CorMedix Inc.
Form 10-K
March 14, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

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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, 2018

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 ofIncorporation or Organization)	(I.R.S. EmployerIdentification 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	Name of each exchange on which registered
Common Stock, $0.001 Par Value	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 if disclosure of delinquent filers pursuant to Item 405 of Regulations S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 $19.2 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 119,014,093 as of March 12, 2019.

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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," 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 dialysis, critical/intensive care, and oncology. Infection and thrombosis represent key complications among dialysis, 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.

Neutrolin – United States

The U.S. Food and Drug Administration, or FDA, has 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. In addition, in January 2015, the FDA granted Fast Track designation to Neutrolin Catheter Lock Solution, highlighting the large unmet need to prevent infections in the U.S. healthcare system. 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 late 2013, we met with the FDA to determine the pathway for U.S. marketing approval of Neutrolin. We launched the Phase 3 clinical trial in hemodialysis catheters in the U.S. in December 2015. The clinical trial, named Catheter Lock Solution Investigational Trial, 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 whether Neutrolin was superior to the active control heparin by documenting the incidence of CRBSI and the time until the occurrence of CRBSI. Secondary endpoints were catheter patency, which is defined as required use of tissue plasminogen activating factor (tPA), or removal of catheter for any reason. On July 25, 2018, we announced that the independent Data Safety Monitoring Board ("DSMB") had completed its review of the interim analysis of the data from the LOCK-IT-100 study and, because the pre-specified level of statistical significance was reached and efficacy had been demonstrated, the DSMB recommended the study be terminated early. No safety concerns were reported by the DSMB based on the interim analysis.

We established the Clinical Adjudication Committee, or CAC, to critically and independently assess CRBSI. 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. In late January 2019, we announced the topline results of the full data set of the LOCK-IT-100 study. Because the study continued enrolling and treating subjects until study termination, 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 is 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 1,000 catheter-days (236 out of 397 subjects) in the Neutrolin arm and 3.23 per 1,000 catheter-days (224 out of 398 subjects) in the control arm (p=0.39). 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 1.01 per 1,000 catheter-days (64 out of 397 subjects) in the Neutrolin arm and 0.74 per 1,000 catheter-days (48 out of 398 subjects) in the control arm (p=0.