin to prevent CRBSIs in the limited population of patients with end-stage renal disease receiving hemodialysis through a central venous catheter.

In the European Union, or EU, Neutrolin is regulated as a Class 3 medical device. In July 2013, we received CE Mark approval for Neutrolin. In December 2013, we commercially launched Neutrolin in Germany for the prevention of CRBSI, and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in certain European Union and Middle Eastern countries for such treatment.

In September 2014, the TUV-SUD and The Medicines Evaluation Board of the Netherlands, or MEB, granted a label expansion for Neutrolin for these same expanded indications for the EU. In December 2014, we received approval from the Hessian District President in Germany to expand the label to include use in oncology patients receiving chemotherapy, IV hydration and IV medications via central venous catheters. The expansion also adds patients receiving medication and IV fluids via central venous catheters in intensive or critical care units (cardiac care unit, surgical care unit, neonatal critical care unit, and urgent care centers). An indication for use in total parenteral nutrition was also approved.

In addition to Neutrolin, we are sponsoring a pre-clinical research collaboration for the use of taurolidine as a possible treatment for rare orphan pediatric tumors. In February 2018, the FDA granted orphan drug designation to taurolidine for the treatment of neuroblastoma in children. We may seek one or more strategic partners or other sources of capital to help us develop and commercialize taurolidine for the treatment of neuroblastoma in children. We are also evaluating opportunities for the possible expansion of taurolidine as a platform compound for use in certain medical devices. Patent applications have been filed in several indications, including wound closure, surgical meshes, and wound management. Based on initial feasibility work, we are advancing pre-clinical studies for taurolidine-infused surgical meshes, suture materials and hydrogels. We will seek to establish development/commercial partnerships as these programs advance.

The FDA regards taurolidine as a new chemical entity and therefore an unapproved new drug. Consequently, there is no appropriate predicate medical device currently marketed in the U.S. on which a 510(k) approval process could be based. As a result, we will be required to submit a premarket approval application, or PMA, for marketing authorization for any medical device indications that we may pursue. In the event that an NDA for Neutrolin is approved by the FDA, the regulatory pathway for these medical device product candidates may be revisited with the FDA. Although there may be no appropriate predicate, de novo Class II designation can be proposed, based on a risk assessment and a reasonable assurance of safety and effectiveness.

In April 2019, we received net proceeds of approximately $5,100,000 from the sale of a portion of our unused New Jersey NOL for the state fiscal year 2018. The NOL was sold through the State of New Jersey's Economic Development Authority, or NJEDA, Technology Business Tax Certificate Transfer program, which allowed us to sell approximately $5,400,000 of our total $6,100,000 in available NOL tax benefits for the state fiscal year 2018.

In September 2019, our registration with the Saudi Arabia Food and Drug Administration, or the SFDA, expired. As a result, we cannot sell Neutrolin in Saudi Arabia. We intend to complete the documentation required to renew our registration with the SFDA, however, we cannot predict how long the renewal process will take. There is no assurance that the registration will be renewed by the SFDA.

Since our inception, our operations have been primarily limited to conducting clinical trials and establishing manufacturing for our product candidates, licensing product candidates, business and financial planning, research and development, seeking regulatory approval for our products, initial commercialization activities for Neutrolin in the EU and other foreign markets, and maintaining and improving our patent portfolio. We have funded our operations primarily through debt and equity financings. We have generated significant losses to date, and we expect to use substantial amounts of cash for our operations as we prepare and submit a NDA for Neutrolin to the FDA, commence pre-launch commercial activities for Neutrolin for the U.S. market and commercialize Neutrolin in the EU and other foreign markets, pursue business development activities, and incur additional legal costs to defend our intellectual property. As of December 31, 2019, we had an accumulated deficit of approximately $195.4 million. We are unable to predict the extent of any future losses or when we will become profitable, if ever.

Financial Operations Overview

Revenue

We have not generated substantial revenue since our inception. Through December 31, 2019, we have funded our operations primarily through debt and equity financings.

Research and Development Expense

Research and development, or R&D, expense consists of: (i) internal costs associated with our development activities; (ii) payments we make to third party contract research organizations, contract manufacturers, investigative sites, and consultants; (iii) technology and intellectual property license costs; (iv) manufacturing development costs; (v) personnel related expenses, including salaries, stock–based compensation expense, benefits, travel and related costs for the personnel involved in drug development; (vi) activities relating to regulatory filings and the advancement of our product candidates through pre-clinical studies and clinical trials; and (vii) facilities and other allocated expenses, which include direct and allocated expenses for rent, facility maintenance, as well as laboratory and other supplies. All R&D is expensed as incurred.

Conducting a significant amount of development is central to our business model. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. We expect to incur significant R&D expenses for the foreseeable future in order to complete development of Neutrolin in the U.S., including the planned filing of an NDA for Neutrolin.

The process of conducting pre-clinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates.

Development timelines, probability of success and development costs vary widely. We are currently focused on completing the necessary requirements for filing an NDA for Neutrolin in the U.S. as well as on continuing sales in foreign markets where Neutrolin is approved. In December 2015, we signed an agreement with a CRO, to help us conduct our LOCK-IT-100 Phase 3 clinical trial in hemodialysis patients with central venous catheters to demonstrate the efficacy and safety of Neutrolin in preventing catheter-related bloodstream infections and blood clotting in subjects receiving hemodialysis therapy as treatment for end stage renal disease. During 2018, we contested a substantial amount of the unpaid clinical trial expense due to the unexpected delay and additional costs we incurred in preparing for the interim analysis of the LOCK-IT-100 study. In November 2018, we signed a settlement agreement with the CRO. In parallel with the settlement agreement, a new work order under the Master Service Agreement was executed specifying certain services the CRO would provide to us related to the closeout of the study. The budgeted amount of the new work order was approximately $1.4 million, which has been completed.

We are pursuing additional opportunities to generate value from taurolidine, an active component of Neutrolin. Based on initial feasibility work, we have completed an initial round of pre-clinical studies for taurolidine-infused surgical meshes, suture materials, and hydrogels, which require a PMA regulatory pathway for approval. We are also involved in a pre-clinical research collaboration for the use of taurolidine as a possible treatment for rare orphan pediatric tumors. In February 2018, the FDA granted orphan drug designation to taurolidine for the treatment of neuroblastoma in children. We may seek one or more strategic partners or other sources of capital to help us develop and commercialize taurolidine for the treatment of neuroblastoma in children.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expense includes costs related to commercial personnel, medical education professionals, marketing and advertising, salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, sales, finance and accounting functions. Other SG&A expense includes facility-related costs not included in R&D expense, promotional expenses, costs associated with industry and trade shows, and professional fees for legal services and accounting services.

Foreign Currency Exchange Transaction Gain (Loss)

Foreign currency exchange transaction gain (loss) is the result of re-measuring transactions denominated in a currency other than our functional currency and is reported in the consolidated statement of operations as a separate line item within other income (expense). The intercompany loans outstanding between our company based in New Jersey and our subsidiary based in Germany are not expected to be repaid in the foreseeable future and the nature of the funding advanced is of a long-term investment nature. As such, unrealized foreign exchange movements related to long-term intercompany loans are recorded in other comprehensive income (loss).

Interest Income

Interest income consists of interest earned on our cash equivalents and short-term investments.

Interest Expense

Interest expense consists of interest incurred on our convertible debt, amortization of debt discount and on financing of expenditures.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

The following is a tabular presentation of our consolidated operating results for the years ended December 31, 2019 and 2018 *(in thousands)*:

	2019	2018	% of Change Increase (Decrease)
Revenue	$ 283	$ 430	(34)%
Cost of sales	(373)	(397)	(6)%
Gross profit (loss)	(90)	33	(373)%
Operating Expenses:			
Research and development	(11,053)	(18,822)	(41)%
Selling, general and administrative	(9,865)	(8,075)	22%
Total operating expenses	(20,918)	(26,897)	(22)%
Loss from operations	(21,008)	(26,864)	(22)%
Interest income	322	37	770%
Foreign exchange transaction loss	(21)	-	-
Interest expense, including amortization of debt discount	(787)	(2)	(393)%
Total other income (expense)	(486)	35	(1489)%
Loss before income taxes	(21,494)	(26,829)	(20)%
Tax benefit	5,061	-	100%
Net loss	(16,433)	(26,829)	(39)%
Other comprehensive income (loss)	1	(2)	(150)%
Comprehensive loss	$ (16,432)	$ (26,831)	(39)%

Revenue. Revenue for the year ended December 31, 2019 was $283,000 as compared to $430,000 for the same period in 2018, a decrease of $147,000. The decrease was attributable to decreased sales in the Middle East of $182,000, partially offset by higher sales in the European Union of $35,000. The sales decrease in the Middle East was mainly due to the expiration of our registration with the Saudi Arabia Food and Drug Administration. The registration must be renewed in order for us to resume selling in Saudi Arabia.

Cost of Sales. Cost of sales for the year ended December 31, 2019 was $373,000 as compared to $397,000 for the same period in 2018, a decrease of $24,000. The decrease was primarily attributable to a decrease in costs related to stability studies of $58,000, a decrease in cost of materials of $25,000 as a result of lower sales, and a decrease in the cost related to replacement of products shipped under warranty of $7,000, partially offset by the write-off in 2019 of expired raw material of $39,000 and increase in inventory reserve of $27,000.

Research and Development Expense. R&D expense for the year ended December 31, 2019 was $11,053,000, a decrease of $7,769,000 from $18,822,000 for the same period in 2018. The decrease was primarily attributable to the winding down and close out of our LOCK-IT-100 clinical trial.

Selling, General and Administrative Expense . SG&A expense for the year ended December 31, 2019 was $9,865,000, an increase of $1,790,000 from $8,075,000 for the same period in 2018. The increase was primarily attributable to higher non-cash charges for stock-based compensation of $1,114,000, an increase in consulting fees of $723,000, mainly due to fees related to recruitment of additional personnel, and an increase in personnel expenses of $553,000, mainly due to additional hires. These increases were partially offset, among other items of lesser significance, by a reduction in legal fees related to general legal advice of $242,000, lower costs related to business development activities of $120,000, reduced selling and distribution expenses in the EU of $104,000, and decreases in marketing and research studies and investor relations activities of $100,000 and $92,000, respectively.

Interest Income. Interest income for the year ended December 31, 2019 was $323,000, an increase of $286,000 from $37,000 for the same period in 2018. The increase was attributable to higher average interest-bearing cash balances and short-term investments during the year ending December 31, 2019 as compared to the same period in 2018.

Foreign Exchange Transaction Gain (Loss). Foreign exchange transaction losses for the year ended December 31, 2019 and 2018 were due to the re-measuring of transactions denominated in a currency other than our functional currency.

Interest Expense. Interest expense for the year ended December 31, 2019 was $787,000 as compared to $2,000 for the same period in 2018. The increase is due primarily to the amortization of debt discount and non-cash interest expense recognized in connection with the senior secured convertible note issued in December 2018.

Tax Benefit. Tax benefit for the year ended December 31, 2019 of $5,061,000 represents an income tax benefit due to the sale of our unused NOL for state fiscal year 2018 through the NJEDA Technology Business Tax Certificate Transfer program. No unused NOL was sold during the year ended December 31, 2018.

Other Comprehensive Income (Loss). Unrealized foreign exchange gains and losses are related to long-term intercompany loans and the translation of the foreign affiliate financial statements to U.S. dollars and unrealized changes related to short-term investments resulted in a gain of $1,000 in 2019 compared to a loss of $2,000 for the same period in 2018.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our cost of sales, R&D and SG&A expenditures and the lack of substantial product sales revenue, we have not been profitable and have generated operating losses since we began operations. During the year ended December 31, 2019, we received net proceeds of $15,235,000 from the issuance of 1,768,012 shares of common stock under our at-the-market-issuance sales agreement, $8,674,000 and $123,000 from the exercise of warrants and stock options, respectively, and $2,000,000 in connection with the exchange agreement. We will continue to be reliant on external sources of cash for the foreseeable future until we are able to generate revenue.

In April 2019, we received net proceeds of approximately $5,100,000 from the sale of a portion of our unused New Jersey NOL for the state fiscal year 2018. The NOL was sold through the NJEDA Technology Business Tax Certificate Transfer program, which allowed us to sell approximately $5,400,000 of our total $6,100,000 in available NOL tax benefits for the state fiscal year 2018.

During January 2020, we raised approximately $2.5 million through the use of our current at-the-market program (ATM) and have approximately $2.1 million remaining under the facility. At December 31, 2019, we also had approximately $30.3 million available under our current shelf registration for the issuance of equity, debt or equity-linked securities unrelated to the current ATM program.

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 was $15,052,000 as compared to $23,701,000 in 2018, a decrease in net cash use of $8,649,000. The decrease was mainly attributable to a decrease in research and development expenses of $7,769,000, primarily due to the winding down and close out of our LOCK-100 clinical trial and the sale of our unused NOL of $5,060,000 during the year ended December 31, 2019, partially offset by decreases in accounts payable and accrued expenses for the year ended December 31, 2019 of $1,564,000 and $363,000, respectively, as compared to increases in accounts payable and accrued expenses for the same period in 2018 of $782,000 and $998,000, respectively.

Net Cash (Used in) Provided by Investing Activities

Cash used in investing activities for the year ended December 31, 2019 was $12,020,000 as compared to $1,555,000 of cash provided by investing activities for the same period in 2018. The increase in cash used during the year ended December 31, 2019 as compared to the year ended December 31, 2018 was primarily due to the purchase of short-term investments of $14,100,000 in 2019.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2019 was $25,804,000 as compared to $29,397,000 for the same period in 2018. During the year ended December 31, 2019, we recognized net proceeds of $15,235,000 from the sale of our common stock in our at-the-market, or ATM program, $8,674,000 from the exercise of warrants, $2,000,000 as part of the exchange agreement, and $123,000 from the exercise of stock options, partially offset by payment of financing fees of $227,000. In the same period last year, we recognized net proceeds of $21,968,000 from the sale of our common stock in our at-the-market program; $7,391,000 from issuance of a 10% convertible note, net of debt issuance costs of $109,000; $26,000 from the exercise of warrants; and $12,000 from the exercise of stock options.

Funding Requirements and Liquidity

Our total cash and cash equivalents and short-term investments as of December 31, 2019 was $28.3 million excluding restricted cash of $0.2 million compared with $17.6 million at December 31, 2018. At December 31, 2019, we had approximately $4.6 million available under our current at-the-market program, of which $2.5 million was utilized during January 2020, and approximately $30.3 million available under our current shelf registration for the issuance of equity, debt or equity-linked securities unrelated to the current ATM program. We may utilize our ATM program, if conditions allow, to support our activities in connection with our planned filing of the NDA for Neutrolin and for activities required for commercial launch of Neutrolin, as well as general corporate expenses.

Because our business has not generated positive operating cash flow, we will need to raise additional capital in order to continue to fund our research and development activities, as well as to fund operations generally. Our continued operations are focused primarily in activities leading to the preparation and submission of an NDA for Neutrolin to the FDA and will depend on our ability to raise sufficient funds through various potential sources, such as equity, debt financings, and/or strategic relationships and potential strategic transactions. We can provide no assurances that financing or strategic relationships will be available on acceptable terms, or at all.

We expect to continue to fund operations from cash on hand and through capital raising sources as previously described, which may be dilutive to existing stockholders, through revenues from the licensing of our products, or through strategic alliances. We expect to continue to utilize our ATM program, if conditions allow, to support our ongoing funding requirements. Additionally, we may seek to sell additional equity or debt securities through one or more discrete transactions, or enter into a strategic alliance arrangement, but can provide no assurances that any such financing or strategic alliance arrangement will be available on acceptable terms, or at all. Moreover, the incurrence of indebtedness would result in increased fixed obligations and could contain covenants that would restrict our operations. Raising additional funds through strategic alliance arrangements with third parties may require significant time to complete and could force us to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders. Our actual cash requirements may vary materially from those now planned due to a number of factors, any change in the focus and direction of our research and development programs, any acquisition or pursuit of development of new product candidates, competitive and technical advances, the costs of commercializing any of our product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights.

Sales of Neutrolin outside the U.S. are not expected to generate significant product revenues for the foreseeable future, and while we expect to grow product sales for Neutrolin in the U.S., should we receive FDA approval, such approval is not anticipated before the second half of 2020. In the absence of significant revenue, we are likely to continue generating operating cash flow deficits. We will continue to use cash as we increase other activities leading to the preparation and submission of an NDA and commercialization upon approval, pursue business development activities, and incur additional legal costs to defend our intellectual property.

We currently estimate that as of December 31, 2019 we have sufficient cash on hand to fund operations into the second quarter of 2021, including the submission of the NDA for Neutrolin and initial preparations for commercial launch. Additional financing will be required to build out our commercial infrastructure and to continue our operations should we decide to market and sell Neutrolin in the U.S. on our own. We currently anticipate that the FDA marketing approval for Neutrolin could be received in the second half of 2020. If we are unable to raise additional funds when needed, we may be forced to slow or discontinue our preparations for the commercial launch of Neutrolin. We may also be required to delay, scale back or eliminate some or all of our research and development programs. Each of these alternatives would likely have a material adverse effect on our business.

Contractual Obligations

In September 2017, we entered into a sublease agreement for approximately 6,960 square feet of office space in Berkeley Heights, New Jersey, which sublease runs from September 15, 2017 to June 29, 2020. This sublease is rent-free. A notice of an intention not to renew our current lease has been received and as a result, we are actively seeking a new space to lease that will meet our current needs.

As of December 31, 2019, we have no lease obligation.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 3 to our financial statements included with this report, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Stock-Based Compensation

We account for stock options according to the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") No. 718, "Compensation — Stock Compensation" ("ASC 718"). Share-based compensation cost is measured at grant date, based on the estimated fair value of the award using a Black-Scholes option pricing model for options with service or performance-based conditions. Stock-based compensation cost is recognized as expense, over the requisite service period on a straight-line basis.

Valuations incorporate several variables, including expected term, expected volatility, expected dividend yield and a risk-free interest rate. We estimate the expected term of the options granted based on anticipated exercises in future periods. The expected stock price volatility for the Company's stock options is calculated based on the historical volatility of the Company's common stock. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. To determine the risk-free interest rate, we utilize the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of our awards which is 5 years for employees and 10 years for non-employees.

Revenue Recognition

We adopted the new revenue recognition, ASC 606, " *Revenue from Contracts with Customers"*, as of January 1, 2018 using the modified retrospective method. ASC 606 prescribes a five-step model for recognizing revenue which includes (i) identifying contracts with customers; (ii) identifying performance obligations; (iii) determining the transaction price; (iv) allocating the transaction price; and (v) recognizing revenue.

Our product Neutrolin received its CE Mark in Europe in July 2013 and shipment of product to the dialysis centers began in December 2013. In accordance with ASC 606, we recognize revenue from product sales based on the five-step model prescribed by ASC 606 as outlined above.

Inventory Valuation

We engage third parties to manufacture and package inventory held for sale and warehouse such goods until packaged for final distribution and sale. Inventories are stated at the lower of cost or net realizable value with cost determined on a first-in, first-out basis. Inventories are reviewed periodically to identify slow-moving or obsolete inventory based on sales activity, both projected and historical, as well as product shelf-life. In evaluating the recoverability of our inventories, we consider the probability that revenue will be obtained from the future sale of the related inventory and, if required, will write down inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are recognized as cost of product sales in our consolidated statements of operations.

We analyze our inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our products is subject to strict quality controls, certain batches or units of product may no longer meet quality specifications or may expire, which would require adjustments to our inventory values.

In the future, reduced demand, quality issues or excess supply beyond those anticipated by management may result in an adjustment to inventory levels, which would be recorded as an increase to cost of product sales. The determination of whether or not inventory costs will be realizable requires estimates by our management. A critical input in this determination is future expected inventory requirements based on our internal sales forecasts which we then compare to the expiry dates of inventory on hand. To the extent that inventory is expected to expire prior to being sold, we will write down the value of inventory. If actual results differ from those estimates, additional inventory write-offs may be required.

Short-Term Investments

We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation as of each balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair values of our investments are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Our marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with maturities of more than 90 days but less than 12 months. Changes in fair value that are considered temporary are reported net of tax in other comprehensive income (loss). Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in income (expense) on the consolidated statements of operations and comprehensive income (loss). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year, if any, are classified as short-term based on management's intent to fund current operations with these securities or to make them available for current operations. For declines, if any, in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other (income) expense, net. We consider available evidence in evaluating potential impairments of our investments, including the duration and extent to which fair value is less than cost and, for equity securities, our ability and intent to hold the investments.

Fair Value Measurements

We categorize our financial instruments into a three-level fair value hierarchy that prioritize the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets (Level 1) and the lowest priority to unobservable inputs (Level 3). If the inputs used to measure fair value fall within different levels of the hierarchy, the category level is based on the lowest priority level input that is significant to the fair value measurement of the instrument. Financial assets recorded at fair value on our consolidated balance sheets are categorized as follows:

• Level 1 inputs—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

• Level 2 inputs— Significant other observable inputs (e.g., quoted prices for similar items in active markets, quoted prices for identical or similar items in markets that are not active, inputs other than quoted prices that are observable such as interest rate and yield curves, and market-corroborated inputs).

• Level 3 inputs—Unobservable inputs for the asset or liability, which are supported by little or no market activity and are valued based on management's estimates of assumptions that market participants would use in pricing the asset or liability.

Recent Authoritative Pronouncements:

In June 2016, the FASB issued new guidance which replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. We have assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have an impact on our consolidated financial statements.

In August 2018, the FASB issued a new guidance which modifies the disclosure requirements on fair value measurements. The guidance is effective for us beginning in the first quarter of fiscal year 2020. Early adoption is permitted. We have assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have a significant impact on our consolidated financial statements.

In November 2018, the FASB issued new guidance to clarify the interaction between the authoritative guidance for collaborative arrangements and revenue from contracts with customers. The new guidance clarifies that, when the collaborative arrangement participant is a customer in the context of a unit-of-account, revenue from contracts with customers guidance should be applied, adds unit-of-account guidance to collaborative arrangements guidance, and requires, that in a transaction with a collaborative arrangement participant who is not a customer, presenting the transaction together with revenue recognized under contracts with customers is precluded. The guidance is effective for us beginning in the first quarter of fiscal year 2020. Early adoption is permitted. We have assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have an impact on our consolidated financial statements.

In November 2019, the FASB issued new guidance which requires that an entity measure and classify share-based payment awards granted to a customer by applying the guidance in ASC 718. The guidance is effective for us beginning in the first quarter of fiscal year 2020. Early adoption is permitted. We have assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have an impact on our consolidated financial statements.

In December 2019, the FASB issued new guidance which removes certain exceptions to the general principles of the accounting for income taxes and also improves consistent application of and simplification of other areas when accounting for income taxes. The guidance is effective for us beginning in the first quarter of fiscal year 2021. Early adoption is permitted. We are assessing the impact of adopting this guidance on our consolidated financial statements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

See the financial statements included at the end of this report beginning on page F-1.

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

Not applicable.

Item 9A. Controls and Procedures

As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Exchange Act Rules 13a-15(e) and 15d-15(e)) (the “Exchange Act”). Based on the foregoing evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during our fourth quarter ended December 31, 2019, or in other factors that could significantly affect these controls, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements in accordance with U.S. generally accepted accounting principles.

Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

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

In connection with the preparation of our annual consolidated financial statements, management, including, our Principal Executive and Financial Officer, has undertaken an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2019, based on the criterial established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2019.

Our independent registered public accounting firm, Friedman, LLP, has expressed an opinion on our internal control over financial reporting as of December 31, 2019 in the audit report which is included herein.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of CorMedix Inc.

Opinion on Internal Control over Financial Reporting

We have audited CorMedix Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the two years in the period ended December 31, 2019, and our report dated March 16, 2020, expressed an unqualified opinion on the consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting appearing under item 9A. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Friedman LLP

Marlton, NJ
March 16, 2020

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

We have adopted a written Code of Conduct and Ethics that applies to our directors, executive officers and all employees. We intend to disclose any amendments to, or waivers from, our code of ethics and business conduct that are required to be publicly disclosed pursuant to rules of the SEC by filing such amendment or waiver with the SEC. This code of ethics and business conduct can be found in the "Investors - Corporate Governance" section of our website, *www.cormedix.com*.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in the ownership of our common stock and other equity securities. Such persons are required to furnish us copies of all Section 16(a) filings. Based solely upon a review of the copies of the forms furnished to us, we believe that our officers, directors and holders of more than 10% of our common stock complied with all applicable filing requirements during the fiscal year ended December 31, 2019, with the exception of the Form 3 for Dr. Mounts, which was due on May 13, 2019 and filed on May 24, 2019.

Directors

The following table sets forth the name, age and position of each of our directors as of December 31, 2019:

Name	Age	Director Since	Position(s) with CorMedix
Khoso Baluch	61	October 2016	Director and Chief Executive Officer
Janet M. Dillione	60	August 2015	Director
Alan Dunton	65	February 2019	Director
Myron Kaplan	74	April 2016	Chairman of the Board
Mehmood Khan	61	June 2017	Director
Steven Lefkowitz	63	June 2017	Director

Khoso Baluch joined our Board in October 2016 upon his appointment as our Chief Executive Officer. As of February 1, 2020, he is serving as our acting Principal Financial Officer and Principal Accounting Officer. Mr. Baluch previously served as Senior Vice President and President Europe, Middle East & Africa of UCB, SA, or UCB, from January 2015 to April 2016, Senior Vice President and President of the European Region of UCB from February 2013 to December 2014, and Senior Vice President and Chief Marketing Officer of UCB from January 2010 to February 2013. Prior to joining UCB, Mr. Baluch worked for Eli Lilly and Company for 24 years, holding international positions spanning Europe, the Middle East and the United States in general management, business development, market access and product leadership. He has served as an independent director of Poxel SA, a French publicly traded biotech company, since 2013, and chairs its compensation committee. He also serves as a member of the business development and scientific committees of Poxel SA. Mr. Baluch holds a BSc in Aeronautical Engineering from City University London and a Masters of Business Administration from Cranfield School of Management. Among other qualifications, attributes and skills, Mr. Baluch's business expertise and significant executive management experience in the pharmaceutical industry led to the conclusion of our Board that he should serve as a director of our Company in light of our business and structure.

Janet Dillione has been a director of CorMedix since August 2015. From May 2014 until May 2019, Ms. Dillione served as the Chief Executive Officer of Bernoulli Enterprise (formerly known as Cardiopulmonary Corp.), a leader in medical device connectivity for EMR integration, and integrated clinical applications and workflows for over 25 years. Previously, she was at Nuance Communications, Inc., a leading provider of voice and language solutions for businesses and consumers around the world, having joined Nuance in April 2010 as Executive Vice President and General Manager of the Healthcare Division and serving as an executive officer from March 2010 until May 2014. From June 2000 to March 2010, Ms. Dillione held several senior level management positions at Siemens Medical Solutions, a global leader in medical imaging, laboratory diagnostics, and healthcare information technology, including President and CEO of the global healthcare IT division. Ms. Dillione received her B.A. from Brown University in 1981 and completed the Executive Program at The Wharton School of Business of the University of Pennsylvania in 1998. She has over 25 years of experience leading global teams in the development and delivery of healthcare technology and services. She is a member of the board of CortiCare, a private U.S. based company. Among other qualifications, attributes and skills, Ms. Dillione's financial expertise and significant executive management experience with medical device and healthcare companies led to the conclusion of our Board that she should serve as a director of our Company in light of our business and structure.

Alan W. Dunton, M.D. has been a director of CorMedix since March 2019. In 2006, Dr. Dunton founded Danerius, LLC, a biotechnology and pharmaceutical consulting business. From November 2015 through March 2018, Dr. Dunton was the Head/Senior Vice President of Research, Development and Regulatory Affairs of Purdue Pharma L.P., a private pharmaceutical company. From January 2007 through March 2009, Dr. Dunton served as President and Chief Executive Officer of Panacos Pharmaceuticals, Inc. From 2003 until 2006, Dr. Dunton was the President and Chief Executive Officer of Metaphore Pharmaceuticals, Inc., until it merged with ActivBiotics. He was also President and Managing Director of the Janssen Research Foundation, the research and development and regulatory arm of the pharmaceuticals division at Johnson & Johnson. Dr. Dunton received his Bachelor of Science degree in biochemistry, magna cum laude, from State University of New York at Buffalo, and received his M.D. from New York University School of Medicine. In addition to CorMedix, Dr. Dunton currently serves on the boards of two public companies, Palatin Technologies, Inc. and Oragenics, Inc. and chairs the compensation committees of both companies. He also serves as a member of the audit committees of these companies. Additionally, Dr. Dunton is a member of the board of Cytogel Pharma LLC, a private bio-pharmaceutical development company focused on acquiring promising early-stage programs, and Regeneus, Ltd., an Austrian public company listed on the ASX. Among other qualifications, Dr. Dunton's significant depth of experience in the pharmaceutical industry, including service as a director of public pharmaceutical companies, led to the conclusion of our Board that he should serve as a director of our Company in light of our business and structure.

Myron Kaplan became a director of CorMedix in April 2016. He is a founding partner of Kleinberg, Kaplan, Wolff & Cohen, P.C., a New York City general practice law firm, where he has practiced corporate and securities law for more than forty years. In 2012, Mr. Kaplan became a trustee of the Lehman Brothers Plan Holding Trust. Previously, he served as a member of the board of directors of SAirGroup Finance (USA) Inc., a subsidiary of SAirGroup that had publicly issued debt securities, Trans World Airlines, Inc. and Kitty Hawk, Inc. Among his business and civic involvements, Mr. Kaplan currently serves on the boards of directors of a number of private companies and has been active for many years on the boards of trustees and various board committees of The Children's Museum of Manhattan and JBI International (formerly The Jewish Braille Institute of America). Mr. Kaplan graduated from Columbia College and holds a Juris Doctor from Harvard Law School. Among other experience, qualifications, attributes and skills, Mr. Kaplan's experience in a broad range of corporate and securities matters and service as a director of public companies led to the conclusion of our Board that he should serve as a director of our Company in light of our business and structure.

Mehmood Khan, M.D. became a director of CorMedix in June 2017. Since March 2019, Dr. Khan has been the Chief Executive Officer of Life Biosciences Inc. Until March 2019, Dr. Khan served as Vice Chairman (from January 2015) and Chief Scientific Officer of Global Research and Development (from December 2007) for PepsiCo, Inc., where he led global R&D and oversaw the company's 2025 sustainability agenda, which includes plans for the further transformation of its current food and beverage portfolio as well as expansion of offerings containing positive nutrition with a focus on reaching more underserved communities and consumers with healthier choices. Prior positions at PepsiCo included Chief Executive Officer, Global Nutrition Group from January 2011 to September 2013. Previously, Dr. Khan served as Head of Medical Affairs and then President of Takeda Pharmaceuticals' Global Research & Development Center from January 2002 to December 2007. Earlier in his career Dr. Khan was a faculty member at the Mayo Clinic and Mayo Medical School in Rochester, Minnesota, serving as Director of the Diabetes, Endocrine and Nutritional Trials Unit in the division of endocrinology. Prior to the Mayo Clinic, Dr. Khan spent nine years leading programs in diabetes, endocrinology, metabolism, and nutrition for the Hennepin County Medical Center in Minneapolis. His practice included extensive work with patients with diabetes requiring hemodialysis as well as parenteral nutrition. Dr. Khan also currently serves as a member of the board of directors of one public company, Reckitt Benckiser Group PLC, which is listed on the London Stock Exchange. Dr. Khan also currently serves as a member of the board of directors for several private companies, HemoShear Therapeutics, LLC, Indigo Ag, Inc., Life Biosciences Inc. and Spectrum Health System. Dr. Khan serves as a member of the compensation committee of the board of directors for Indigo Ag, Inc. and a member of the audit committee of the board of directors for both of Indigo Ag, Inc. and Spectrum Health System. He earned his medical degree from the University of Liverpool Medical School, England. Among other qualifications, attributes and skills, Dr. Khan's business expertise and significant executive management experience, as well as his medical background and pharmaceutical company experience led to the conclusion of our Board that he should serve as a director of our Company in light of our business and structure.

Steven Lefkowitz was a director of CorMedix from August 2011 to June 2016. He was reappointed to the Board in June 2017. He also served as our acting Chief Financial Officer from August 2013 to July 2014. Mr. Lefkowitz has been the President and Founder of Wade Capital Corporation, a financial advisory services company, since June 1990. Mr. Lefkowitz has been a director of both public and private companies. Mr. Lefkowitz received his A.B. from Dartmouth College in 1977 and his M.B.A. from Columbia University in 1985. Among other experience, qualifications, attributes and skills, Mr. Lefkowitz's education, experience and financial expertise led to the conclusion of our Board that he should serve as a director of our Company in light of our business and structure.

Board Independence

Our Board has undertaken a review of the independence of our directors and has determined that (i) all current directors except Khoso Baluch are independent within the meaning of Section 803A(2) of the NYSE American Rules, (ii) all members of our Audit Committee meet the additional test for independence for audit committee members imposed by SEC regulation and Section 803B(2) of the NYSE American Rules, (iii) all of the members of our Compensation Committee are independent within the meaning of Section 805(c) of the NYSE American Rules, and (iv) all of the members of our Nominating and Governance Committee are independent within the meaning of Section 805(c) of the NYSE American Rules.

Board Committees

Our Board has established an Audit Committee, Compensation Committee and Nominating and Governance Committee. Our Audit Committee currently consists of Mr. Lefkowitz (Chair), Dr. Dunton and Ms. Dillione. Our Compensation Committee currently consists of Ms. Dillione (Chair), Dr. Dunton and Mr. Lefkowitz. Our Nominating and Governance Committee currently consists of Dr. Khan (Chair) and Mr. Kaplan. The membership of these Committees may be changed after the annual meeting.

Each of the above-referenced committees operates pursuant to a formal written charter. The charters for each committee, which have been adopted by our Board, contain a detailed description of the respective committee's duties and responsibilities and are available on our website at www.cormedix.com under the "Investor Relations—Corporate Governance" tab.

Audit Committee

The Audit Committee monitors our corporate financial statements and reporting and our external audits, including, among other things, our internal controls and audit functions, the results and scope of the annual audit and other services provided by our independent registered public accounting firm and our compliance with legal matters that have a significant impact on our financial statements. The Audit Committee also consults with our management and our independent registered public accounting firm prior to the presentation of financial statements to stockholders and, as appropriate, initiates inquiries into aspects of our financial affairs. The Audit Committee is responsible for establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters, and for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters. In addition, the Audit Committee is directly responsible for the appointment, retention, compensation and oversight of the work of our independent registered public accounting firm, including approving services and fee arrangements. All related party transactions will be approved by the Audit Committee before we enter into them.

Both our independent registered public accounting firm and internal financial personnel regularly meet with, and have unrestricted access to, the Audit Committee.

The Board has determined that each of Mr. Lefkowitz, Dr. Dunton and Ms. Dillione qualifies as an "audit committee financial expert" as that term is defined in the rules and regulations of the SEC. The designation of each of Mr. Lefkowitz, Dr. Dunton and Ms. Dillione as an "audit committee financial expert" does not impose on them any duties, obligations or liability that are greater than those that are generally imposed on them as a member of the Audit Committee and the Board, and their designation as an "audit committee financial expert" pursuant to this SEC requirement does not affect the duties, obligations or liability of any other member of the Audit Committee or the Board.

Compensation Committee

The Compensation Committee reviews and approves our compensation policies and all forms of compensation to be provided to our executive officers and directors, including, among other things, annual salaries, bonuses, and other incentive compensation arrangements. In addition, the Compensation Committee administers our stock option and employee stock purchase plans, including granting stock options to our executive officers and directors. The Compensation Committee also reviews and approves employment agreements with executive officers and other compensation policies and matters.

Since 2016, we have periodically engaged Frederic W. Cook & Co., an independent compensation consultant, for input on the compensation of our Named Executive Officers and directors. The Compensation Committee assessed the independence of Frederic W. Cook & Co., considering the factors required by the NYSE American Rules and concluded that no conflict of interest exists that would prevent Frederic W. Cook & Co. from independently representing our Company. In the future, we, or the Compensation Committee, may engage or seek the advice of Frederic W. Cook & Co., or another compensation consultant.

Each member of the Compensation Committee is a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue of 1986, as amended (the "Code").

Nominating and Governance Committee

The Nominating and Governance Committee identifies, evaluates and recommends nominees to the Board and committees of the Board, conducts searches for appropriate directors and evaluates the performance of the Board and of individual directors. The Nominating and Governance Committee also is responsible for reviewing developments in corporate governance practices, evaluating the adequacy of our corporate governance practices and reporting and making recommendations to the Board concerning corporate governance matters.

Executive Officers

The following table sets forth information concerning our current executive officers:

Name	Age	Position(s) with CorMedix
Khoso Baluch	62	Chief Executive Officer
Phoebe Mounts	69	Executive Vice President and General Counsel and Head of Regulatory, Compliance and Legal
John Armstrong	75	Executive Vice President for Technical Operations
Elizabeth Masson-Hurlburt	40	Executive Vice President and Head of Clinical Operations

See the biography for ***Khoso Baluch*** under "Directors."

Phoebe Mounts became our Executive Vice President and General Counsel and Head of Regulatory, Compliance and Legal in May 2019. Prior to her employment with us, Dr. Mounts was a partner at Morgan, Lewis & Bockius LLP, where she provided legal counsel to life sciences companies for over 20 years. As part of her work at Morgan Lewis, Dr. Mounts had been providing us legal services as outside counsel since 2013, with responsibility for developing our FDA regulatory strategies for Neutrolin. Prior to graduating from Georgetown University Law Center, Dr. Mounts was on the faculty of the Johns Hopkins University School of Public Health for 16 years, specializing in molecular biology and infectious disease. She received her Ph.D. in molecular biology from the University of Edinburgh in Scotland.

John Armstrong became our Executive Vice President for Technical Operations in March 2017. Prior to that, he was employed by us as a consultant beginning in November 2014, performing the same services that he now performs as our Executive Vice President for Technical Operations. Jack has over 45 years' experience in the pharmaceutical industry with broad senior level cross functional experience and has held a number of general management positions. Most recently, from August 2010 to January 2013, he was President, Operations for Correvio, a private pharmaceutical company supplying product to over 50 countries, and prior positions include President/CEO of Genaera Corporation, Sr. Vice President of Urocor Corporation, CEO of Mills Biopharma, President of Oread CMO, President of Endo Laboratories (subsidiary of DuPont Merck), President of World-wide Manufacturing for DuPont Merck Pharmaceuticals, Vice President Operations for Marion/ Marion Merrill Dow, and he has held varied roles in manufacturing, quality assurance, and integrated business systems development for three companies, as well as having expertise in business development. Mr. Armstrong holds a B.S. from Juniata College and an executive M.B.A. from Century University. He is also a CPIM (Certified in Production and Inventory Management).

Elizabeth Masson-Hurlburt became our Executive Vice President and Head of Clinical Operations in March 2018. Prior to her employment, Ms. Masson-Hurlburt had been providing us clinical operations expertise as a consultant since late November 2017. Before she began her consulting career, she held several progressive management roles in clinical operations, most recently at Gemphire Therapeutics, as a Senior Director, Clinical Operations from April 2015 to October 2016, then as Vice President, Clinical Operations from October 2016 to March 2018. Ms. Masson-Hurlburt received her B.A. in Leadership and Organizational Management from Bay Path College.

Item 11. Executive Compensation

DIRECTOR COMPENSATION

Director Compensation in Fiscal 2019

The following table shows the compensation earned by each non-employee director of our company for the year ended December 31, 2019.

Name	Fees Earned ($)	Option Awards [1] [2] ($)	Restricted Stock Units Awards [1] [3] ($)	Total ($)
Janet M. Dillione	36,500[4]	95,250	29,050	160,800
Alan Dunton	29,334	182,542	11,188	223,064
Myron Kaplan	40,250	95,250	70,550	206,050
Mehmood Khan	31,500	95,250	25,730	152,480
Steven Lefkowitz	36,250	95,250	49,800	181,300

(1) The amounts included in this column are the dollar amounts representing the full grant date fair value of each stock option award or restricted stock unit award calculated in accordance with FASB ASC Topic 718 and do not represent the actual value that may be recognized by the directors upon option exercise or payment of restricted stock units. For information on the valuation assumptions used in calculating these amounts, see Note 8 to our audited financial statements included in this Annual Report on Form 10-K.

(2) As of December 31, 2019, the number of shares underlying options held by each non-employee director was as follows: 60,000 shares for Ms. Dillione; 27,500 shares for Dr. Dunton; 41,000 shares for Mr. Kaplan; 38,000 shares for Dr. Khan; and 38,000 shares for Mr. Lefkowitz.

(3) As of December 31, 2019, the number of restricted stock units held by each non-employee director was as follows: 292 shares for Ms. Dillione; 730 shares for Dr. Dunton; 709 shares for Mr. Kaplan; 259 shares for Dr. Khan; and 500 shares for Mr. Lefkowitz.

(4) Includes fees of $36,500 for Ms. Dillione that were deferred. See “Director Compensation Plan” below for a description of the deferral plan pursuant to which the deferrals were made.

Director Compensation Plan

In July 2014, we adopted a Deferred Compensation Plan for Directors, pursuant to which our non-employee directors may defer all of their cash director fees and restricted stock units. Any cash fees due a participating director will be converted into a number of shares of our common stock by dividing the dollar amount of fees payable by the closing price of our common stock on the date such fees would be payable, and the director’s unfunded account would be credited with the shares. The shares that accumulate in a director’s account will be paid to the director on the tenth business day in January following the year in which the director’s service terminates for whatever reason, other than death, in which case the account will be paid within 30 days of the date of death. In the event of a change in control of our Company, the director would receive cash in an amount equal to the number of shares in the account multiplied by the fair market value of our common stock on the change in control date, and the payment would be accelerated to five business days after the effective date of the change in control.

In late 2016 and again in late 2018, with the assistance of Frederic W. Cook & Co., the Compensation Committee reviewed a peer group of 14 public companies, which group was used by Frederic W. Cook & Co. to conduct a compensation study for purposes of establishing director compensation. The composition of the peer group was based on the following criteria: (i) companies operating in a similar industry sector, (ii) publicly traded companies, (iii) companies of similar size, and (iv) companies of similar business operation and stage of research and development. The Compensation Committee also used this data in various combinations in an effort to establish director compensation that reflects our particular facts and circumstances.

In February 2017, based upon the information provided by Frederic W. Cook & Co. in late 2016, we adopted a cash and equity compensation program for non-employee directors.

In December 2018, as a result of the 2018 compensation study provided by Frederic W. Cook & Co., we determined that our non-employee director compensation program was significantly below market. Accordingly, we increased compensation levels effective January 1, 2019 to bring non-employee director compensation closer to our peer group. Effective as of July 1, 2019, we implemented Board committee fees (differentiating fees between heads of committees and committee members) to recognize the substantial work done by our Board committees. As of January 1, 2020, we will discontinue granting restricted stock units to non-employee directors and will correspondingly increase the cash retainers, in order to bring the compensation program more in line with the forms of payment provided by peer companies and to minimize dilution. Each of the 2019 and 2020 compensation programs are set forth below in the table. All equity awards are subject to continued service on the Board through the vesting date. The exercise price per share of each stock option granted to our non-employee directors is equal to the fair market value of our common stock as determined in good faith by our Board on the date of the grant.

	Effective January 1, 2019 to December 31, 2019			Effective January 1, 2020		
	Cash	Stock Options	Number of Restricted Stock Units	Cash	Stock Options	Number of Restricted Stock Units
Annual Fee	$ 25,000			$ 55,000		
First Election to Board		20,000(1)			20,000(1)	
Annual Grant, Prorated in First Year Following Election to the Board		15,000(2)	Lesser of 2,500 units or $30,000 divided by stock price on grant date (2)		15,000(2)	
Additional Annual Fee - Board Chair	$ 8,000(3)		Lesser of 3,000 units or $30,000 divided by stock price on grant date (2)	$ 45,000		
Additional Annual Fee - Audit Chair	$ 8,000(3)		Lesser of 1,500 units or $15,000 divided by stock price on grant date (2)	$ 23,000		
Additional Annual Fee - Compensation Chair	$ 8,000(3)		Lesser of 1,000 units or $10,000 divided by stock price on grant date (2)	$ 18,000		
Additional Annual Fee - Nomination and Governance Chair	$ 8,000(3)		Lesser of 600 units or $6,000 divided by stock price on grant date (2)	$ 14,000		
Additional Annual Fee - Strategic Finance Committee has two Co-Chairs (4)			Lesser of 2,000 units or $10,000 divided by stock price on grant date (2)	$20,000 each (if continued after its current expiration date of December 31, 2019)		
Annual Fee - Audit Committee Non-Chair Members (4)	$ 10,000			$ 10,000		
Annual Fee - Compensation Committee Non-Chair Members (4)	$ 7,000			$ 7,000		
Annual Fee - Nomination and Governance Committee Non-Chair Members (4)	$ 5,000			$ 5,000		

(1) Vest one third each on the date of grant and the first and second anniversary date of grant.
(2) Vest monthly over one year after the grant date.
(3) Increased from $5,000 effective July 1, 2019.
(4) Effective July 1, 2019.

Components of Compensation

The key components of our executive compensation package are cash compensation (salary and annual bonuses), long-term equity incentive awards and change in control and other severance agreements. These components are administered with the goal of providing total compensation that recognizes meaningful differences in individual performance, is competitive, varies the opportunity based on individual and corporate performance, and is valued by our Named Executive Officers. For 2019, our Named Executive officers were Khoso Baluch, Phoebe Mounts, John Armstrong, Elizabeth Masson-Hurlburt and our former Chief Financial Officer, Robert W. Cook, who served in such capacity until January 31, 2020.

Base Salary

It is the Compensation Committee's objective to set a competitive rate of annual base salary for each Named Executive Officer. The Compensation Committee believes competitive base salaries are necessary to attract and retain top quality executives, since it is common practice for public companies to provide their named executive officers with a guaranteed annual component of compensation that is not subject to performance risk. The Compensation Committee, on its own or with outside consultants, may establish salary ranges for the Named Executive Officers, with minimum to maximum opportunities that cover the normal range of market variability. The actual base salary for each Named Executive Officer is then derived from those salary ranges based on his or her responsibility, tenure and past performance and market comparability. Annual base salaries for the Named Executive Officers are reviewed and approved by the Compensation Committee in the first quarter following the end of the previous performance year. Changes in base salary are based on the scope of an individual's current job responsibilities, individual performance in the previous performance year, target pay position relative to the peer group, and our salary budget guidelines. The Compensation Committee reviews established goals and objectives and determines an individual's achievement of those goals and objectives and considers the recommendations provided by the Chief Executive Officer to assist it in determining appropriate salaries for the Named Executive Officers other than the Chief Executive Officer.

The base salary information for our Named Executive Officers for 2018 and 2019 is set forth in the Summary Compensation Table below. In September 2019, February 2017, March 2019, March 2017 and March 2018, respectively, we entered into an employment agreement with each of Khoso Baluch, our Chief Executive Officer, Robert Cook, our Chief Financial Officer (at such time), Phoebe Mounts, our Executive Vice President and General Counsel and Head of Regulatory, Compliance and Legal, John Armstrong, our Executive Vice President for Technical Operations, and Elizabeth Masson-Hurlburt, our Executive Vice President and Head of Clinical Operations. These agreements provide for a salary for each Named Executive Officer and are described under the caption "Employment Agreements."

Annual Bonuses

As part of their compensation package, our Named Executive Officers generally have the opportunity to earn annual non-equity incentive bonuses. Annual non-equity bonuses are designed to reward superior executive performance while reinforcing our short-term strategic operating goals. The Compensation Committee establishes each year a corporate target award for the Named Executive Officers based on a percentage of base salary and any applicable terms in any individual employment agreements. Annual bonus targets as a percentage of salary increase with executive rank so that for the more senior executives, a greater proportion of their total cash compensation is contingent upon annual performance.

At the beginning of the performance year, the Named Executive Officers, in conjunction with the Chief Executive Officer, establish annual corporate goals and objectives. Actual bonus awards for each Named Executive Officer are based on the achievement of the pre-established corporate goals. For any given performance year, proposed annual bonuses may range from 0% to 100% of target, or higher under certain circumstances, based solely on the achievement of corporate objectives. Corporate performance has a significant impact on the annual bonus amounts because the Compensation Committee believes it is a precise measure of how the Named Executive Officer contributed to business results.

Pursuant to their respective employment agreements, Messrs. Baluch and Armstrong, Ms. Masson-Hurlburt and Dr. Mounts are each eligible for an annual bonus, which may equal up to 80%, 30%, 35%, 30% and 30%, respectively, of his or her base salary then in effect, as determined by our Board or Compensation Committee. In determining such bonus, our Board or Compensation Committee will take into consideration the achievement of specified Company objectives, predetermined by the Board in consultation with the Chief Executive Officer.

Long-Term Incentive Equity Awards

We believe that long-term performance is achieved through an ownership culture that encourages high performance by our Named Executive Officers through the use of stock-based awards. Our 2006 Plan and our 2013 Plan were each established to provide our employees, including our Named Executive Officers, with incentives to help align employees' interests with the interests of our stockholders. Effective upon the approval by our stockholders of our 2013 Plan and 2019 Plan, we were no longer able to issue any award under the 2006 Plan and 2013 Plan, respectively. The compensation committee believes that the use of stock-based awards offers the best approach to achieving our compensation goals. We have historically elected to use stock options as the primary long-term equity incentive vehicle; however, the compensation committee has used restricted stock in the past and may in the future utilize restricted stock as part of our long-term incentive program. We have selected the Black-Scholes method of valuation for share-based compensation. Due to the early stage of our business and our desire to preserve cash, we may provide a greater portion of total compensation to our Named Executive Officers through stock options and restricted stock grants than through cash-based compensation. The Compensation Committee generally oversees the administration of our 2006 Plan and our 2013 Plan and 2019 Plan.

Stock Options

Our 2019 Omnibus Stock Incentive Plan approved by the shareholders on November 26, 2019, (and formerly our 2013 and 2006 Stock Plans) authorizes us to grant options to purchase shares of common stock to our employees, directors and consultants.

The Compensation Committee reviews and approves stock option awards to Named Executive Officers based upon a review of competitive compensation data, its assessment of individual performance, a review of each Named Executive Officer's existing long-term incentives, and retention considerations. Periodic stock option grants are made at the discretion of the Compensation Committee to eligible employees and, in appropriate circumstances, the Compensation Committee considers the recommendations of our Chief Executive Officer.

Stock options granted to employees have an exercise price equal to the fair market value of our common stock on the day of grant, typically vest over a time or upon the achievement of certain performance-based milestones and are based upon continued employment, and generally expire 10 years after the date of grant. The fair value of the options granted to the Named Executive Officers in the Summary Compensation Table is determined in accordance with the Black-Scholes method of valuation for share-based compensation. Incentive stock options also include certain other terms necessary to ensure compliance with the Code.

We expect to continue to use stock options as a long-term incentive vehicle because:

- Stock options align the interests of our Named Executive Officers with those of our stockholders, supporting a pay-for performance culture, foster employee stock ownership, and focus the management team on increasing value for our stockholders.
- Stock options are performance-based. All of the value received by the recipient of a stock option is based on the growth of the stock price. In addition, stock options can be issued with vesting based on the achievement of specified milestones.
- Stock options help to provide balance to the overall executive compensation program as base salary and annual bonuses focus on short-term compensation, while the vesting of stock options increases stockholder value over the longer term.
- The vesting period of stock options encourages executive retention and the preservation of stockholder value. In determining the number of stock options to be granted to our Named Executive Officers, we take into account the individual's position, scope of responsibility, ability to affect profits and stockholder value and the individual's historic and recent performance and the value of stock options in relation to other elements of the individual Named Executive Officer's total compensation.

Restricted Stock

Our 2019 Omnibus Stock Incentive Plan (and formerly our 2013 and 2006 Stock Plans) authorizes us to grant restricted stock. In order to implement our long-term incentive goals, we may grant shares of restricted stock in the future.

Executive Benefits and Perquisites

Our Named Executive Officers are parties to employment agreements, as described below. In addition, consistent with our compensation philosophy, we intend to continue to maintain our current benefits for our Named Executive Officers, including medical, dental and life insurance and the ability to contribute to a 401(k) plan; however, the Compensation Committee in its discretion may revise, amend or add to the officer's executive benefits if it deems it advisable. We believe these benefits are currently comparable to benefit levels for comparable companies.

Employment Agreements

Employment Agreements with Current Named Executive Officers

On September 27, 2016, we entered into an employment agreement with Khoso Baluch, our Chief Executive Officer, which, upon its expiration in September 2019, was replaced with a new agreement, dated September 26, 2019, that is nearly identical to the old agreement (except as noted below). On March 1, 2017, we entered into an employment agreement with John Armstrong to serve as our Executive Vice President for Technical Operations. On March 19, 2018, we entered into an employment agreement with Elizabeth Masson-Hurlburt to serve as our Executive Vice President and Head of Clinical Operations. On March 19, 2019, we entered into an employment agreement with Phoebe Mounts to serve as our Executive Vice President and General Counsel effective May 1, 2019.

After the initial three-year term of each employment agreement, the agreement will automatically renew for additional successive one-year periods, unless either party notifies the other in writing at least 90 days before the expiration of the then current term that the agreement will not be renewed.

On January 30, 2017, we entered into an employment agreement, effective February 1, 2017, with Robert Cook to serve as our Chief Financial Officer. On November 6, 2019, Mr. Cook and the Company mutually agreed not to renew his employment agreement, which expired on January 31, 2020. Mr. Cook will assist the Company in transitioning his responsibilities.

Pursuant to their respective agreements, Mr. Baluch receives an annual salary of $375,000 (amended to $425,000 in September 2019), Mr. Armstrong an annual salary of $310,000, Ms. Masson-Hurlburt an annual salary of $280,000, and Dr. Mounts an annual salary of $350,000, which cannot be decreased unless all officers and/or members of our executive management team experience an equal or greater percentage reduction in base salary and/or total compensation, provided that any reduction in an executive's salary may be no greater than 25%. Each executive will be eligible for an annual bonus, which may equal up to 80% for Mr. Baluch (effective September 2019, pursuant to Mr. Baluch's new agreement, the target amount is 80%, but the bonus may exceed that amount), up to 35% for Mr. Armstrong, up to 30% for Ms. Masson-Hurlburt, and up to 30% for Dr. Mounts, of his or her base salary then in effect, as determined by our Board or the Compensation Committee. In determining such bonus, our Board or the Compensation Committee will take into consideration the achievement of specified Company objectives, predetermined by our Board and Chief Executive Officer, in the case of Mr. Baluch, and by our Chief Executive Officer in the case of Mr. Armstrong, Ms. Masson-Hurlburt, and Dr. Mounts, and approved by the Board or the Compensation Committee, and personal objectives, for each executive. For fiscal year 2018, Ms. Masson-Hurlburt's bonus was prorated, and for fiscal year 2019, Dr. Mounts' bonus was contingent upon each meeting performance objectives. Each executive must be employed through December 31 of a given year to be eligible to earn that year's annual bonus.

The following provisions of the employment agreements with Messrs. Baluch and Armstrong, Ms. Masson-Hurlburt and Dr. Mounts are identical except where noted.

If we terminate the executive's employment for Cause (as defined below), the executive will be entitled to receive only the accrued compensation due to him or her as of the date of such termination, rights to indemnification and directors' and officers' liability insurance, and as otherwise required by law. All unvested equity awards then held by any executive, as well as, in the case of Mr. Baluch, any vested equity awards granted after September 26, 2019, will be forfeited to us as of such date.

If we terminate the executive's employment other than for Cause, death, or disability, other than by notice of nonrenewal, or if the executive resigns for Good Reason (as defined below) (each such termination, a "Qualifying Termination"), including in each case within 24 months of a Change of Control (as defined in the agreement, which is the same definition as in our 2013 Plan), the executive will receive the following benefits: (i) payment of any accrued compensation and any unpaid bonus for the prior year, as well as rights to indemnification and directors' and officers' liability insurance and any rights or privilege otherwise required by law; (ii) we will continue to pay his or her base salary and benefits for a period of twelve months in the case of Mr. Baluch and nine months for the other executives following the effective date of the termination of employment; (iii) payment on a prorated basis for any target bonus for the year of termination based on the actual achievement of the specified bonus objectives; (iv) if the executive timely elects continued health insurance coverage under COBRA, then we will pay the premium to continue such coverage for him or her and his or her eligible dependents in an amount equal to the portion paid for by us during the executive's employment until the conclusion of the time when he or she is receiving continuation of base salary payments or until he or she becomes eligible for group health insurance coverage under another employer's plan, whichever occurs first, provided however that we have the right to terminate such payment of COBRA premiums on behalf of the executive and instead pay him a lump sum amount equal to the COBRA premium times the number of months remaining in the specified period if we determine in our discretion that continued payment of the COBRA premiums is or may be discriminatory under Section 105(h) of the Code; and (v) in the case of Mr. Baluch, all restricted shares and time-based stock options, and in the case of Ms. Masson-Hurlburt, all unvested time-based stock options that are scheduled to vest on or before the next succeeding anniversary of the date of termination shall be accelerated and deemed to have vested as of the termination date. The separation benefits set forth above are conditioned upon the executive executing a release of claims against us, our parents, subsidiaries, and affiliates, and each such entities' officers, directors, employees, agents, successors, and assigns in a form acceptable to us, within a time specified therein, which release is not revoked within any time period allowed for revocation under applicable law.

For purposes of the agreement, "Cause" is defined as: (i) the willful failure, disregard, or refusal by the executive to perform his or her material duties or obligations under the agreement (other than as a result of executive's mental incapacity or illness, as confirmed by medical evidence provided by a physician selected by us) that, in the case of Mr. Armstrong, and Ms. Masson-Hurlburt, is not cured, to the extent subject to cure, by the executive to our reasonable satisfaction within 30 days after we gave written notice thereof to executive; (ii) any willful, intentional, or grossly negligent act by the executive having the effect of materially injuring (whether financially or otherwise) our business or reputation or any of our affiliates; (iii) executive's conviction of any felony involving moral turpitude (including entry of a guilty or nolo contendere plea); (iv) the executive's qualification as a "bad actor," as defined by 17 CFR 230.506(a); (v) the good faith determination by the Board, after a reasonable and good-faith investigation by us that the executive engaged in some form of harassment or discrimination prohibited by law (including, without limitation, harassment on the basis of age, sex or race) unless the executive's actions were specifically directed by the Board; (vi) any material misappropriation or embezzlement by the executive of our or our affiliates' property (whether or not a misdemeanor or felony); or (vii) material breach by the executive of the agreement that is not cured, to the extent subject to cure, by executive to our reasonable satisfaction within 30 days after we give written notice thereof to the executive (20 days in the case of Mr. Baluch).

For purposes of the agreement, "Good Reason" is defined as: (i) any material breach of the agreement by us; (ii) any material diminution by us of the executive's duties, responsibilities, or authority; (iii) a material reduction in the executive's annual base salary unless all officers and/or members of our executive management team experience an equal or greater percentage reduction in annual base salary and/or total compensation, provided that, for Mr. Baluch, any reduction may be no greater than 25%; (iv) in the case of Mr. Armstrong, a required relocation of the primary place of performance of the executive's duties to a location more than 50 miles from our then location in Bedminster, New Jersey, provided that a change in the location of the primary place of performance of the executive's duties will not constitute Good Reason if such change occurs prior to a change in control and we only require the executive to physically work at that new location two days or less per workweek and provide reimbursement of the executive's reasonable travel expenses in commuting to such new location; or (v) a material reduction in the executive's target bonus level unless all officers and/or members of our executive management team experience an equal or greater percentage reduction related to target bonus levels, provided that, for Mr. Baluch, any reduction may be no greater than 25%.

If the executive terminates his or her employment by written notice of termination or if the executive or we terminate his or her employment by providing a notice of nonrenewal at least 90 days before the agreement is set to expire, the executive will not be entitled to receive any payments or benefits other than any accrued compensation, any unpaid prior year's bonus, rights to indemnification and directors' and officers' liability insurance, and as otherwise required by law.

If the executive's employment is terminated as a result of his or her death or disability, we will pay him or her or his or her estate, as applicable, any accrued compensation and any unpaid prior year's bonus.

Our agreements with Messrs. Baluch and Armstrong, Ms. Masson-Hurlburt and Dr. Mounts each contain a non-compete provision that provides that during the term of each agreement and the 12-month period immediately following the executive's separation from employment for any reason, the executive is prohibited from engaging in any business involving the development or commercialization of a preventive anti-infective product that would be a direct competitor of Neutrolin or a product containing taurolidine or any other product being actively developed or produced by us within the United States and the European Union (in the case of Mr. Baluch, worldwide, effective September 2019, pursuant to his new agreement) on the date of termination of his or her employment.

Tax and Accounting Considerations

U.S. federal income tax generally limits the tax deductibility of compensation we pay to our Named Executive Officers to $1.0 million each in the year the compensation becomes taxable to the executive officers. Although deductibility of compensation is preferred, tax deductibility is not a primary objective of our compensation programs. Rather, we seek to maintain flexibility in how we compensate our executive officers so as to meet a broader set of corporate and strategic goals and the needs of stockholders, and as such, we may be limited in our ability to deduct amounts of compensation from time to time. Accounting rules require us to expense the cost of our stock option grants. Because of option expensing and the impact of dilution on our stockholders, we pay close attention to, among other factors, the type of equity awards we grant and the number and value of the shares underlying such awards.

Pension Benefits

We do not maintain any qualified or non-qualified defined benefit pension plans. As a result, none of our Named Executive Officers participate in or have benefits under qualified or non-qualified defined benefit pension plans sponsored by us. Our Compensation Committee may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

Nonqualified Deferred Compensation

None of our Named Executive Officers participate in our have account balances in nonqualified defined contribution plans or other non-qualified deferred compensation plans maintained by us. Our Compensation Committee may elect to provide our officers and other employees with non-qualified defined contribution or other non-qualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Summary Compensation Table

The following table sets forth information with respect to compensation earned by our Named Executive Officers in the years ended December 31, 2019 and 2018:

Name and Principal Position	Year	Salary ($)	Option Awards (1) ($)	Restricted Stock Units Awards (1) ($)	Non-equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Khoso Baluch	2019	387,885	1,133,600	—	248,000(5)	26,344(6)	1,795,829
Chief Executive Officer	2018	375,000	—	—	240,000(5)	22,841(7)	637,841
Robert W. Cook (2)	2019	350,000	127,100	—	—	20,763(8)	497,863
Chief Financial Officer	2018	350,000	—	—	84,000(5)	23,546(8)	457,546
Phoebe Mounts (3)	2019	232,885	426,790	—	84,000(5)	2,479(8)	746,154
Executive Vice President and General Counsel and Head of Regulatory, Compliance and Legal	2018	—	—	—	—	—	—
John Armstrong	2019	310,000	57,195	—	86,800(5)	11,001(9)	464,996
Executive Vice President for Technical Operations	2018	312,308	—	—	86,800(5)	—	399,108
Elizabeth Masson-Hurlburt (4)	2019	280,000	298,504	—	67,200(5)	25,734(8)	671,438
Executive Vice President and Head of Clinical Operations	2018	277,345(4)	65,410	—	56,000(5)	21,723(8)	420,478

(1) The amounts included in this column are the dollar amounts representing the full grant date fair value of each award calculated in accordance with FASB ASC Topic 718 and do not represent the actual value that may be recognized by the Named Executive Officers upon option exercise.

(2) Mr. Cook and the Company mutually agreed not to renew his employment agreement which expired on January 31, 2020.

(3) Dr. Mounts became our Executive Vice President and General Counsel and Head of Regulatory, Compliance and Legal on May 1, 2019.

(4) Ms. Masson-Hurlburt became our Executive Vice President and Head of Clinical Operations on March 19, 2018. Her salary for 2018 included fees as a consultant.

(5) The non-equity incentive plan bonuses reflected in 2019 were for the performance for the year 2019 which were accrued in 2019 but will be paid in 2020. The non-equity incentive bonuses reflected in 2018 were for the performance for the year 2018 which were accrued in 2018 and paid in 2019.

(6) Consists of health benefits, 401(k) employer match, and reimbursed commuter expenses.

(7) Consists of health benefits, 401(k) employer match and reimbursed moving expenses.

(8) Consists of health benefits and 401(k) employer match.

(9) Consists of health benefits.

Outstanding Equity Awards at Fiscal Year-End 2019

The following table contains certain information concerning unexercised options for the Named Executive Officers as of December 31, 2019.

Name	Number of Shares Underlying Unexercised Options (#) – Exercisable	Number of Shares Underlying Unexercised Options (#) – Unexercisable	Equity Incentive Plan Awards: Number of Shares Underlying Unexercised Unearned Options #	Option Exercise Price ($)	Option Expiration Date
Khoso Baluch	207,500	62,500	40,000	12.60	10/03/2026
	48,600	21,000	—	8.30	01/10/2029
	—	120,000	—	6.82	09/26/2029
Robert W. Cook (1)	35,650	27,750	—	8.45	1/30/2027
	9,550	5,250	—	8.30	01/10/2029
Phoebe Mounts	—	42,000	28,000	7.92	05/01/2029
John Armstrong	2,000	—	—	7.60	11/14/2024
	3,000	—	—	16.25	7/28/2025
	39,876	124	—	12.55	3/08/2026
	6,600	—	6,800	10.90	3/01/2027
	5,467	2,363	—	8.30	01/10/2029
Elizabeth Masson-Hurlburt	26,100	27,900	—	1.45	3/19/2028
	14,580	6,300	—	8.30	01/10/2029

(1) Mr. Cook and the Company mutually agreed not to renew his employment agreement, which expired on January 31, 2020. 31,250 of his unvested stock options were forfeited upon termination of his employment. His vested options may be exercised until 90 days following his cessation of transition services to the Company.

Option Repricings

We did not engage in any repricings or other modifications to any of our Named Executive Officers' outstanding options during the year ended December 31, 2019.

Potential Payments on a Qualifying Termination

If the severance payments called for in our agreements for Mr. Baluch, Mr. Cook, Dr. Mounts, Mr. Armstrong and Ms. Masson-Hurlburt had been triggered on December 31, 2019, we would have been obligated to make the following payments:

Name	Cash Payment ($ per month) and (# of months paid)		Benefits ($ per month) and (# of months paid)		Number of Options (# that would vest) and ($ market value) [1]	
Khoso Baluch	$ 35,417[2]	12 mos.	$ 1,731	12 mos.	243,500	$ -0-
Robert W. Cook	$ 29,167[3]	9 mos.	$ 1,731	9 mos.	33,000	$ -0-
Phoebe Mounts	$ 29,167[4]	9 mos.	$ 1,195	9 mos.	70,000	$ -0-
John Armstrong	$ 25,833[5]	9 mos.	$ 917	9 mos.	9,287	$ -0-
Elizabeth Masson-Hurlburt	$ 23,333[6]	9 mos.	$ 2,587	9 mos.	34,200	$ 162,657

(1) The market value equals the difference the fair market value of the shares that could be acquired based on the closing sale price per share of our common stock on the NYSE American on December 31, 2019, which was $7.28, and the exercise prices of the applicable stock options.

(2) Represents severance based on monthly base salary, payable for 12 months. Any bonus for the year of termination based on performance would also be paid.

(3) Represents severance based on monthly base salary, payable for 9 months. Any bonus for the year of termination based on performance would also be paid.

(4) Represents severance based on monthly base salary, payable for 9 months. Any bonus for the year of termination based on performance would also be paid.

(5) Represents severance based on monthly base salary, payable for 9 months. Any bonus for the year of termination based on performance would also be paid.

(6) Represents severance based on monthly base salary, payable for 9 months. Any bonus for the year of termination based on performance would also be paid.

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

Principal Stockholders

The following table shows the number of shares of our common stock beneficially owned as of December 31, 2019 by:

- each person known by us to own beneficially more than 5% of the outstanding shares of our common stock;
- each director;
- each of our Named Executive Officers and our current executive officers; and
- all of our current directors and executive officers as a group.

This table is based upon the information supplied by our Named Executive Officers, directors and principal stockholders and from Schedules 13D and 13G filed with the SEC. Except as indicated in footnotes to this table, the persons named in this table have sole voting and investment power with respect to all shares of common stock shown, and their address is c/o CorMedix Inc., 400 Connell Drive, Suite 5000, Berkeley Heights, New Jersey 07922. As December 31, 2019, we had 25,665,350 shares of common stock outstanding. Beneficial ownership in each case also includes shares issuable upon exercise of outstanding options that can be exercised within 60 days after December 31, 2019 for purposes of computing the percentage of common stock owned by the person named. Options owned by a person are not included for purposes of computing the percentage owned by any other person.

Name and Address of Beneficial Owner	Common Stock Beneficially Owned (1)	
	Shares	%
5% or Greater Stockholders		
Elliott Associates, L.P. (2)	1,303,411	4.99%
BlackRock, Inc. (3)	1,712,901	6.7%
Directors and Named Executive Officers:		
Khoso Baluch (4)	315,675	1.2%
Robert Cook (5)	86,317	*
Phoebe Mounts (6)	1,425	*
John Armstrong (7)	127,233	*
Elizabeth Masson-Hurlburt (8)	50,780	*
Janet M. Dillione (9)	113,473	*
Alan Dunton (10)	18,436	*
Myron Kaplan (11)	150,734	*
Mehmood Khan (12)	171,017	*
Steven Lefkowitz (13)	129,928	*
All executive officers and directors as a group (8 persons) (14)	1,165,018	4.4%

* *Less than 1%*

(1) Based upon 25,665,350 shares of our common stock outstanding on December 31, 2019 and, with respect to each individual holder, rights to acquire our common stock exercisable within 60 days of December 31, 2019.

(2) Based solely on information contained in a Schedule 13D filed with the SEC on September 10, 2019 by Elliott Associates, L.P. ("Elliott Associates"), Elliott International, L.P. ("Elliott International") and Elliott International Capital Advisors Inc. ("Elliott International Capital Advisors", and together with Elliott Associates and Elliott International, the "Elliott Reporting Entities"), the investment manager of Elliott International, and other information known to us. Due to the Ownership Limitation (as defined below), the Elliott Reporting Entities may be deemed to collectively beneficially own 1,303,411 shares of our common stock through securities held by Elliott Associates and Elliott International. Elliott Associates beneficially holds: (i) 464,706 shares of our common stock, (ii) 32,480 shares of Series G preferred stock convertible into 1,805,932 shares of our common stock (subject to the Ownership Limitation) and (iii) 89,623 shares of our Series E preferred stock convertible into 391,953 shares of our common stock (subject to the Ownership Limitation). Elliott International beneficially holds (i) 368,668 shares of our common stock and (ii) 67,520 shares of Series G preferred stock convertible into 3,754,205 shares of our common stock (subject to the Ownership Limitation. In accordance with Rule 13d-4 under the Exchange Act, the number of shares of our common stock into which the Series E and Series G preferred stock are convertible into, as applicable, are limited pursuant to the terms of the convertible securities to that number of shares of our common stock which would result in the Elliott Reporting Entities having aggregate beneficial ownership of not more than 4.99% of the total issued and outstanding shares of our common stock (the "Ownership Limitation"). The Elliott Reporting Entities disclaim beneficial ownership of any and all shares of our common stock issuable upon any conversion of the convertible securities if such conversion would cause the Elliott Reporting Entities aggregate beneficial ownership of our common stock to exceed or remain above the Ownership Limitation (as is currently the case). Therefore, the Elliott Reporting Entities disclaim beneficial ownership of any shares of our common stock, issuable upon any conversion of the Series E preferred stock and the Series G preferred stock, which conversion would be prohibited by the Ownership Limitation. The Ownership Limitation does not prevent the Elliott Reporting Entities or their affiliates from voting the shares of Series E and Series G preferred stock held by Elliott Associates and Elliott International. Accordingly, the shares of Series E preferred stock and Series G preferred stock, as of the record date, will be entitled to an aggregate of 2,918,776 votes. The business address of Elliott Associates is 40 West 57th Street, 30th Floor, New York, New York 10019. The business address of Elliott International is c/o Maples & Calder, P.O. Box 309, Ugland House, South Church Street, George Town, Cayman Islands, British West Indies.

(3) Based solely on information contained in a statement on Schedule 13G filed with the SEC on February 7, 2020 by BlackRock, Inc. BlackRock, Inc. has the sole voting power with respect to 1,693,926 shares of our common stock and the sole dispositive power with respect to 1,712,901 shares of our common stock. The business address of BlackRock, Inc. is 55 East 52nd Street, New York, New York 10055.

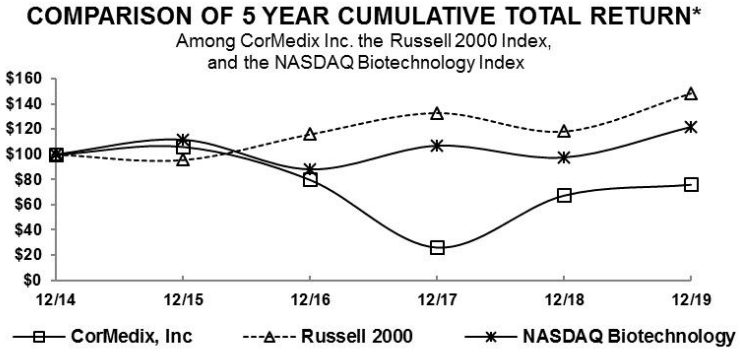
(4) Consists of (i) 52,575 shares of our common stock held in a joint account with Mr. Baluch's spouse, and (ii) 263,100 shares of our common stock issuable upon exercise of stock options.

(5) Consists of (i) 27,517 shares of our common stock, and (ii) 58,800 shares of our common stock issuable upon exercise of stock options.
(6) Consists of 1,425 shares of our common stock.
(7) Consists of (i) 69,378 shares of our common stock, of which 23,606 shares are directly owned by Mr. Armstrong's spouse, and (ii) 57,855 shares of our common stock issuable upon exercise of stock options.
(8) Consists of (i) 8,000 shares of our common stock, and (ii) 42,780 shares of our common stock issuable upon exercise of stock options.
(9) Consists of (i) 53,181 shares of our common stock, (ii) 60,000 shares of our common stock issuable upon exercise of stock options, and (iii) 292 shares of our common stock upon issuance of restricted stock units.
(10) Consists of (i) 520 shares of our common stock, (ii) 17,708 shares of our common stock issuable upon exercise of stock options. and (iii) 208 shares of our common stock upon issuance of restricted stock units.
(11) Consists of (i) 109,025 shares of our common stock, and (ii) 41,000 shares of our common stock issuable upon exercise of stock options, and (iii) 709 shares of our common stock upon issuance of restricted stock units.
(12) Consists of (i) 132,758 shares of our common stock, and (ii) 38,000 shares of our common stock issuable upon exercise of stock options, and (iii) 259 shares of our common stock upon issuance of restricted stock units.
(13) Consists of (i) 83,928 shares of our common stock, of which 24,963 shares are held for the benefit of Mr. Lefkowitz's minor son and 2,000 shares are directly owned by Mr. Lefkowtiz's spouse, (ii) 38,000 shares of our common stock issuable upon exercise of stock options, (iii) 4,500 shares of our common stock issuable upon exercise of warrants, and (iv) 3,000 shares of our common stock issuable upon exercise of warrants through Wade Capital Corporation Money Purchase Plan, an entity for which Mr. Lefkowitz has voting and investment control, and (v) 500 shares of our common stock upon issuance of restricted stock units.
(14) Consists of (i) the following held by our directors and executive officers (A) 538,307 shares of our common stock, (B) 590,579 shares of our common stock issuable upon exercise of stock options, (C) 7,500 shares of our common stock upon exercise of warrants, and (D) 1,968 shares of our common stock upon issuance of restricted stock units, as referenced in footnotes 9 through 13.

Stock Performance Graph

The following performance graph shall not be deemed to be "soliciting material" or "filed" or incorporated by reference in future filings with the SEC, or subject to the liabilities of Section 18 of the Exchange Act except as shall be expressly set forth by specific reference in such filing. The performance graph compares the performance of our common stock to the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph covers the most recent five-year period ended December 31, 2019. The graph assumes that the value of the investment in our common stock and each index was $100.00 at December 31, 2014, and that all dividends are reinvested.

On March 26, 2019, we effected a 1-for-5 reverse stock split of our issued and outstanding shares of common stock, par value $0.001, per share, by combining, reclassifying and changing each authorized and outstanding five shares of "old" common stock into one share of "new" common stock. No fractional shares were issued, and, in lieu thereof, where applicable, one whole share was issued. To reflect the reverse stock split, reclassification, combination and change, proportional adjustments were also made to our number of shares of common stock issuable upon conversion of outstanding preferred shares and the convertible note payable, warrants and options and other equity awards. The reverse stock split did not affect the par value per share of our common stock (which remains at $0.001 per share) or the total number of shares of common stock that are authorized to be issued pursuant to our Amended and Restated Certificate of Incorporation, as amended, which remains at 160 million shares. All issued and outstanding share and per share amounts included in the accompanying consolidated financial statements and in this report have been adjusted to reflect the reverse stock split, reclassification, combination and change for all periods presented.



*$100 invested on 12/31/14 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

	Cumulative Total Return					
	12/2014	12/2015	12/2016	12/2017	12/2018	12/2019
CorMedix Inc.	$ 100	$ 106.28	$ 80.10	$ 26.28	$ 67.54	$ 76.23
Russel 2000	$ 100	$ 95.59	$ 115.95	$ 132.94	$ 118.30	$ 148.49
NASDAQ Biotechnology	$ 100	$ 111.77	$ 87.91	$ 106.92	$ 97.45	$ 121.92

Item 13. Certain Relationships and Related Transactions and Director Independence

Related Party Transactions

On September 6, 2019, we consummated a securities exchange agreement (the "Exchange Agreement"), dated as of August 14, 2019, with Elliott Associates, Elliott International, and Manchester Securities Corp. (together "Elliott"), pursuant to which we exchanged certain of our outstanding securities (the "Exchanged Securities") together with an aggregate cash payment of $2,000,000 for 100,000 shares of Series G Preferred Stock. The Exchanged Securities, which in the aggregate were exercisable or convertible for 5,017,769 shares of common stock, consisted of (i) all of the shares of our Series C-2 Preferred Stock, Series D Preferred Stock and Series F Preferred Stock held by Elliott, (ii) all of the warrants held by Elliott, and (iii) all of the 10% Senior Secured Convertible Notes issued on December 31, 2018 held by Elliott, with an aggregate principal amount of $7,879,688, including accrued interest compounded quarterly of $379,688. The Exchanged Securities, other than the Series E Warrants, were cancelled upon delivery of such Exchanged Securities to us and the issuance of the Series G Preferred Stock to the holders. No shares of Series G Preferred Stock were issued in exchange for the surrender and cancellation of the Series E Warrants owned by Elliott, which were cancelled upon delivery to the Company. Additionally, our Series E Preferred Stock, which is owned by Elliott, was amended to conform certain of the restrictive covenants to those in the Series G Preferred Stock, and to provide the shares of Series E Preferred Stock with similar rights to vote on an as-converted basis.

Additionally, on September 6, 2019, in connection with the closing of the transactions under the Exchange Agreement, we also amended and restated the Registration Rights Agreement, dated as of November 9, 2017, by and between us and Elliott, in order to include the shares of common stock currently held by Elliott, and the shares of common stock issuable upon conversion of the Series G Preferred Stock and the Series E Preferred Stock as registrable securities thereunder.

Procedures for Review and Approval of Transactions with Related Persons

Pursuant to the Audit Committee Charter, the Audit Committee is responsible for reviewing and approving all related party transactions as defined under Item 404 of Regulation S-K, after reviewing each such transaction for potential conflicts of interests and other improprieties. Our policies and procedures for review and approval of transactions with related persons are in writing in our Code of Conduct and Ethics available on our website at www.cormedix.com under the "Investor Relations—Corporate Governance" tab.

The information on Board independence is found in Item 10 of this Report under the heading "Board Independence."

Item 14. Principal Accounting Fees and Services

Fees Paid to the Independent Registered Public Accounting Firm

The following table sets forth fees billed to us by Friedman LLP, our independent registered public accounting firm for the years ended December 31, 2019 and 2018, for services relating to: auditing our annual financial statements; reviewing our financial statements included in our quarterly reports on Form 10-Q; reviewing registration statements during 2019 and 2018; financing activities in 2019 and 2018; and services rendered in connection with tax compliance, tax advice and tax planning, and all other fees for services rendered.

	2019	2018
Audit Fees	$ 188,790	$ 195,500
Audit Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total	**$ 188,790**	**$ 195,500**

Audit Committee Pre-Approval Policies and Procedures

Pursuant to its charter, the Audit Committee is responsible for reviewing and approving in advance any audit and any permissible non-audit engagement or relationship between us and our independent registered public accounting firm. The Audit Committee may delegate to one or more designated members of the Audit Committee the authority to grant pre-approvals, provided such approvals are presented to the Audit Committee at a subsequent meeting. If the Audit Committee elects to establish pre-approval policies and procedures regarding non-audit services, the Audit Committee must be informed of each non-audit service provided by our independent registered public accounting firm. Audit Committee pre-approval of audit and non-audit services will not be required if the engagement for the services is entered into pursuant to pre-approval policies and procedures, provided the policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service provided and such policies and procedures do not include delegation of the Audit Committee's responsibilities under the Exchange Act to our management. Audit Committee pre-approval of non-audit services (other than review and attestation services) also will not be required if such services fall within available exceptions established by the SEC. All services performed by our independent registered public accounting firm during 2019 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) List of documents filed as part of this report:

1. Financial Statements:

The financial statements of the Company and the related reports of the Company's independent registered public accounting firms thereon have been filed under Item 8 hereof.

2. Financial Statement Schedules:

None.

3. Exhibit Index

The following is a list of exhibits filed as part of this Form 10-K:

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
1.1	At Market Issuance Sales Agreement, dated March 9, 2018, between CorMedix Inc. and B. Riley FBR, Inc.	S-3	3/09/2018	1.1	
3.1	Form of Amended and Restated Certificate of Incorporation.	S-1/A	3/01/2010	3.3	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated February 24, 2010.	S-1/A	3/19/2010	3.5	
3.3	Form of Amended and Restated Bylaws as amended April 19, 2016.	10-Q	5/10/2016	3.1	
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated December 3, 2012.	10-K	3/27/2013	3.3	
3.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated August 9, 2017.	8-K	8/10/2017	3.1	
3.6	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated March 25, 2019	8-K	3/25/2019	3.1	
3.7	Amended and Restated Certificate of Designation of Series C-3 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on September 15, 2014.	8-K	9/16/2014	3.16	
3.8	Second Amended and Restated Certificate of Designation of Series E Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on September 5, 2019.	8-K	9/11/2019	3.2	
3.9	Certificate of Designation of Series G Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on September 5, 2019	8-K	9/11/2019	3.1	
4.1	Specimen of Common Stock Certificate.	S-1/A	3/19/2010	4.1	
4.2	Form of Warrant issued on January 8, 2014.	8-K	1/09/2014	4.23	
4.3	Form of Series B Warrant to Purchase Common Stock of CorMedix Inc. issued on May 3, 2017.	8-K	5/03/2017	4.2	
4.4	Form of Underwriter's Warrant to Purchase Common Stock of CorMedix Inc., issued May 3, 2017.	8-K	5/03/2017	4.3	
4.5	Description of Capital Stock of CorMedix Inc.				X
10.1*	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC.	S-1/A	12/31/2009	10.5	
10.2	Escrow Agreement, dated as of January 30, 2008, among the Company, ND Partners LLC and the Secretary of the Company, as Escrow Agent.	S-1	11/25/2009	10.6	
10.3	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl.	S-1	11/25/2009	10.12	
10.4	Amended and Restated 2006 Stock Incentive Plan.	S-1/A	3/01/2010	10.8	
10.5	Form of Indemnification Agreement between the Company and each of its directors and executive officers.	S-1/A	3/01/2010	10.17	
10.6	2013 Stock Incentive Plan	10-K	3/27/2013	10.27	
10.7	Preliminary Services Agreement dated April 8, 2015, between CorMedix Inc. and [RC]2 Pharma Connect LLC.	10-Q	8/06/2015	10.1	
10.8	Release of Claims and Severance Modification, dated July 17, 2015, between Randy Milby and CorMedix Inc.	10-K	3/15/2016	10.16	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.9	Executive Employment Agreement, dated as of September 26, 2019, between CorMedix Inc. and Khoso Baluch	8-K	10/01/2019	10.1	
10.10*	Employment Agreement, effective February 1, 2017, between CorMedix Inc. and Robert Cook.	10-K	3/16/2017	10.12	
10.11	Employment Agreement, effective March 1, 2017, between CorMedix Inc. and John Armstrong.	10-K	3/16/2017	10.14	
10.12	Form of Securities Purchase Agreement, dated November 17, 2017, between CorMedix Inc. and the investors signatory thereto.	8-K	11/13/2017	10.1	
10.13	Backstop Agreement, dated November 9, 2017, between CorMedix Inc. and the investor named therein.	8-K	11/13/2017	10.2	
10.14	Form of Registration Rights Agreement, dated November 9, 2017, by and between CorMedix Inc. and the investor named therein.	8-K	11/13/2017	10.3	
10.15	Amendment No. 1, dated as of December 11, 2017, to Registration Rights Agreement, dated November 9, 2017, by and between CorMedix Inc. and the investor named therein.	8-K	12/11/2017	10.1	
10.16*	Employment Agreement, effective March 19, 2018, between CorMedix Inc. and Elizabeth Masson-Hurlburt	10-Q	5/15/2018	10.1	
10.17	Securities Purchase Agreement, dated December 31, 2018, between CorMedix Inc. and the investor named therein.	8-K	1/03/2019	10.1	
10.18*	Employment Agreement, dated as of March 19, 2019, between CorMedix Inc. and Phoebe Mounts	10-Q	5/13/19	10.1	
10.19	Securities Exchange Agreement, dated August 14, 2019, by and among CorMedix Inc. and the Existing Security holders listed on the Schedule of Holders thereto.	8-K	8/15/2019	10.1	
10.20	Amended and Restated Registration Rights Agreement, dated as of September 6, 2019, by and among CorMedix Inc. and Manchester Securities Corp., and Elliot International, L.P. and Elliot Associates, L.P.	8-K	9/11/2019	10.1	
10.21	2019 Omnibus Stock Incentive Plan	8-K	11/27/2019	10.1	
21.1	List of Subsidiaries.	10-K	3/27/2013	21.1	
23.1	Consent of Independent Registered Public Accounting Firm.				X
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following materials from CorMedix Inc. Form 10-K for the year ended December 31, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2019 and 2018, (ii) Statements of Operations for the years ended December 31, 2019 and 2018, (iii) Statements of Changes in Stockholders' Equity for the years ended December 31, 2019 and 2018, (iv) Statements of Cash Flows for the years ended December 31, 2019 and 2018 and (v) Notes to the Financial Statements.**				X

* Confidential treatment has been granted for portions of this document. The omitted portions of this document have been filed separately with the SEC.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

CORMEDIX INC.

March 16, 2020

By: /s/ Khoso Baluch
Khoso Baluch
Chief Executive Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Khoso Baluch Khoso Baluch	Chief Executive Officer and Director (Principal Executive Officer and Principal Financial and Accounting Officer)	March 16, 2020
/s/ Myron Kaplan Myron Kaplan	Chairman of the Board and Director	March 16, 2020
/s/ Janet Dillione Janet Dillione	Director	March 16, 2020
/s/ Alan Dunton Alan Dunton	Director	March 16, 2020
/s/ Mehmood Khan Mehmood Khan	Director	March 16, 2020
/s/ Steven Lefkowitz Steven Lefkowitz	Director	March 16, 2020

CORMEDIX INC. AND SUBSIDIARY

FINANCIAL STATEMENTS

Financial Statements Index

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of CorMedix Inc.

Opinion on the Consolidated Financial Statements

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 16, 2020, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the 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 audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Friedman LLP
We have served as the Company's auditor since 2014.

Marlton, New Jersey
March 16, 2020

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
December 31, 2019 and 2018

	December 31, 2019	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 16,350,237	$ 17,623,770
Restricted cash	174,950	171,553
Short-term investments	11,984,157	-
Trade receivables, net	35	10,904
Inventories, net	338,465	428,515
Prepaid research and development expenses	34,831	8,113
Security deposit	20,000	-
Other prepaid expenses and current assets	446,415	422,199
Total current assets	29,349,090	18,665,054
Property and equipment, net	126,820	160,860
TOTAL ASSETS	$ 29,475,910	$ 18,825,914
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,024,280	$ 2,588,977
Accrued expenses	4,800,486	5,166,224
Deferred revenue	2,206	11,029
Total current liabilities	5,826,972	7,766,230
Operating lease liabilities, net of current portion	2,678	-
Convertible note, related party, net	-	6,125,428
TOTAL LIABILITIES	5,829,650	13,891,658
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY		
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 241,623 and 419,585 shares issued and outstanding at December 31, 2019 and 2018	242	420
Common stock - $0.001 par value: 160,000,000 shares authorized at December 31, 2019; 25,665,350 and 21,775,173 shares issued and outstanding at December 31, 2019 and 2018, respectively	25,665	21,775
Accumulated other comprehensive gain	97,257	96,522
Additional paid-in capital	218,944,268	183,803,637
Accumulated deficit	(195,421,172)	(178,988,098)
TOTAL STOCKHOLDERS' EQUITY	23,646,260	4,934,256
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 29,475,910	$ 18,825,914

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
Years Ended December 31, 2019 and 2018

	December 31,	
	2019	**2018**
Revenue:		
Net sales	$ 283,266	$ 429,797
Cost of sales	(373,234)	(396,786)
Gross profit	(89,968)	33,011
Operating Expenses:		
Research and development	(11,052,903)	(18,822,488)
Selling, general and administrative	(9,865,005)	(8,074,719)
Total operating expenses	(20,917,908)	(26,897,207)
Loss From Operations	(21,007,876)	(26,864,196)
Other Income (Expense):		
Interest income	322,668	36,618
Foreign exchange transaction loss	(21,156)	(179)
Interest expense including amortization of debt discount	(787,488)	(1,873)
Total other income (expense)	(485,976)	34,566
Net Loss Before Income Taxes	(21,493,852)	(26,829,630)
Tax benefit	5,060,778	-
Net Loss	(16,433,074)	(26,829,630)
Other Comprehensive Income (Loss):		
Unrealized gain from investments	268	-
Foreign currency translation (loss) gain	467	(1,911)
Total other comprehensive (loss) income	735	(1,911)
Comprehensive Loss	$ (16,432,339)	$ (26,831,541)
Net Loss	$ (16,433,074)	$ (26,829,630)
Deemed dividend as a result of warrant modification	(369,500)	-
Deemed dividend as a result of exchange of convertible note and Series C-2, Series D and Series F preferred stock, related party	(26,733,098)	-
Net Loss Attributable to Common Shareholders	(43,535,672)	(26,829,630)
Net Loss Per Common Share – Basic and Diluted	$ (1.80)	$ (1.51)
Weighted Average Common Shares Outstanding – Basic and Diluted	24,152,088	17,816,624

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
Years Ended December 31, 2019 and 2018

	Common Stock		Preferred Stock – Series C-2, C-3, Series D, Series E, Series F and Series G		Accumulated Other Comprehensive	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Gain (Loss)	Capital	Deficit	Equity
Balance at December 31, 2017	14,282,758	$ 14,283	419,585	$ 420	$ 98,433	$ 159,255,081	$ (152,174,866)	$ 7,193,351
Stock issued in connection with ATM sale of common stock, net	7,177,754	7,178	-	-	-	21,960,828	-	21,968,006
Value of warrants related to convertible note	-	-	-	-	-	1,122,355	-	1,122,355
Beneficial conversion feature related to convertible note	-	-	-	-	-	143,431		143,431
Stock issued in connection with warrants exercised	5,000	5	-	-	-	26,245	-	26,250
Stock issued in connection with warrants cashless exercised	249,770	250	-	-	-	(250)	-	-
Stock issued in connection with stock options exercised	8,000	8	-	-	-	11,592	-	11,600
Issuance of restricted stock	26,365	26	-	-	-	(26)	-	-
Stock issued for payment of deferred fees	25,526	25	-	-	-	173,748	-	173,773
Stock-based compensation	-	-	-	-	-	1,110,632	-	1,110,632
Cumulative effect of adoption of ASC 606	-	-	-	-	-	-	16,398	16,398
Other comprehensive gain	-	-	-	-	(1,911)	-	-	(1,911)
Net loss	-	-	-	-	-	-	(26,829,630)	(26,829,630)
Balance at December 31, 2018	21,775,173	21,775	419,585	420	96,522	183,803,636	(178,988,098)	4,934,255
Stock issued in connection with ATM sale of common stock, net	1,768,012	1,768	-	-	-	15,232,761	-	15,234,529
Stock issue in connection with warrants exercised	1,948,207	1,948	-	-	-	8,672,036	-	8,673,984
Exchange of convertible note for Series G preferred stock, net, related party	-	-	-	-	-	8,673,509	-	8,673,509
Exchange of Series C-2, Series D and Series F preferred stock for Series G preferred stock, related party	-	-	(225,962)	(226)	-	226	-	-
Issuance of Series G preferred stock, related party	-	-	100,000	100	-	(100)	-	-
Stock issued in connection with stock options exercised	38,090	38	-	-	-	122,666	-	122,704
Conversion of Series C-3 non-voting preferred stock to common stock	104,000	104	(52,000)	(52)	-	(52)	-	-
Issuance of vested restricted stock	25,346	25	-	-	-	(25)	-	-
Issuance of common stock as a result of reverse stock split rounding	6,522	7	-	-	-	(7)	-	-
Stock-based compensation	-	-	-	-	-	2,439,618	-	2,439,618
Other comprehensive loss	-	-	-	-	735	-	-	735
Net loss	-	-	-	-	-	-	(16,433,074)	(16,433,074)
Balance at December 31, 2019	25,665,350	$ 25,665	241,623	$ 242	$ 97,257	$ 218,944,268	$ (195,421,172)	$ 23,646,260

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2019 and 2018

	December 31, 2019	December 31, 2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (16,433,074)	$ (26,829,630)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,439,618	1,110,632
Amortization of debt discount	313,097	-
Non-cash interest expense	461,839	-
Inventory reserve	27,163	-
Depreciation	73,286	74,218
Changes in operating assets and liabilities:		
Decrease in trade receivables	10,631	51,986
Decrease in inventory	59,285	165,679
(Increase) decrease in prepaid expenses and other current assets	(67,385)	23,165
Increase (decrease) in accounts payable	(1,564,381)	782,062
Increase (decrease) in accrued expenses	(363,280)	997,724
Decrease in deferred revenue	(8,823)	(76,401)
Net cash used in operating activities	(15,052,024)	(23,700,565)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term investments	(14,106,369)	-
Sale of short-term investments	2,122,481	1,604,307
Purchase of equipment	(36,571)	(48,893)
Net cash used in (provided by) investing activities	(12,020,459)	1,555,414
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock from at-the-market program, net	15,234,529	21,968,007
Proceeds from senior convertible note	-	7,500,000
Payment of debt issuance costs in connection with senior convertible note	-	(108,787)
Proceeds from exchange agreement, related party	2,000,000	-
Proceeds from exercise of warrants	8,673,984	26,250
Proceeds from exercise of stock options	122,704	11,600
Payment of financing fees	(226,855)	-
Net cash provided by financing activities	25,804,362	29,397,070
Foreign exchange effects on cash	(2,015)	(7,878)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(1,270,136)	7,244,041
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH – BEGINNING OF YEAR	17,795,323	10,551,282
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH – END OF YEAR	$ 16,525,187	$ 17,795,323
Cash paid for interest	$ 12,552	$ 1,873
Supplemental Disclosure of Non-Cash Financing and Investing Activities:		
Deemed dividend as a result of warrant modification	$ 369,500	$ -
Deemed dividend as a result of exchange of convertible note, Series C-2, Series D and Series F convertible preferred shares, related party	$ 26,733,098	-
Non-cash portion of debt discount on senior convertible notes	$ -	$ 1,271,861
Issuance of common stock for vested restricted stock units	$ 25	$ 132
Issuance of common stock for payment of deferred fees	$ -	$ 173,773
Right-of-use asset and lease liability recognized under ASC 842	$ 5,000	$ -
Conversion of preferred stock to common stock	$ 52	$ -
Write-off of fully depreciated computer equipment	$ 47,850	$ -

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

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business:

CorMedix Inc. ("CorMedix" or the "Company") was incorporated in the State of Delaware on July 28, 2006. The Company is a biopharmaceutical company focused on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases. In 2013, the Company formed a wholly-owned subsidiary, CorMedix Europe GmbH.

The Company's primary focus is to develop its lead product candidate, Neutrolin®, for potential commercialization in the United States ("U.S.") and other key markets. The Company has in-licensed the worldwide rights to develop and commercialize Neutrolin, which is a novel anti-infective solution (a formulation of 1.35% taurolidine, 3.5% citrate and 1000 u/ml heparin) intended for the reduction and prevention of catheter-related infections and thrombosis in patients requiring central venous catheters in clinical settings such as hemodialysis, critical/intensive care, and oncology.

In late 2013, the Company met with the U.S. Food and Drug Administration ("FDA") to determine the pathway for U.S. marketing approval of Neutrolin. The Company launched the Phase 3 clinical trial in patients with hemodialysis catheters in the U.S. in December 2015. The clinical trial, named Phase 3 Prospective, Multicenter, Double-blind, Randomized, Active Control Study to Demonstrate Safety and Effectiveness of Neutrolin in Preventing Catheter-related Bloodstream Infection in Subjects on Hemodialysis for End Stage Renal Disease ("LOCK-IT-100"), was a prospective, multicenter, randomized, double-blind, active control trial which aimed to demonstrate the efficacy and safety of Neutrolin in preventing catheter-related bloodstream infections ("CRBSI"), in subjects receiving hemodialysis therapy as treatment for end stage renal disease. The primary endpoint for the trial was time to CRBSI. The trial evaluated Neutrolin relative to the active control heparin by documenting the incidence of CRBSI and the time until the occurrence of CRBSI for each study subject. Secondary endpoints were catheter patency, which was defined as required use of tissue plasminogen activating factor ("tPA"), or removal of catheter due to dysfunction, and removal of catheter for any reason.

The Company established the Clinical Adjudication Committee ("CAC"), to critically and independently assess CRBSI while being blinded to treatment assignment. In July 2018, the CAC reviewed potential cases of CRBSI in the Company's LOCK-IT-100 study that occurred through early December 2017 and identified 28 such cases. An interim efficacy analysis was performed when the first 28 CRBSIs were identified. In July 2018, the independent Data Safety Monitoring Board ("DSMB"), had completed its review of the interim analysis of the data from the LOCK-IT-100 study. Based on the first 28 cases, there was a highly statistically significant 72% reduction in CRBSI relative to the control (p=0.0034). Because the pre-specified level of statistical significance was reached for the primary endpoint and efficacy had been demonstrated with no safety concerns, the DSMB recommended the study be terminated early.

Following discussions with the FDA, the Company proceeded with an orderly termination of LOCK-IT-100. Although the FDA usually requires two pivotal clinical trials to provide substantial evidence of safety and effectiveness for approval of an NDA, the FDA will in some cases accept one adequate and well-controlled trial, where it is a large multicenter trial with a broad range of subjects and investigation sites with procedures to include trial quality that has demonstrated a clinically meaningful and statistically very persuasive effect on prevention of a disease with potentially serious outcome. The Company plans to proceed with submission of the NDA for Neutrolin® based on the results of LOCK-IT-100. Whether data from LOCK-IT-100 are sufficient will be a review issue with the FDA.

The FDA has agreed that the Neutrolin NDA is eligible for both priority review and for submission under rolling review. In January 2020, the FDA granted the request for rolling review. A determination on priority review will not be made until the submitted NDA is reviewed by the FDA to determine the acceptance for filing. The FDA informs the applicant of a Priority Review designation within sixty days of the receipt of the complete original application, if it determines the criteria have been met. Priority Review designation would mean FDA's goal is to take action on an application within 6 months, compared to a standard review period of ten months.

The FDA also agreed that the Company could request consideration of Neutrolin for approval under the Limited Population Pathway for Antibacterial and Antifungal Drugs ("LPAD"). LPAD, passed as part of the 21st Century Cures Act, is a new program intended to expedite the development and approval of certain antibacterial and antifungal drugs to treat serious or life-threatening infections in limited populations of patients with unmet needs. Given that the LPAD pathway provides for a streamlined clinical development program for a limited population that may involve smaller, shorter, or fewer clinical trials, the Company believes that LPAD will provide additional flexibility for the FDA to approve Neutrolin to prevent CRBSIs in the limited population of patients with end-stage renal disease receiving hemodialysis through a central venous catheter.

In the European Union (“EU”), Neutrolin is regulated as a Class 2 medical device. In July 2013, the Company received CE Mark approval for Neutrolin. In December 2013, the Company started commercial sales of Neutrolin in Germany for the prevention of CRBSI, and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in certain EU and Middle Eastern countries for such treatment.

In September 2014, the TUV-SUD and The Medicines Evaluation Board of the Netherlands (“MEB”), granted a label expansion for Neutrolin for these same expanded indications for the EU. In December 2014, the Company received approval from the Hessian District President in Germany to expand the label to include use in oncology patients receiving chemotherapy, IV hydration and IV medications via central venous catheters. The expansion also adds patients receiving medication and IV fluids via central venous catheters in intensive or critical care units (cardiac care unit, surgical care unit, neonatal critical care unit, and urgent care centers). An indication for use in total parenteral nutrition was also approved.

In addition to Neutrolin, the Company is sponsoring a pre-clinical research collaboration for the use of taurolidine as a possible treatment for rare orphan pediatric tumors. In February 2018, the FDA granted orphan drug designation to taurolidine for the treatment of neuroblastoma in children. The Company may seek one or more strategic partners or other sources of capital to help develop and commercialize taurolidine for the treatment of neuroblastoma in children. The Company is also evaluating opportunities for the possible expansion of taurolidine as a platform compound for use in certain medical devices. Patent applications have been filed in several indications, including wound closure, surgical meshes, and wound management.

The FDA regards taurolidine as a new chemical entity and therefore, it is currently an unapproved new drug. The Company might in the future pursue product candidates that would involve devices impregnated with taurolidine, and the Company believes that at the current time such products would be combination products subject to device premarket submission requirements (while subject also, under review by the FDA, to the standards for drug approvability). Consequently, given that there is no appropriate predicate medical device currently marketed in the U.S. on which a 510(k) approval process could be based and that taurolidine is not yet approved in any application, the Company anticipates that it would be required to submit a premarket approval application (“PMA”) for marketing authorization for any medical device indications that we may pursue for devices containing taurolidine. In the event that an NDA for Neutrolin is approved by the FDA, the regulatory pathway for these medical device product candidates may be revisited with the FDA. Although there may be no appropriate predicate, de novo Class II designation can be proposed, based on a risk assessment and a reasonable assurance of safety and effectiveness.

On March 26, 2019, the Company effected a 1-for-5 reverse stock split of its issued and outstanding shares of common stock, par value $0.001, per share (“Common Stock”), by combining, reclassifying and changing each authorized and outstanding five shares of “old” common stock into one share of “new” common stock. No fractional shares were issued, and, in lieu thereof, where applicable, one whole share was issued. To reflect the reverse stock split, reclassification, combination and change, proportional adjustments were also made to the number of shares of our common stock issuable upon conversion of outstanding preferred shares and the convertible note payable, warrants and options and other equity awards. The reverse stock split did not affect the par value per share of our common stock (which remains at $0.001 per share) or the total number of shares of common stock that are authorized to be issued pursuant to our Amended and Restated Certificate of Incorporation, as amended, which remains at 160 million shares. All issued and outstanding share and per share amounts included in the accompanying consolidated financial statements and in this report have been adjusted to reflect the reverse stock split, reclassification, combination and change for all periods presented.

The Company is using its current cash resources for the preparation and submission of the NDA for Neutrolin and for certain pre-launch activities. Commercial preparations are dependent on the Company’s ability to raise sufficient additional funds through various potential sources, such as equity, debt financings, and/or strategic relationships and potential strategic transactions. The Company can provide no assurances that financing or strategic relationships will be available on acceptable terms, or at all, to complete its clinical development program for Neutrolin.

Note 2 — Liquidity and Uncertainties:

The financial statements have been prepared in conformity with generally accepted accounting principles which contemplate continuation of the Company as a going concern. To date, the Company's commercial operations have not generated sufficient revenues to enable profitability. As of December 31, 2019, the Company had an accumulated deficit of $195.4 million, and incurred net losses of $16.4 million and $26.8 million for the years ended December 31, 2019 and 2018, respectively. Based on the Company's current development plans for Neutrolin in both the U.S. and foreign markets and its other operating requirements, the Company's existing cash and cash equivalents at December 31, 2019 are expected to fund its operations into the second quarter of 2021, after taking into consideration the net proceeds received through March 12, 2020 from the At-the-Market Issuance Sales Agreement (the "ATM program") of $2.5 million and the exercise of warrants of $0.4 million (see Note 11).

The Company's continued operations will depend on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, potential strategic transactions or out-licensing of its products in order to undertake a second Phase 3 clinical trial, if required by the FDA, commercially launch Neutrolin upon NDA approval and until profitability is achieved, if ever. Management can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. As of the filing date of this Annual Report on Form 10-K, the Company has approximately $2.1 million available under its current ATM program and $30.3 million available under its current shelf registration for the issuance of equity, debt or equity-linked securities unrelated to the current ATM program.

The Company's operations are subject to a number of other factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's product candidates; the ability to obtain regulatory approval to market the Company's products; ability to manufacture successfully; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, Company products; the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products; and the Company's ability to raise capital to support its operations.

Note 3 — Summary of 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 disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Basis of Consolidation

The consolidated financial statements include the accounts of the Company and CorMedix Europe GmbH, a wholly owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Financial Instruments

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and short-term investments. The Company maintains its cash and cash equivalents in bank deposit and other interest-bearing accounts, the balances of which, at times, may exceed federally insured limits.

The following table is the reconciliation of the accounting standard that modifies certain aspects of the recognition, measurement, presentation and disclosure of financial instruments as shown on the Company's consolidated statement of cash flows:

	December 31,	
	2019	2018
Cash and cash equivalents	$ 16,350,237	$ 17,623,770
Restricted cash	174,950	171,553
Total cash, cash equivalents and restricted cash	$ 16,525,187	$ 17,795,323

The appropriate classification of marketable securities is determined at the time of purchase and reevaluated as of each balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair value is determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in other comprehensive income (loss). Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in income (expense). For declines in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other (income) expense, net. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. There were no deemed permanent impairments at December 31, 2019 or 2018.

The Company's marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with original maturities of more than 90 days. As of December 31, 2019 and 2018, all of the Company's investments had contractual maturities which were less than one year. The following table summarizes the amortized cost, unrealized gains and losses and the fair value at December 31, 2019 and 2018:

December 31, 2019:	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Fair Value
Money Market Funds and Cash Equivalents	$ 3,472,043	$ -	$ 51	$ 3,472,094
U.S. Government Agency Securities	2,691,091	(42)	869	2,691,918
Corporate Securities	6,058,265	(1,438)	440	6,057,267
Commercial Paper	3,234,583	(16)	405	3,234,972
Subtotal	11,983,939	(1,496)	1,714	11,984,157
Total December 31, 2019	$ 15,455,982	$ (1,496)	$ 1,765	$ 15,456,251
December 31, 2018:				
Money Market Funds	$ 1,179,673	$ -	$ -	$ 1,179,673
Total December 31, 2018	$ 1,179,673	$ -	$ -	$ 1,179,673

Fair Value Measurements

The Company's financial instruments recorded in the consolidated balance sheets include cash and cash equivalents, accounts receivable, investment securities, accounts payable and accrued expenses. The carrying value of certain financial instruments, primarily cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their estimated fair values based upon the short-term nature of their maturity dates. The Company's senior secured convertible note (prior to its extinguishment in August 2019) falls into the Level 3 category within the fair value level hierarchy. The fair value was determined using market data for valuation.

The Company categorizes its financial instruments into a three-level fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value, which is set out below. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets (Level 1) and the lowest priority to unobservable inputs (Level 3). If the inputs used to measure fair value fall within different levels of the hierarchy, the category level is based on the lowest priority level input that is significant to the fair value measurement of the instrument.

- Level 1 inputs—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2 inputs— Significant other observable inputs (e.g., quoted prices for similar items in active markets, quoted prices for identical or similar items in markets that are not active, inputs other than quoted prices that are observable such as interest rate and yield curves, and market-corroborated inputs).
- Level 3 inputs—Unobservable inputs for the asset or liability, which are supported by little or no market activity and are valued based on management's estimates of assumptions that market participants would use in pricing the asset or liability.

The following table provides the carrying value and fair value of the Company's financial assets measured at fair value as of December 31, 2019 and 2018:

December 31, 2019:	Carrying Value	Level 1	Level 2	Level 3
Money Market Funds and Cash Equivalents	$ 3,472,094	$ 3,472,094	$ -	$ -
U.S. Government Agency Securities	2,691,918	2,691,918	-	-
Corporate Securities	6,057,267	-	6,057,267	-
Commercial Paper	3,234,972	-	3,234,972	-
Subtotal	11,984,157	2,691,918	9,292,239	-
Total December 31, 2019	$ 15,456,251	$ 6,164,012	$ 9,292,239	$ -
December 31, 2018:				
Money Market Funds	$ 1,179,673	$ 1,179,673	$ -	$ -
Total December 31, 2018	$ 1,179,673	$ 1,179,673	$ -	$ -

Foreign Currency Translation and Transactions

The consolidated financial statements are presented in U.S. Dollars (USD), the reporting currency of the Company. For the financial statements of the Company's foreign subsidiary, whose functional currency is the EURO, foreign currency asset and liability amounts, if any, are translated into USD at end-of-period exchange rates. Foreign currency income and expenses are translated at average exchange rates in effect during the year. Translation gains and losses are included in other comprehensive income (loss). The Company had a foreign currency translation gain of $467 in 2019 and a loss of $1,911 in 2018.

Foreign currency exchange transaction gain (loss) is the result of re-measuring transactions denominated in a currency other than the functional currency of the entity recording the transaction.

Geographic Information

The following table summarizes the segment and geographic information:

	December 31,	
	2019	2018
Reported revenues	$ 283,266	$ 429,327
Revenues attributable to European and Mideast operations, which are based in Germany	274,443	420,973
Total assets	29,475,910	18,825,914
Total assets located in the United States, with the remainder in the European Union	$ 28,919,276	$ 18,154,463

Restricted Cash

As of December 31, 2019 and 2018 the Company has restricted cash in connection with the patent and utility model infringement proceedings against TauroPharm (see Note 7). The Company was required by the District Court Mannheim to provide a security deposit of approximately €110,000 to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The Company furthermore had to provide a deposit in the amount of €36,000 and €10,000 for the first and second instances, respectively, in connection with the unfair competition proceedings in Cologne.

Prepaid Research and Development and Other Prepaid Expenses

Prepaid expenses consist of payments made in advance to vendors relating to service contracts for clinical trial development, manufacturing, pre-clinical development and insurance policies. These advanced payments are amortized to expense either as services are performed or over the relevant service period using the straight-line method.

Inventories, net

Inventories are valued at the lower of cost or net realizable value on a first in, first out basis. Inventories consist of raw materials (including labeling and packaging), work-in-process, and finished goods, if any, for the Neutrolin product. Inventories consist of the following:

	December 31,	
	2019	2018
Raw materials	$ 6,893	$ 71,275
Work in process	-	86,957
Finished goods	461,735	373,283
Inventory reserve	(130,163)	(103,000)
Total	$ 338,465	$ 428,515

Property and Equipment

Property and equipment consist primarily of furnishings, fixtures, leasehold improvements, office equipment and computer equipment all of which are recorded at cost. Depreciation is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. Property and equipment, as of December 31, 2019 and 2018 were $126,820 and $160,860, respectively, net of accumulated depreciation of $244,328 and $218,948, respectively. Depreciation and amortization of property and equipment is included in selling, general and administrative expenses.

Description	Estimated Useful Life
Office equipment and furniture	5 years
Leasehold improvements	5 years
Computer equipment	5 years
Computer software	3 years

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use (“ROU”) assets, current portion of operating lease liabilities (included in accrued expenses), and operating lease liabilities, net of current portion, on the consolidated balance sheet.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company’s leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

The Company has elected, as an accounting policy, not to apply the recognition requirements in ASC 842 to short-term leases. Short-term leases are leases that have a term of 12 months or less and do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise. The Company recognizes the lease payments for short-term leases on a straight-line basis over the lease term.

The Company has also elected, as a practical expedient, by underlying class of asset, not to separate lease components from non-lease components and, instead, account for them as a single component.

Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2019	**2018**
Professional and consulting fees	$ 214,777	$ 258,352
Accrued payroll and payroll taxes	1,287,047	1,102,143
Clinical trial related	2,435,953	3,408,032
Manufacturing development related	806,032	210,577
Product development	-	49,200
Other	56,677	137,920
Total	$ 4,800,486	$ 5,166,224

In December 2015, the Company entered into a Master Service Agreement and Work Orders (the "Master Service Agreement") with a clinical research organization ("CRO") to help the Company conduct its LOCK-IT-100 Phase 3 multicenter, double-blind, randomized active control study to demonstrate the safety and effectiveness of Neutrolin in preventing catheter-related bloodstream infections and blood clotting in subjects receiving hemodialysis therapy as treatment for end stage renal disease.

During 2018, the Company contested a substantial amount of the unpaid clinical trial expense accrued during 2018 due to the unexpected delay and additional costs the Company incurred in preparing for the interim analysis of the LOCK-IT-100 study. Negotiations with the CRO concluded in November 2018 with the signing of a confidential settlement agreement. In parallel with the settlement agreement, a new work order under the Master Service Agreement was executed specifying certain services the CRO will continue to provide to the Company related to the closeout of the study. The budgeted amount of the new work order was approximately $1.4 million, of which $1.4 million was incurred through December 31, 2019.

Through December 31, 2019, approximately $30.0 million of clinical trial expense has been recorded in connection with the Master Service Agreement and new work orders, of which approximately $27.4 million has been paid. During the years ended December 31, 2019 and 2018, the Company recognized $1.5 and $7.7 million, respectively, in research and development expense related to this agreement. At December 31, 2019, the Company had accrued approximately $2.4 million in accounts payable and accrued expenses related to the settlement agreement and the new work order.

Revenue Recognition

The Company uses Accounting Standards Codification ("ASC") 606, "*Revenue from Contracts with Customers,"* issued by the Financial Accounting Standards Board ("FASB"), that prescribes a five-step model for recognizing revenue which includes (i) identifying contracts with customers; (ii) identifying performance obligations; (iii) determining the transaction price; (iv) allocating the transaction price; and (v) recognizing revenue.

The Company recognizes net sales upon shipment of product to the dialysis centers and upon meeting the five-step model prescribed by ASC 606 outlined above.

Deferred Revenue

In August 2014, the Company entered into an exclusive distribution agreement (the "Wonik Agreement") with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis and oncolytic patients upon receipt of regulatory approval in South Korea. Upon execution, Wonik paid the Company a non-refundable $50,000 payment and will pay an additional $50,000 upon receipt of the product registration necessary to sell Neutrolin in South Korea (the "Territory"). The term of the Wonik Agreement commenced on August 8, 2014 and will continue for three years after the first commercial sale of Neutrolin in the Territory. The non-refundable up-front payment has been recorded as deferred revenue and will be recognized as revenue on a straight-line basis over the contractual term of the Agreement. Deferred revenue related to this agreement at December 31, 2019 and 2018 amounted to approximately $2,000 and $11,000, respectively.

Loss Per Common Share

Basic loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity.

The Company's outstanding shares of Series E preferred stock entitle the holders to receive dividends on a basis equivalent to the dividends paid to holders of common stock. As a result, the Series E preferred stock meet the definition of participating securities requiring the application of the two-class method. Under the two-class method, earnings available to common shareholders, including both distributed and undistributed earnings, are allocated to each class of common stock and participating securities according to dividends declared and participating rights in undistributed earnings, which may cause diluted earnings per share to be more dilutive than the calculation using the treasury stock method. No loss has been allocated to these participating securities since they do not have contractual obligations that require participation in the Company's losses.

Since the Company has only incurred losses, basic and diluted loss per share are the same as potentially dilutive shares have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive. The shares outstanding at the end of the respective periods presented below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Number of Shares of Common Stock Issuable At December 31,	
	2019	2018
Series C non-voting preferred stock	104,000	508,000
Series D non-voting preferred stock	-	295,848
Series E voting preferred stock	391,953	391,953
Series F non-voting preferred stock	-	2,469,136
Series G voting preferred stock	5,560,137	-
Shares issuable upon conversion of convertible debt	-	1,000,000
Restricted stock units	2,490	5,817
Shares issuable for payment of deferred board compensation	33,597	28,578
Shares underlying outstanding warrants	341,328	3,319,003
Shares underlying outstanding stock options	1,376,394	1,011,265
Total potentially dilutive shares	7,809,899	9,029,600

Stock-Based Compensation

Share-based compensation cost is measured at grant date, based on the estimated fair value of the award using the Black-Scholes option pricing model for options with service or performance-based conditions. Stock-based compensation is recognized as expense over the requisite service period on a straight-line basis or when the achievement of the performance condition is probable.

Research and Development

Research and development costs are charged to expense as incurred. Research and development includes fees associated with operational consultants, contract clinical research organizations, contract manufacturing organizations, clinical site fees, contract laboratory research organizations, contract central testing laboratories, licensing activities, and allocated executive, human resources and facilities expenses. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial and the invoices received from its external service providers. As actual costs become known, the Company adjusts its accruals in the period when actual costs become known. Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development expense.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some or all of the deferred tax assets will not be realized.

Debt Issuance Costs

The Company accounts for debt issuance costs as a direct deduction from the carrying amount of the respective debt liability, consistent with debt discounts. The Company amortizes the debt discount, including debt issuance costs over the term of the associated debt using the effective interest method.

Recently Adopted Authoritative Pronouncements

In June 2018, the Financial Accounting Standards Board ("FASB") issued new guidance which expands the scope of the FASB's Accounting Standards Codification ("ASC") 718, to include share-based payment transactions for acquiring goods and services from nonemployees. Early adoption is permitted and the Company elected to adopt the guidance effective in the first quarter of fiscal year 2019. This adoption on January 1, 2019 did not have a material impact on the Company's consolidated financial statements.

In July 2017, the FASB issued new guidance which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features and recharacterizes the indefinite deferral of certain provisions within the guidance for distinguishing liabilities from equity. Early adoption is permitted and the Company elected to adopt the guidance effective in the first quarter of fiscal year 2019. This adoption on January 1, 2019 did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued new guidance related to how an entity should recognize lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. The Company adopted the standard on January 1, 2019 using the transition method provided by the FASB. Under this transition method, the Company applied the new requirements to only those leases that exist as of January 1, 2019, rather than at the earliest comparative period presented in the financial statements. Prior periods will be presented under existing lease guidance. Upon transition, the Company applied the package of practical expedients permitted under ASC 842 transition guidance. As a result, the Company did not reassess (1) whether expired or existing contracts contain leases under the new definition of a lease, including whether an existing or expired contract contains an embedded lease, (2) lease classification for expired or existing leases and (3) any initial direct costs of existing leases. As a result of the adoption, the Company recorded right-of-use assets and lease liabilities of approximately $6,000 each. Adoption of the standard did not have a material impact on the Company's consolidated statements of operations and comprehensive loss or cash from or used in operating, investing or financing activities on its consolidated statements of cash flows.

Recent Authoritative Pronouncements

In June 2016, the FASB issued new guidance which replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The Company has assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have a significant impact on its consolidated financial statements.

In August 2018, the FASB issued a new guidance which modifies the disclosure requirements on fair value measurements. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted. The Company assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have a significant impact on its consolidated financial statements

In November 2018, the FASB issued new guidance to clarify the interaction between the authoritative guidance for collaborative arrangements and revenue from contracts with customers. The new guidance clarifies that, when the collaborative arrangement participant is a customer in the context of a unit-of-account, revenue from contracts with customers guidance should be applied, adds unit-of-account guidance to collaborative arrangements guidance, and requires, that in a transaction with a collaborative arrangement participant who is not a customer, presenting the transaction together with revenue recognized under contracts with customers is precluded. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted. The Company has assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have a significant impact on its consolidated financial statements.

In November 2019, the FASB issued new guidance which requires that an entity measure and classify share-based payment awards granted to a customer by applying the guidance in ASC 718. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted. The Company has assessed the impact of adopting this guidance and the adoption on January 1, 2020 will not have a significant impact on its consolidated financial statements.

In December 2019, the FASB issued new guidance which removes certain exceptions to the general principles of the accounting for income taxes and also improves consistent application of and simplification of other areas when accounting for income taxes. The guidance is effective for the Company beginning in the first quarter of fiscal year 2021. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

Note 4 — Related Party Transactions:

On August 14, 2019, the Company entered into an exchange agreement (the "Exchange Agreement") with Manchester Securities Corp. ("Manchester"), an existing institutional investor and a wholly owned subsidiary of Elliott Associates, L.P. (together with Manchester, "Elliott"), who collectively beneficially own the largest portion of the Company's common stock, pursuant to which Elliott agreed to exchange all of its outstanding warrants, its 10% senior secured convertible note and its shares of Series C-2 preferred stock, Series D preferred stock and Series F preferred stock, and make a cash payment of $2.0 million to the Company, for 100,000 shares of Series G preferred stock (see Notes 6 and 8). On September 6, 2019, the Company completed the transactions contemplated by the Exchange Agreement.

On December 31, 2018, the Company entered into a securities purchase agreement with Elliott, for the purchase and sale of a 10% senior secured convertible note in the aggregate principal amount of $7,500,000 and a warrant to purchase up to an aggregate of 90,000 shares of the Company's common stock, for gross proceeds of $7,500,000 (see Note 6). The warrant with a grant date fair value of $433,365, is immediately exercisable, has an exercise price of $7.50 per share, subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock, and has a term of five years. The note has a conversion price of $7.50 per share. The conversion price is subject to appropriate adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock. As of December 31, 2019, this note is no longer outstanding as a result of the Exchange Agreement (see Notes 6 and 8).

In May 2013, the Company issued a warrant to purchase up to 100,000 shares of the Company's common stock to Elliott. The warrant had an expiration date of May 30, 2019. In May 2019, to allow the Company and Elliott time to discuss and possibly conclude the Exchange Agreement, the Company extended the expiration date of the warrant to July 1, 2019, which was subsequently extended to August 16, 2019. The warrant, which was canceled in connection with the terms of the Exchange Agreement, had an exercise price of $0.005 (see Note 6). The incremental value of the warrant extended was immaterial.

Note 5 — Income Taxes:

The Company's U.S. and foreign loss before income taxes are set forth below:

	December 31,	
	2019	**2018**
United States	$ (20,943,703)	$ (25,882,114)
Foreign	(550,149)	(947,516)
Total	$ (21,493,853)	$ (26,829,630)

There were no current or deferred income tax provision for the years ended December 31, 2019 and 2018 because the Company has incurred operating losses since inception.

The Company's deferred tax assets consist of the following:

	December 31,	
	2019	**2018**
Net operating loss carryforwards – Federal	$ 33,494,000	$ 29,303,000
Net operating loss carryforwards – State	6,171,000	8,441,000
Net operating loss carryforwards – Foreign	2,128,000	1,876,000
Capitalized licensing fees	757,000	912,000
Stock-based compensation	2,892,000	2,447,000
Accrued compensation	349,000	307,000
Other	24,000	110,000
Totals	45,815,000	43,396,000
Less valuation allowance	(45,815,000)	(43,396,000)
Deferred tax assets	$ -	$ -

The Company had the following potentially utilizable net operating loss tax carryforwards:

	December 31,	
	2019	2018
Federal	$ 155,400,000	$ 139,538,000
State	$ 82,700,000	$ 118,719,000
Foreign	$ 7,091,000	$ 6,250,000

The net operating loss tax generated before January 1, 2019 carryforwards will start to expire in 2027 for Federal purposes and have already begun to expire for state purposes. The Tax Cuts and Jobs Act of 2017 (the "Act") limits the net operating loss deduction to 80% of taxable income for losses arising in tax years beginning after December 31, 2017. However, the net operating losses now have an indefinite carryforward as opposed to the current 20-year carryforward. The foreign net operating loss tax carryforwards do not expire. Our federal and state operating loss carryforwards include windfall tax deductions from stock option exercises.

The utilization of the Company's net operating losses may be subject to a substantial limitation due to the "change of ownership provisions" under Section 382 of the Internal Revenue Code and similar state provisions. Such limitation may result in the expiration of the net operating loss carryforwards before their utilization.

The Company's foreign earnings are derived from its German subsidiary. The Company does not expect any foreign earnings to be repatriated in the U.S. in the near future.

The Company's effective tax rate varied from the statutory rate as follows:

	December 31,	
	2019	2018
Statutory federal tax rate	21.0%	21.0%
State income tax rate (net of federal)	7.2%	4.5%
Effect of foreign operations	0.8%	1.1%
Federal deferred tax rate change	0.1%	0.0%
NJ NOL adjustment	6.2%	0.0%
Other permanent differences	(0.4)%	(0.3)%
Effect of valuation allowance	(11.3)%	(26.3)%
Effective tax rate	23.6%	0.0%

In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income of the appropriate character during the periods in which those temporary differences become deductible and the loss carryforwards are available to reduce taxable income. In making its assessment, the Company considered all sources of taxable income including carryback potential, future reversals of existing deferred tax liabilities, prudent and feasible tax planning strategies, and lastly, objectively verifiable projections of future taxable income exclusive of reversing temporary differences and carryforwards. At December 31, 2019 and 2018, the Company maintained a full valuation allowance against its net deferred tax assets. The Company will continue to assess all available evidence during future periods to evaluate the realization of its deferred tax assets.

The following table presents the changes in the deferred tax asset valuation allowance for the periods indicated:

Year Ended	Balance at Beginning of Year	Increase (Decrease) Charged (Credited) to Income Taxes (Benefit)	Increase (Decrease) Charged (Credited) to OCI	Balance at End of Year
December 31, 2019	$ 43,396,000	$ 2,449,000	$ (30,000)	$ 45,815,000
December 31, 2018	$ 36,346,000	$ 7,082,000	$ (32,000)	$ 43,396,000

Accounting for uncertainty in income taxes requires uncertain tax positions to be classified as non-current income tax liabilities unless they are expected to be paid within one year. The Company has concluded that there are no uncertain tax positions requiring recognition in its consolidated financial statements as of December 31, 2019 and 2018. The Company recognizes interest and penalties related to uncertain tax positions if any as a component of income tax expense.

The Company files income tax returns in the U.S. federal, state and foreign jurisdictions. Tax years 2014 to 2018 remain open to examination for both the U.S. federal and state jurisdictions. Tax years 2015 to 2018 remain open for Germany.

In April 2019, the Company sold a portion of its unused net operating losses ("NOL") carryforwards through the State of New Jersey's Economic Development Authority ("NJEDA") Technology Business Tax Certificate Transfer program which allowed the Company to sell $5,413,000 of its total $6,085,000 in available NOL tax benefits for the state fiscal year 2018. The Company realized net proceeds of $5,061,000 from the sale of its NOL.

Note 6 — Senior Secured Convertible Note, Related Party:

On December 31, 2018, the Company entered into a securities purchase agreement with Elliott for the purchase and sale of a 10% senior secured convertible note in the aggregate principal amount of $7,500,000 and a warrant to purchase up to an aggregate of 90,000 shares of the Company's common stock, for gross proceeds of $7,500,000. The senior secured convertible note and warrant to purchase up to an aggregate of 90,000 shares of the Company's common stock were cancelled in connection with the terms of the Exchange Agreement.

The note was a senior obligation, secured by all of the Company's assets. The note bore interest at a rate of 10.0% per annum, compounded quarterly. Interest was first payable on January 2, 2019, and on the first trading day of each month thereafter, until its cancellation. The note was to mature on December 30, 2021. Any accrued but unpaid interest for the applicable interest period was added to the principal outstanding under the notes. The note had a conversion price of $7.50 per share. The conversion price was subject to appropriate adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting the Company's common stock. The noteholder was able to convert its outstanding note principal amount, and any accrued and unpaid interest, at any time into shares of common stock at the conversion rate. Additionally, the note would automatically convert into shares of common stock if, prior to the maturity date, the average closing sale price of the Company's common stock for any 20 trading days during any consecutive 30 trading days equals or exceeds 150% of the conversion price. The Company held the right to pay any accrued interest in cash for any calendar month during which the average closing sale price of its common stock averaged at least 150% of the conversion price of the notes. On or after July 1, 2020, the Company was able to prepay any principal amount outstanding on the notes in amounts of $2,000,000 (or in full, if less than $2,000,000), provided that if the prepayment occurs between July 2, 2020 and March 30, 2021, the prepayment amount would have equaled 110% of the principal amount being repaid and if the prepayment occurs after March 31, 2021, the prepayment amount would have equaled 105% of the principal amount being repaid. For year ended December 31, 2019, approximately $462,000 was recognized as interest expense on the consolidated statement of operations and comprehensive loss. The senior secured convertible note, including accrued interest, was exchanged as a result of the Exchange Agreement.

The warrant was immediately exercisable, had an exercise price of $7.50 per share, subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock, and had a term of five years. The closing of the note and warrant sale and purchase occurred simultaneously with entry into the securities purchase agreement. No placement agent or underwriter was involved in the offering.

On the same date, and in connection with the sale of the note and warrant, the Company amended and restated the following warrants held by Elliott and its affiliates to reduce the exercise price of each warrant to $0.005 per share: warrants issued in May 2013 to purchase up to an aggregate of 100,000 shares of the Company's common stock with a pre-amendment exercise price of $3.25 per share and an expiration date of May 30, 2019, which was subsequently extended to August 16, 2019 (the "May 30, 2019 Warrants"), (see Note 4); and warrants issued in October 2013 to purchase up to an aggregate of 150,000 shares of the Company's common stock with a pre-amendment exercise price of $4.50 per share and an expiration date of October 22, 2019 (the "October 22, 2019 Warrants"). These warrants were subsequently cancelled in connection with the Exchange Agreement (see Note 8).

Also in conjunction with the December 2018 securities purchase agreement, the Company and Elliott and certain of its affiliates that hold shares of various series of the Company's preferred stock and warrants to purchase shares of the Company's common stock agreed to waive any rights of conversion or exercise for all of the shares of its Series C-2, D, E and F preferred stock and shares issuable upon the exercise of certain warrants (collectively with the shares of Series C-2, D, E, and F preferred stock, the "Elliott Derivative Securities"), until the earliest to occur of (i) the effective date on which the Company's Certificate of Incorporation is amended to increase the number of authorized shares of common stock, (ii) the effective date on which the Company effects a reverse stock split of its common stock, (iii) one business day immediately prior to the consummation of a fundamental transaction (as defined in the instruments governing the applicable Elliott Derivative Securities), and (iv) April 30, 2019. The 1-for-5 reverse stock split that was effective on March 26, 2019 satisfied this condition, however, with the exception of the Series E preferred stock, the Elliot Derivative Securities were cancelled in connection with the Exchange Agreement.

The Company was required to have a majority of the Series C-2, Series D, Series E and Series F non-voting preferred stock consent to any indebtedness other than trade payables incurred in the ordinary course of business consistent with past practice, and letters of credit incurred in an aggregate amount of $3,000,000 at any point in time. At the time of the securities purchase agreement, Elliott was the holder of all of the shares of the Series C-2, Series D, Series E and Series F non-voting preferred stock and implicitly consented to the convertible note financing. Elliott is currently the holder of all of the shares of the Series E and Series G preferred stock.

The $7,500,000 in gross proceeds, along with the legal fees of approximately $267,000, were allocated between the senior secured convertible note and warrants based on their relative fair values. The portion of the proceeds allocated to the warrants of approximately $396,000, net of allocated fees of approximately $6,000, was accounted for as additional paid-in capital. The remainder of the proceeds of approximately $7,000,000, net of allocated fees of approximately $103,000 was allocated to the senior convertible note, with the fair value of the warrants resulting in a debt discount. In addition, the incremental cost of approximately $710,000 associated with the warrant modification was recorded as a debt discount. An additional debt discount of approximately $143,000 was recorded as a beneficial conversion feature as the stock price was greater than the effective conversion price (after allocation of the total proceeds) on the measurement date.

The debt discount was being amortized to interest expense using the effective interest method in accordance with ASC 835 over the term of the agreement. For the year ended December 31, 2019, approximately $313,000 was recognized as amortization of debt discount and is included in interest expense on the consolidated statement of operations and comprehensive loss.

The Company used a hybrid valuation model to determine the fair value of the senior secured convertible note. The hybrid model incorporated both a present value analysis and the use of the Black Scholes option pricing model to reflect the senior secured convertible note's conversion feature. The Black-Scholes option pricing model was also used to determine the fair value of the warrants in order to allocate the gross proceeds based on relative fair values (see Note 1). ASC 820, *"Fair Value Measurements,"* states that the reporting entity should use the valuation technique(s) appropriate for the measurement, considering the availability of data with which to develop inputs that represent the assumptions that market participants would use when pricing the asset or liability. Market participants price options based on expected volatility, not historical volatility. In estimating the expected volatility of the Company's common stock, the Company followed the guidance of ASC 820 and considered a number of factors - including the implied volatility of put and call options on the Company's common stock that are traded over the counter.

A summary of the assumptions used in the Black Scholes pricing model are as follows:

	Conversion Option At Issuance Date	New Warrants At Issuance Date
Expected term (months)	36	60
Volatility	161.5%	161.5%
Dividend yield	0%	0%
Risk-free interest rate	2.43%	2.48%

As part of the Exchange Agreement, the senior secured convertible note, along with certain warrants and the Series C-2, Series D and Series F preferred stock, and the payment of $2,000,000, was exchanged for 100,000 shares of Series G preferred stock. As a result of this transaction, the Company recognized a deemed dividend of $26,733,098 on its consolidated statement of operations and comprehensive loss for the year ended December 31, 2019 (see Note 8).

Note 7 — Commitments and Contingencies:

Contingency Matters

On September 9, 2014, the Company filed in the District Court of Mannheim, Germany, a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of the Company's European Patent EP 1 814 562 B1, which was granted by the European Patent Office (the "EPO") on January 8, 2014 (the "Prosl European Patent"). The Prosl European Patent covers the formulation of taurolidine and citrate with low dose heparin in a catheter lock solution for maintaining patency and preventing infection in hemodialysis catheters. In this action, the Company claims that the Defendants infringe on the Prosl European Patent by manufacturing and distributing catheter locking solutions to the extent they are covered by the claims of the Prosl European Patent. The Company believes that its patent is sound and is seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. Separately, TauroPharm has filed an opposition with the EPO against the Prosl European Patent alleging that it lacks novelty and inventive step. The Company cannot predict what other defenses the Defendants may raise, or the ultimate outcome of either of these related matters. At present, the EPO has revoked the Prosl European Patent as invalid, and the Company has filed an appeal, which is currently pending.

In the same complaint against the same Defendants, the Company also alleged an infringement (requesting the same remedies) of ND Partners' utility model DE 20 2005 022 124 U1 (the "Utility Model"), which the Company believes is fundamentally identical to the Prosl European Patent in its main aspects and claims. The Court separated the two proceedings and the Prosl European Patent and the Utility Model claims are now being tried separately. TauroPharm has filed a cancellation action against the Utility Model before the German Patent and Trademark Office (the "German PTO") based on the similar arguments as those in the opposition against the Prosl European Patent.

On March 27, 2015, the District Court held a hearing to evaluate whether the Utility Model has been infringed by TauroPharm in connection with the manufacture, sale and distribution of its TauroLock-HEP100™ and TauroLock-HEP500™ products. A hearing before the same court was held on January 30, 2015 on the separate, but related, question of infringement of the Prosl European Patent by TauroPharm.

The Court issued its decisions on May 8, 2015, staying both proceedings. In its decisions, the Court found that the commercialization by TauroPharm in Germany of its TauroLock catheter lock solutions Hep100 and Hep500 infringes both the Prosl European Patent and the Utility Model and further that there is no prior use right that would allow TauroPharm to continue to make, use or sell its product in Germany. However, the Court declined to issue an injunction in favor of the Company that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the EPO, in the case of the Prosl European Patent, or the German PTO, in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by the Company for injunctive and other relief until such time as the EPO or the German PTO made a final decision on the underlying validity of the Prosl European Patent and the Utility Model. It is safe to assume that the complaint regarding the infringement of the Utility Model will be dismissed now that the German PTO has voided the Utility Model (see below). This does, however, not have a direct effect on the infringement proceedings concerning the Prosl European Patent.

The opposition proceeding against the Prosl European Patent before the EPO is ongoing. The EPO held a hearing in the opposition proceeding on November 25, 2015. In its preliminary consideration of the matter, the EPO (and the German PTO) had regarded the patent as not inventive or novel due to publication of prior art. However, the EPO did not issue a decision at the end of the hearing but adjourned the matter due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in a further hearing in order to close some gaps in the documentation presented by TauroPharm as regards the publication of the prior art.

The German PTO held a hearing in the validity proceedings relating to the Utility Model on June 29, 2016, at which the panel affirmed its preliminary finding that the Utility Model was invalid based upon prior publication of a reference to the benefits that may be associated with adding heparin to a taurolidine based solution. The Company filed an appeal against the ruling on September 7, 2016. An oral hearing was held on September 17, 2019 in which the German Federal Patent affirmed the first instance decision that the Utility Model was invalid. The decision has only a declaratory effect, as the Utility Model had expired in November 2015.

In October 2016, TauroPharm submitted a further writ to the EPO requesting a date for the hearing and bringing forward further arguments, in particular in view of the June 2016 decision of the German PTO on the invalidity of the utility model. On November 22, 2017, the EPO in Munich, Germany held a further oral hearing in this matter. At the hearing, the panel held that the Prosl European Patent would be invalidated because it did not meet the requirements of novelty based on a technical aspect of the European intellectual property law. The Company disagrees with this decision and, after the written opinion was issued by the Opposition Division in September 2018, has appealed the decision. The Company continues to believe that the Prosl European Patent is indeed novel and that its validity should be maintained. There can be no assurance that the Company will prevail in this matter. In addition, the ongoing Unfair Competition litigation brought by the Company against TauroPharm is not affected and will continue.

On January 16, 2015, the Company filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, the Company alleges violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. The Company alleges that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLock™, TauroLock-HEP100 and TauroLock-HEP500. The Company seeks a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider the Company's claims. In this hearing, the presiding judge explained that the court needed more information with regard to several aspects of the case. As a consequence, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to the court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. The Company's legal team has prepared the requested reply and produced the respective documentation. TauroPharm has also filed another writ within the same deadline and both parties have filed further writs at the end of April 2016 setting out their respective argumentation in more detail. A further oral hearing in this matter was held on November 15, 2016. In this hearing, the court heard arguments from CorMedix and TauroPharm concerning the allegations of unfair competition. The court made no rulings from the bench and indicated that it is prepared to further examine the underlying facts of the Company's allegations. On March 7, 2017, the court issued another interim decision in the form of a court order outlining again several issues relating to the argumentation of both sides in the proceedings. In particular the court requested the Company to further specify its requests and to further substantiate in even more detail which know-how was provided by Biolink (the company who developed Neutrolin that was acquired by ND Partners) to TauroPharm by whom and when. The court also raised the question whether the know-how provided at the time to TauroPharm could still be considered to be secret know-how or may have become public in the meantime. The court granted both sides the opportunity to reply to this court order and provide additional facts and evidence until May 15, 2017. Both parties have submitted further writs in this matter and the court scheduled a further hearing on May 8, 2018. After having been rescheduled several times, the hearing took place on November 20, 2018. A decision was rendered by the court on December 11, 2018, dismissing the complaint in its entirety. However, the Company intends to continue to pursue this matter, and still believes firmly that its claims are well-founded. The Company therefore appealed in January 2019 and filed its grounds of appeal in March 2019. An oral hearing was held on September 6, 2019 in which the legal counsel of the Company brought forward further arguments for the fact that the manufacturing process of the respective catheter locking solution is indeed protectable as a trade secret. In view of these new arguments, the court issued an evidentiary order on September 27, 2019 ordering an expert opinion. Next steps will be taken after the receipt of the expert opinion.

In connection with the aforementioned patent and utility model infringement and unfair competition proceedings against TauroPharm, the Company was required by the District Courts of Mannheim and Cologne to provide security deposits of an aggregate of approximately $170,000, to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The Company recorded the deposits as restricted cash on the consolidated balance sheets.

Commitments

In-Licensing

In 2008, the Company entered into a License and Assignment Agreement (the "NDP License Agreement") with ND Partners, LLP ("NDP"). Pursuant to the NDP License Agreement, NDP granted the Company exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the "NDP Technology"). The Company acquired such licenses and patents through its assignment and assumption of NDP's rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann and Dr. Johannes Reinmueller. As consideration in part for the rights to the NDP Technology, the Company paid NDP an initial licensing fee of $325,000 and granted NDP a 5% equity interest in the Company, consisting of 7,996 shares of the Company's common stock.

The Company is required to make payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The maximum aggregate number of shares issuable upon achievement of milestones is 29,109 shares. In 2014, a certain milestone was achieved resulting in the release of 7,277 shares held in escrow. The number of shares held in escrow as of December 31, 2019 is 21,832 shares of common stock. The maximum aggregate amount of cash payments due upon achievement of milestones is $3,000,000 with the balance being $2,500,000 as of December 31, 2019 and 2018. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval and upon achieving certain worldwide net sales amounts. There were no milestones achieved during the years ended December 31, 2019 and 2018.

The NDP License Agreement may be terminated by the Company on a country-by-country basis upon 60 days prior written notice. If the NDP License Agreement is terminated by either party, the Company's rights to the NDP Technology will revert back to NDP.

Other

In September 2017, the Company entered into a sublease agreement for approximately 6,960 square feet of office space in Berkeley Heights, New Jersey, which sublease runs from September 15, 2017 to June 29, 2020. This sublease is rent-free to the Company. A notice of an intention not to renew the Company's current lease has been received and as a result, the Company is actively seeking for a new space to lease that will meet its current needs.

Note 8 — Stockholders' Equity:

Common Stock:

The Company had a prior sales agreement with B. Riley for its ATM program, which expired on April 16, 2018, under which the Company could issue and sell up to an aggregate of $60.0 million of shares of its common stock. On March 9, 2018, the Company entered into a new agreement with B. Riley for the sale of up to $14.7 million of the Company's common stock under the ATM program, pursuant to a registration statement filed on March 9, 2018 for an aggregate of $70 million of the Company's securities, which became effective on April 16, 2018. This new ATM agreement replaced a prior sales agreement with B. Riley that expired on April 16, 2018. The ATM program amount was increased by $25.0 million in November 2018. Under the ATM program, the Company may issue and sell common stock from time to time through B. Riley acting as agent, subject to limitations imposed by the Company and subject to B. Riley's acceptance, such as the number or dollar amount of shares registered under the registration statement to which the offering relates. B. Riley is entitled to a commission of up to 3% of the gross proceeds from the sale of common stock sold under the ATM program. During the years ended December 31, 2019 and 2018, the Company sold 1,768,012 and 7,177,755 shares of common stock under the new and expired ATM programs, respectively, and realized net proceeds of approximately $15.2 million and $22.0 million during the years ended December 31, 2019 and 2018, respectively. At December 31, 2019, the Company has approximately $4.6 million available under its current ATM program and $30.3 million available under its current shelf registration for the issuance of equity, debt or equity-linked securities unrelated to the current ATM program (see note 11 for subsequent event sales under ATM).

Restricted Stock Units

During the year ended December 31, 2019 and 2018, the Company granted an aggregate of 24,850 and 18,900 restricted stock units ("RSUs") to its officers and directors under its 2013 Stock Incentive Plan with a weighted average grant date fair value of $8.33 and $3.50 per share, respectively. The fair value of each RSU was estimated to be the closing price of the Company's common stock on each date of grant. These RSUs vest monthly over one year after grant date, subject to continued service on the board through the vesting date. During the year ended December 31, 2019 and 2018, compensation expense recorded for these RSUs was $198,000 and $93,000, respectively. Unrecognized compensation expense as of December 31, 2019 and 2018 was $11,000 and $23,000, respectively. The expected weighted average period for the expense to be recognized is 0.19 years. During the year ended December 31, 2019, 2,830 RSU's were forfeited and no RSUs were forfeited during the year ended December 31, 2018. At December 31, 2019, there were 2,490 RSUs outstanding to vest.

During the year ended December 31, 2019, the Company issued an aggregate of 25,346 shares of its common stock upon the vesting of restricted stock units issued to the Company's board of directors.

Preferred Stock

The Company is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without stockholder approval. The Company's board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. Of the 2,000,000 shares of preferred stock authorized, the Company's board of directors has designated (all with par value of $0.001 per share) the following:

	As of December 31, 2019			As of December 31, 2018		
	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference
Series C-2	-	-	-	150,000	$ 10.00	$ 1,500,000
Series C-3	52,000	$ 10.00	$ 520,000	104,000	$ 10.00	$ 1,040,000
Series D	-	-	-	73,962	$ 21.00	$ 1,553,202
Series E	89,623	$ 49.20	$ 4,409,452	89,623	$ 49.20	$ 4,409,452
Series F	-	-	-	2,000	$ 1,000.00	$ 2,000,000
Series G	100,000	$ 187.36	$ 18,736,452	-	-	-
Total	241,623		$ 23,665,904	419,585		$ 10,502,654

On November 9, 2017, the Company entered into a securities purchase agreement which, on November 16, 2017, resulted in the Company selling $2.0 million of its Series F preferred stock ("Series F Stock") at $1,000 per share. Based on the terms of the Series F Stock, the conversion price was $0.81. The conversion price of the Series F Stock was subject to anti-dilution adjustment for customary recapitalization events such as stock splits, as well as full ratchet anti-dilution protection in the event that the Company did not obtain the subordination of the Series C-3 preferred stock to that of the Series F Stock or obtain stockholder approval, if required by NYSE American rules, of the issuance of common stock that exceeds NYSE American rules. All outstanding shares of Series F Stock were cancelled in connection with the terms of the Exchange Agreement, as described below.

On August 14, 2019, the Company entered into the Exchange Agreement with Elliott, pursuant to which Elliott agreed to exchange all of its outstanding warrants, its 10% senior secured convertible note and its shares of Series C-2 preferred stock, Series D preferred stock and Series F preferred stock, and make a cash payment of $2.0 million to the Company, for 100,000 shares of Series G preferred stock, with an aggregate liquidation preference of $18,736,452, which are convertible into an aggregate of 5,560,138 shares of the Company's common stock at a conversion price of $3.37 per share. Elliott retained the shares of the Company's common stock and Series E preferred stock that it held at the time of the consummation of the Exchange Agreement. Other than with respect to conversion price and liquidation preference, the Series G preferred stock has substantially the same terms as the Company's outstanding Series E preferred stock, including the restrictive covenants contained therein as modified as set forth in the Exchange Agreement. However, Elliott is prohibited from converting the Series G preferred stock into shares of the Company's common stock to the extent that, as a result of such conversion, Elliott would own more than 4.99% of the total number of shares of the Company's common stock then issued and outstanding. The shares of Series G preferred stock are entitled to vote on an as-converted basis with respect to the number of shares of common stock into which they are convertible, based upon an assumed conversion price, solely for the purpose of the voting rights, equal to $7.93, the closing price of the Company's common stock on August 14, 2019, and the Series E preferred stock was modified to provide for similar rights to vote on an as-converted basis. The Company filed the Certificate of Designation of the Series G preferred stock and the Second Amended and Restated Certificate of Designation of the Series E preferred stock with the Secretary of State of the State of Delaware on September 5, 2019. On September 6, 2019, the Company closed this transaction and issued the Series G preferred stock.

Pursuant to the terms of the Exchange Agreement, the exchange of the Series C-2 preferred stock, Series D preferred stock, Series F preferred stock and the 10% senior secured convertible note was considered an extinguishment. As a result, the difference between the fair value allocated to the Series G preferred stock and the carrying value of the Series C-2 preferred stock, Series D preferred stock, Series F preferred stock and the 10% senior secured convertible note is being treated as a deemed dividend and is added to net loss to arrive at loss available to common stockholders.

The Series G preferred stock was valued using the Black Scholes option pricing model. The Black-Scholes option pricing model was also used to determine the fair value of the warrants and the Series C-2 preferred stock, Series D preferred stock and Series F preferred stock. These fair values, along with the fair value of the 10% senior secured convertible note were utilized to allocate the fair value of the Series G preferred stock based on relative fair values. ASC 820, Fair Value Measurements, states that the reporting entity should use the valuation technique(s) appropriate for the measurement, considering the availability of data with which to develop inputs that represent the assumptions that market participants would use when pricing the asset or liability. Market participants price options based on expected volatility, not historical volatility. In estimating the expected volatility of the Company's common stock, the Company followed the guidance of ASC 820 and considered a number of factors - including the implied volatility of the Company's listed warrant contracts.

A summary of the assumptions used in the Black Scholes pricing model are as follows:

Expected term, years	3.0
Volatility	93.3%
Dividend yield	0.0%
Risk-free interest rate	1.53%

As a result of the Exchange Agreement, the Company recognized a deemed dividend of $26,733,098. The deemed dividend was comprised of (1) a beneficial conversion related to the 10% secured senior convertible note recognized at extinguishment; (2) the difference between the allocated fair value of the Series G Preferred Stock issued and the carrying values of the 10% secured senior convertible note, the Series C-2 Preferred Stock, Series D Preferred Stock and Series F Preferred Stock; (3) the difference between the fair value of the exchanged warrants before and after the Exchange Agreement; and (4) the difference between the fair value and the carrying value of Series E Preferred Stock, less the fair value of the Series E warrants that were cancelled as part of the Exchange Agreement.

During the year ended December 31, 2019, the Company issued 104,000 shares of its common stock upon conversion of 52,000 shares of Series C-3 non-voting preferred stock.

The following rights, privileges, terms and condition apply to the outstanding preferred stock at December 31, 2019:

Series C-3 Non-Voting Preferred Stock

Rank. The Series C-3 non-voting preferred stock will rank senior to our common stock; senior to any class or series of capital stock created after the issuance of the Series C-3 non-voting preferred stock; and junior to the Series E voting convertible preferred stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion. Each share of Series C-3 preferred stock is convertible into 2 shares of our common stock (subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock) at a per share price of $5.00 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series C-3 preferred stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of Series C-3 preferred stock will receive a payment equal to $10.00 per share of Series C-3 preferred stock before any proceeds are distributed to the holders of our common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series C-3 preferred stock and holders of Series C-3 preferred stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

Voting Rights. Shares of Series C-3 preferred stock will generally have no voting rights, except as required by law and except that the consent of holders of two thirds of the outstanding Series C-3 preferred Stock will be required to amend the terms of the Series C-3 preferred stock or the certificate of designation for the Series C-3 preferred stock.

Dividends. Holders of Series C-3 preferred stock are entitled to receive, and we are required to pay, dividends on shares of the Series C-3 preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series C-3 preferred stock. Shares of Series C-3 preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing. There is no established public trading market for the Series C-3 preferred stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series C-3 preferred stock on any national securities exchange or trading system.

Fundamental Transactions. If, at any time that shares of Series C-3 preferred stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series C-3 preferred stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

Series E Voting Convertible Preferred Stock

Rank. The Series E voting preferred stock will rank senior to our common stock; senior to any class or series of capital stock created after the issuance of the Series E voting convertible preferred stock; senior to the Series C-3 non-voting convertible preferred stock; and on parity with the Series G voting convertible preferred stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion. Each share of Series E preferred stock is convertible into 4.3733 shares of our common stock (subject to adjustment as provided in the certificates of designation for the Series E preferred stock) at a per share price of $3.75 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series E preferred stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 4.99% of the total number of shares of our common stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of Series E preferred stock will receive a payment equal to $49.20 per share of Series E preferred stock on parity with the payment of the liquidation preference due the Series G preferred stock, but before any proceeds are distributed to the holders of common stock, and the Series C-3 non-voting convertible preferred stock. After the payment of this preferential amount, holders of Series E preferred stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock that participates with the common stock in such distributions.

Voting Rights. Shares of Series E preferred stock are entitled to vote on an as-converted basis, based upon an assumed conversion price of $7.93.

Dividends. Holders of Series E preferred stock are entitled to receive, and we are required to pay, dividends on shares of the Series E preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series E preferred stock. Shares of Series E preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing. There is no established public trading market for the Series E preferred stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series E preferred stock on any national securities exchange or trading system.

Fundamental Transactions. If, at any time that shares of Series E preferred stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series E preferred stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

Debt Restriction. As long as any of the Series E preferred stock is outstanding, we cannot create, incur, guarantee, assume or suffer to exist any indebtedness, other than (i) trade payables incurred in the ordinary course of business consistent with past practice, and (ii) up to $10 million aggregate principal amount of indebtedness with a maturity less than twelve months outstanding at any time, which amount may include up to $5 million of letters of credit outstanding at any time.

Other Covenants. In addition to the debt restrictions above, as long as any of the Series E preferred stock is outstanding , we cannot, among others things: create, incur, assume or suffer to exist any encumbrances on any of our assets or property; redeem, repurchase or pay any cash dividend or distribution on any of our capital stock (other than as permitted, which includes the dividends on the Series E preferred stock and Series G preferred stock); redeem, repurchase or prepay any indebtedness (other than as permitted); or engage in any material line of business substantially different from our current lines of business.

Purchase Rights. In the event we issue any options, convertible securities or rights to purchase stock or other securities pro rata to the holders of common stock, then a holder of Series E preferred stock will be entitled to acquire, upon the same terms a pro rata amount of such stock or securities as if the Series E preferred stock had been converted to common stock.

Series G Voting Convertible Preferred Stock

Rank. The Series G voting convertible preferred stock will rank senior to our common stock; senior to any class or series of capital stock created after the issuance of the Series G voting convertible preferred stock; junior to the Series C-3 non-voting convertible preferred stock, pending the consent of the holders of such series to the subordination thereof; and on parity with the Series E voting convertible preferred stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion. Each share of Series G preferred stock is convertible into approximately 55.5978 shares of our common stock (subject to adjustment as provided in the certificate of designation for the Series G preferred stock) at a per share price of $3.37 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series G preferred stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 4.99% of the total number of shares of our common stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of Series E preferred stock will receive a payment equal to $187.36452 per share of Series G preferred stock on parity with the payment of the liquidation preference due the Series E preferred stock, but before any proceeds are distributed to the holders of Series C-3 preferred stock (pending the consent of the holders of such series to the subordination thereof) and any proceeds are distributed to the holders of common stock. After the payment of this preferential amount, holders of Series G preferred stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock that participates with the common stock in such distributions.

Voting Rights. Shares of Series G preferred stock are entitled to vote on an as-converted basis, based upon an assumed conversion price of $7.93.

Dividends. Holders of Series G Preferred stock are entitled to receive, and we are required to pay, dividends on shares of the Series G preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series G preferred stock. Shares of Series G preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing. There is no established public trading market for the Series G preferred stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series G preferred stock on any national securities exchange or trading system.

Fundamental Transactions. If, at any time that shares of Series G preferred stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series G preferred stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

Debt Restriction. As long as any of the Series G preferred stock is outstanding, we cannot create, incur, guarantee, assume or suffer to exist any indebtedness, other than (i) trade payables incurred in the ordinary course of business consistent with past practice, and (ii) up to $10 million aggregate principal amount of indebtedness with a maturity less than twelve months outstanding at any time, which amount may include up to $5 million of letters of credit outstanding at any time.

Other Covenants. In addition to the debt restrictions above, as long as any of the Series G preferred stock is outstanding, we cannot, among others things: create, incur, assume or suffer to exist any encumbrances on any of our assets or property; redeem, repurchase or pay any cash dividend or distribution on any of our capital stock (other than as permitted, which includes the dividends on the Series E preferred stock and the Series G preferred stock); redeem, repurchase or prepay any indebtedness (other than as permitted); or engage in any material line of business substantially different from our current lines of business.

Purchase Rights. In the event we issue any options, convertible securities or rights to purchase stock or other securities pro rata to the holders of common stock, then a holder of Series G preferred stock will be entitled to acquire, upon the same terms a pro rata amount of such stock or securities as if the Series G preferred stock had been converted to common stock.

Stock Options:

The Company's 2013 Stock Incentive Plan (the "2013 Plan") was approved by the shareholders in July 2013. The 2013 Plan provides for the issuance of equity grants in the form of options, restricted stock, stock awards and other forms of equity compensation. Awards under the 2013 Plan may be made to directors, officers, employees and consultants. Initially, an aggregate of 1,000,000 shares of the Company's common stock was reserved for issuance under the 2013 Plan. On January 19, 2016, the shareholders approved an increase of the shares issuable under the 2013 Plan from 1,000,000 to 1,600,000 and on June 13, 2016 from 1,600,000 to 2,200,000.

On November 26, 2019, the Company's shareholders approved the CorMedix Inc. 2019 Omnibus Stock Incentive Plan (the "2019 Plan"). Pursuant to the 2019 Plan and subject to certain adjustments as described below, the Company may issue up to 3,000,000 shares of its common stock, plus any shares that remain available for grant under its 2013 Plan as of the effective date (up to a maximum carry-forward of 522,606 shares plus any outstanding options under the 2013 Plan that were canceled, forfeited and expired after the approval of the 2019 Plan), as long-term equity incentives to the Company's employees, consultants, and directors. The long-term incentives may be in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, dividend equivalent rights, or other rights or benefits (collectively, stock rights) to employees, consultants, and directors of the Company or a related entity (collectively, participants). The Company believes that the effective use of long- term equity incentives is essential to attract, motivate, and retain employees, consultants and directors, to further align participants' interests with those of the Company's stockholders, and to provide participants incentive compensation opportunities that are competitive with those offered by other companies in the same industry and locations as the Company.

The 2019 Plan is a new equity compensation plan for the Company's employees, consultants, and directors which replaced the 2013 Plan. The 2013 Plan and the Amended and Restated 2006 Stock Incentive Plan (the "2006 Plan") are referred to collectively as the "Prior Plans". No further awards will be granted under the Prior Plans after the approval of the 2019 Plan. Awards outstanding under the Prior Plans will remain outstanding in accordance with their terms and the Prior Plans.

During the year ended December 31, 2019, the Company granted ten-year qualified and non-qualified stock options to its officers, directors, employees and consultants covering an aggregate of 496,300 shares of the Company's common stock under the 2013 Plan. The weighted average exercise price of these options is $7.64 per share.

During the years ended December 31, 2019 and 2018, total compensation expense for stock options issued to employees, directors, officers and consultants was $2,242,000 and $1,018,000, respectively. As of December 31, 2019, there was $1,856,000 total unrecognized compensation expense related to unvested stock options granted which expense is expected to be recognized over an expected remaining weighted average period of 1.6 years. All share-based awards are recognized on a straight-line method, assuming all awards granted will vest. Forfeitures of share-based awards are recognized in the period in which they occur.

The fair value at grants dates of the grants issued subject to service and performance-based vesting conditions were determined using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,	
	2019	**2018**
Risk-free interest rate	1.51% - 2.74%	2.63% - 2.96%
Expected volatility	103% - 110%	93% - 103%
Expected term (years)	5 – 10 years	5 years
Expected dividend yield	0.0%	0.0%
Weighted-average grant date fair value of options granted during the period	$6.11	$8.00

The Company estimated the expected term of the stock options granted based on anticipated exercises in future periods. The expected term of the stock options granted to consultants is based upon the full term of the respective option agreements. The expected stock price volatility for the Company's stock options is calculated based on the historical volatility since the initial public offering of the Company's common stock in March 2010. The expected dividend yield of 0.0% reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards which is 5 years for employees and 10 years for non-employees.

The following table summarizes the Company's stock options activity and related information for the year ended December 31, 2019:

	Shares Underlying Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at beginning of year	1,011,266	$ 9.32	6.7	$ 1,006,743
Granted	496,300	$ 7.64		156,744
Exercised	(38,090)	$ 3.22		154,589
Expired/Canceled	(7,093)	$ 10.29		664
Forfeited	(85,989)	$ 7.73		53,047
Outstanding at end of year	1,376,394	$ 8.98	6.8	$ 1,232,545
Vested at end of year	932,959	$ 9.31	6.0	$ 950,659
Expected to vest in the future	443,435	$ 8.28	8.6	$ 281,887

The total intrinsic value of stock options exercised during the years ended December 31, 2019 and 2018 was $154,589 and $42,400, respectively. The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying options and the quoted closing price of the common stock of the Company at the end of the reporting period for those options that have an exercise price below the quoted closing price.

Warrants:

The following table is the summary of warrant activities:

	Shares Underlying Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at December 31, 2018	3,319,008	$ 5.50	3.1
Issued	-	-	-
Exercised	(1,948,207)	$ 4.45	-
Canceled in connection with the Exchange Agreement	(892,973)	$ 4.68	-
Expired	(136,500)	$ 12.50	-
Outstanding at December 31, 2019	341,328	$ 6.24	1.42

On December 31, 2018, the Company sold to Elliott a senior secured convertible note in the aggregate principal amount of $7,500,000 and a warrant to purchase up to an aggregate of 90,000 shares of common stock, for gross proceeds of $7,500,000. The warrant is immediately exercisable, has an exercise price of $7.50 per share, subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting the Company's common stock, and has a term of five years (see Note 6). On December 31, 2018, the Company amended and restated the following warrants held by Elliott and its affiliates to reduce the exercise price of each warrant to $0.001 per share: warrants issued in May 2013 to purchase up to an aggregate of 100,000 shares of the Company's common stock with a pre-amendment exercise price of $3.25 per share and an expiration date of May 30, 2019 (the "May 30, 2019 Warrants"); and warrants issued in October 2013 to purchase up to an aggregate of 150,000 shares of common stock with a pre-amendment exercise price of $4.50 per share and an expiration date of October 22, 2019 (the "October 22, 2019 Warrants"). The incremental cost of approximately $710,000 associated with the warrant modification was recorded as a debt discount. The senior secured convertible note and warrant to purchase up to an aggregate of 90,000 shares of the Company's common stock were cancelled in connection with the terms of the Exchange Agreement.

The fair value of the warrant was determined using a Black-Scholes option pricing model using the following assumptions at the grant date of the warrant:

Expected Term	5.0 years
Volatility	102.85%
Dividend yield	0.0%
Exercise Price	$ 1.50
Risk-free interest rate	2.51%

On September 25, 2019, the Company entered into Letter Agreements with Holders of Series B Warrants. Pursuant to each Letter Agreement, the Company agreed to reduce the exercise price of each Holder's Series B Warrants from $5.25 to $4.00, provided that the Holder exercised its Warrant for cash at the time of entry into such Letter Agreement. Each Holder exercised its Series B Warrants in full and the Company issued an aggregate of 1,224,263 shares of Common Stock to them. The Company received net proceeds of approximately $4,900,000. As a result of the modification of the exercise price of these warrants, the Company recognized an incremental value of $369,500, which was recorded as a deemed dividend on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2019, using the Black-Scholes pricing model with the following assumptions:

Expected term	2.88 years
Volatility	111.5%
Dividend yield	0.0%
Risk-free interest rate	1.62%

During the year ended December 31, 2019, the expiration date of a warrant to purchase up to 100,000 shares of the Company's common stock was extended from May 30, 2019 to August 16, 2019, then subsequently canceled in connection with the Exchange Agreement transaction (see Note 6). The warrant had an exercise price of $0.005. The incremental value of the warrant extended was immaterial.

During the year ended December 31, 2019, the Company issued an aggregate of 1,948,207 shares of its common stock upon exercise of warrants, resulting in net proceeds of $8,674,000.

Stock-based Deferred Compensation Plan for Non-Employee Directors

In 2014, the Company established an unfunded stock-based deferred compensation plan, providing non-employee directors the opportunity to defer up to one hundred percent of fees and compensation, including restricted stock units. The amount of fees and compensation deferred by a non-employee director is converted into stock units, the number of which is determined based on the closing price of the Company's common stock on the date such compensation would have otherwise been payable. At all times, the plan participants are one hundred percent vested in their respective deferred compensation accounts. On the tenth business day of January in the year following a director's termination of service, the director will receive a number of common shares equal to the number of stock units accumulated in the director's deferred compensation account. The Company accounts for this plan as stock-based compensation under ASC 718. During the year ended December 31, 2019 and 2018, the amount of compensation that was deferred under this plan was $36,500 and $30,000, respectively.

Note 9 — Concentrations:

At December 31, 2019 and 2018, no net accounts receivable was due from a customer that exceeded 10%. During the year ended December 31, 2019, the Company had revenue from four customers that exceeded 10% of its total sales (42%, 18%, 17% and 12%) and the Company had revenue from a single customer that exceeded 10% of its total sales (70%) for the year ended December 31, 2018.

Note 10 — Leases:

The Company entered into an operating lease for office space in Germany that began in July 2017. The rental agreement has a three-month term which automatically renews and includes a monthly cost of 400 Euros. The Company elected to apply the short-term practical expedient to the office lease. The Company also has an operating lease for office equipment.

Prior to the adoption of ASC 842, operating lease expense of approximately $6,000 was recognized in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2019.

Operating lease expense in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2019 was approximately $6,000, which includes costs associated with leases for which ROU assets have been recognized as well as short-term leases.

At December 31, 2019, the Company has a total operating lease liability of $4,000. Approximately $2,000 each are included in accrued expenses and operating lease liabilities, net of current portion on the consolidated balance sheet. Operating ROU assets as of December 31, 2019 is $5,000 and is included in property and equipment, net on the consolidated balance sheet.

For the year ended December 31, 2019, cash paid for amounts included in the measurement of lease liabilities in operating cash flows from operating leases was $6,000.

The weighted average remaining lease term and weighted average discount rate for operating leases were 2.8 years and 10%, respectively, as of December 31, 2019.

As of December 31, 2019, maturities of lease liabilities were as follows:

2020	$ 2,000
2021	2,000
2022	1,000
Total future minimum lease payments	5,000
Less imputed interest	(1,000)
Total	$ 4,000

Note 11 — Subsequent Events:

During January 2020, the Company sold an aggregate of 368,144 shares of its common stock under the at-the-market program and realized net proceeds of approximately $2.5 million.

In January 2020, the Company issued an aggregate of 91,500 shares of its common stock upon exercise of warrants, resulting in net proceeds of approximately $412,000.

DESCRIPTION OF CAPITAL STOCK OF CORMEDIX INC.

Common Stock

The following is a summary of certain provisions of the capital stock of CorMedix Inc. (referred to herein as "we," "us," "our" and "Company"). Such summary does not purport to be complete. You should refer to our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated Bylaws and each Certificate of Designation for our Series C-3, E and G preferred stock, in each case, incorporated by reference as an exhibit to this Form 10-K. The summary below is also qualified by provisions of such documents and applicable law.

Pursuant to our Amended and Restated Certificate of Incorporation, as amended, we are authorized to issue 160,000,000 shares of common stock, $0.001 par value per share. As of March 9, 2020, we had [__] shares of common stock outstanding.

The holders of our common stock are entitled to one vote per share on all matters to be voted on by the stockholders, and there are no cumulative voting rights. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all shares of common stock present in person or represented by proxy, subject to any voting rights granted to holders of any preferred stock.

The holders of common stock are entitled to receive ratable dividends, if any, payable in cash, in stock or otherwise if, as and when declared from time to time by our Board of Directors out of funds legally available for the payment of dividends, subject to any preferential rights that may be applicable to any outstanding preferred stock. In the event of a liquidation, dissolution, or winding up of our Company, after payment in full of all outstanding debts and other liabilities, the holders of common stock are entitled to share ratably in all remaining assets, subject to prior distribution rights of preferred stock, if any, then outstanding. No shares of common stock have preemptive rights or other subscription rights to purchase additional shares of common stock. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable. The rights, preferences and privileges of holders of our common stock will be subject to, and might be adversely affected by, the rights of holders of any preferred stock that we may issue in the future. All shares of common stock that are acquired by us shall be available for reissuance by us at any time.

Issued and Outstanding Preferred Stock

Under the terms of our Amended and Restated Certificate of Incorporation, as amended, our Board of Directors is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without stockholder approval. Our Board of Directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. As of December 31, 2019, of the 2,000,000 shares of preferred stock authorized, our Board of Directors has designated (all with par value of $0.001 per share): 200,000 shares as Series C-3 Non-Voting Convertible Preferred Stock; 89,623 shares as Series E Convertible Preferred Stock and 100,000 as Series G Convertible Preferred Stock. At December 31, 2019, we had outstanding: 54,000 shares as Series C-3 Non-Voting Convertible Preferred Stock; 89,623 shares as Series E Convertible Preferred Stock and 100,000 shares as Series G Convertible Preferred Stock.

Series C-3 Non-Voting Convertible Preferred Stock

The Series C-3 Preferred Stock has the rights, privileges and terms described below.

Rank. The Series C Preferred Stock will rank:

- senior to our common stock;
- senior to any class or series of capital stock created after the issuance of the Series C-3 Preferred Stock; and
- junior to the Series E Non-Voting Convertible Preferred Stock.

in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion. Each share of Series C-3 Preferred Stock is convertible into 2 shares of our common stock (subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock) at a per share price of $5 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series C-3 Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of Series C-3 Preferred Stock will receive a payment equal to $10.00 per share of Series C-3 Preferred Stock before any proceeds are distributed to the holders of our common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series C-3 Preferred Stock and holders of Series C-3 Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

Voting Rights. Shares of Series C-3 Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of two thirds of the outstanding Series C-3 Preferred Stock will be required to amend the terms of the Series C-3 Preferred Stock or the certificate of designation for the Series C-3 Preferred Stock.

Dividends. Holders of Series C-3 Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series C-3 Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series C-3 Preferred Stock. Shares of Series C-3 Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing. There is no established public trading market for the Series C-3 Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series C-3 Preferred Stock on any national securities exchange or trading system.

Fundamental Transactions. If, at any time that shares of Series C-3 Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series C-3 Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

Series E Convertible Preferred Stock

Rank. The Series E Preferred Stock will rank:

- senior to our common stock;
- senior to any class or series of capital stock created after the issuance of the Series E Preferred Stock;
- senior to the Series C-3 Non-Voting Convertible Preferred Stock; and
- on parity with the Series G Convertible Preferred Stock.

in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion. Each share of Series E Preferred Stock is convertible into 4.3733 shares of our common stock (subject to adjustment as provided in the certificates of designation for the Series E Preferred Stock) at a per share price of $3.75 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series E Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 4.99% of the total number of shares of our common stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of Series E Preferred Stock will receive a payment equal to $49.20 per share of Series E Preferred Stock on parity with the payment of the liquidation preference due the Series G Preferred Stock, but before any proceeds are distributed to the holders of common stock, and the Series C-3 Non-Voting Convertible Preferred Stock. After the payment of this preferential amount, holders of Series E Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock that participates with the common stock in such distributions.

Voting Rights. Shares of Series E Preferred Stock are entitled to vote on an as-converted basis, based upon an assumed conversion price of $7.93.

Dividends. Holders of Series E Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series E Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series E Preferred Stock. Shares of Series E Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing. There is no established public trading market for the Series E Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series E Preferred Stock on any national securities exchange or trading system.

Fundamental Transactions. If, at any time that shares of Series E Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series E Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

Debt Restriction. As long as any of the Series E Preferred Stock is outstanding, we cannot create, incur, guarantee, assume or suffer to exist any indebtedness, other than (i) trade payables incurred in the ordinary course of business consistent with past practice, and (ii) up to $10 million aggregate principal amount of indebtedness with a maturity less than twelve months outstanding at any time, which amount may include up to $5 million of letters of credit outstanding at any time.

Other Covenants. In addition to the debt restrictions above, as long as any the Series E Preferred Stock is outstanding , we cannot, among others things: create, incur, assume or suffer to exist any encumbrances on any of our assets or property; redeem, repurchase or pay any cash dividend or distribution on any of our capital stock (other than as permitted, which includes the dividends on the Series E Preferred Stock and Series G Preferred Stock); redeem, repurchase or prepay any indebtedness (other than as permitted); or engage in any material line of business substantially different from our current lines of business.

Purchase Rights. In the event we issue any options, convertible securities or rights to purchase stock or other securities pro rata to the holders of common stock, then the a holder of Series E Preferred Stock will be entitled to acquire, upon the same terms a pro rata amount of such stock or securities as if the Series E Preferred Stock had been converted to common stock.

Series G Convertible Preferred Stock

Rank. The Series G Preferred Stock will rank:

- senior to our common stock;
- senior to any class or series of capital stock created after the issuance of the Series G Preferred Stock;
- junior to the Series C-3 Non-Voting Convertible Preferred Stock, pending the consent of the holders of such series to the subordination thereof; and
- on parity with the Series E Convertible Preferred Stock.

in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion. Each share of Series G Preferred Stock is convertible into approximately 55.5978 shares of our common stock (subject to adjustment as provided in the certificate of designation for the Series G Preferred Stock) at a per share price of $3.37 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series G Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 4.99% of the total number of shares of our common stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of Series E Preferred Stock will receive a payment equal to $187.36452 per share of Series G Preferred Stock on parity with the payment of the liquidation preference due the Series E Preferred Stock, but before any proceeds are distributed to the holders of Series C-3 Preferred Stock (pending the consent of the holders of such series to the subordination thereof) and after any proceeds are distributed to the holders of common stock. After the payment of this preferential amount, holders of Series G Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock that participates with the common stock in such distributions.

Voting Rights. Shares of Series G Preferred Stock are entitled to vote on an as-converted basis, based upon an assumed conversion price of $7.93.

Dividends. Holders of Series G Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series G Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series G Preferred Stock. Shares of Series G Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing. There is no established public trading market for the Series G Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series G Preferred Stock on any national securities exchange or trading system.

Fundamental Transactions. If, at any time that shares of Series G Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series G Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

Debt Restriction. As long as any of the Series G Preferred Stock is outstanding, we cannot create, incur, guarantee, assume or suffer to exist any indebtedness, other than (i) trade payables incurred in the ordinary course of business consistent with past practice, and (ii) up to $10 million aggregate principal amount of indebtedness with a maturity less than twelve months outstanding at any time, which amount may include up to $5 million of letters of credit outstanding at any time.

Other Covenants. In addition to the debt restrictions above, as long as any the Series G Preferred Stock is outstanding, we cannot, among others things: create, incur, assume or suffer to exist any encumbrances on any of our assets or property; redeem, repurchase or pay any cash dividend or distribution on any of our capital stock (other than as permitted, which includes the dividends on the Series E Preferred Stock and the Series G Preferred Stock); redeem, repurchase or prepay any indebtedness (other than as permitted); or engage in any material line of business substantially different from our current lines of business.

Purchase Rights. In the event we issue any options, convertible securities or rights to purchase stock or other securities pro rata to the holders of common stock, then the a holder of Series G Preferred Stock will be entitled to acquire, upon the same terms a pro rata amount of such stock or securities as if the Series G Preferred Stock had been converted to common stock.

Transfer Agent and Registrar

We act as our own transfer agent and registrar for the Series C-3, E and G Preferred Stock.

Certain Anti-Takeover Provisions of Delaware Law and of Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Certain provisions of the Delaware General Corporation Law (the “DGCL”) and our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated Bylaws discussed below may have the effect of making more difficult or discouraging a tender offer, proxy contest or other takeover attempt. These provisions are expected to encourage persons seeking to acquire control of our Company to first negotiate with our Board of Directors. We believe that the benefits of increasing our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our Company outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-takeover Law

We are subject to Section 203 of the DGCL, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date the person became an interested stockholder, unless:

- the Board of Directors approves the transaction in which the stockholder became an interested stockholder prior to the date the interested stockholder attained that status;

- when the stockholder became an interested stockholder, he or she owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers and certain shares owned by employee benefits plans; or

- on or subsequent to the date the business combination is approved by the Board of Directors, the business combination is authorized by the affirmative vote of at least 66 2/3% of the voting stock of the corporation at an annual or special meeting of stockholders.

Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or is an affiliate or associate of the corporation and within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock.

The existence of Section 203 of the DGCL would be expected to have an anti-takeover effect with respect to transactions not approved in advance by our Board of Directors, including discouraging attempts that might result in a premium over the market price for the shares of our common stock.

Charter Documents

Our Amended and Restated Certificate of Incorporation, as amended, and Amended and Restated Bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our Company. First, our Amended and Restated Bylaws limit who may call special meetings of the stockholders, such meetings may only be called by the chairman of the Board of Directors, the chief executive officer, the Board of Directors or holders of an aggregate of at least 15% of our outstanding entitled to vote. Second, our Amended and Restated Certificate of Incorporation does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. Third, our Amended and Restated Bylaws provide that the number of directors on our Board of Directors, which may range from five to nine directors, shall be exclusively fixed by our Board of Directors, which has set the number of directors at seven. Fourth, newly created directorships resulting from any increase in our authorized number of directors and any vacancies in our Board of Directors resulting from death, resignation, retirement, disqualification or other cause (including removal from office by a vote of the shareholders) will be filled by a majority of our Board of Directors then in office. Finally, our Amended and Restated Bylaws establish procedures, including 90-day advance notice requirement, with regard to the nomination of candidates for election as directors and stockholder proposals. These and other provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and Delaware law could discourage potential acquisition proposals and could delay or prevent a change in control or management of our Company.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-170498, 333-192840, 333-212430 and 333-235556) and on Form S-3 (File Nos. 333-211695, 333-223562 and 333-227846) of CorMedix Inc. and subsidiary (the "Company") of our report dated March 16, 2020, on our audits of the consolidated financial statements as of December 31, 2019 and 2018, and for each of the years in the two-year period ended December 31, 2019 which appear in this Form 10-K.

/s/ Friedman LLP
March 16, 2020
Marlton, New Jersey

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Khoso Baluch, certify that:

1. I have reviewed this annual report on Form 10-K of CorMedix Inc. for the year ended December 31, 2019;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

   (c) Any incidents of cybersecurity that have a significant impact on internal controls over financial reporting and financial statements.

March 16, 2020

/s/ Khoso Baluch

Name: Khoso Baluch
Title: Chief Executive Officer
(Principal Executive Officer and
Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of CorMedix Inc. (the "Company") on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Khoso Baluch, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 16, 2020

/s/ Khoso Baluch

Name: Khoso Baluch
Title: Chief Executive Officer
(Principal Executive Officer and
Principal Financial Officer)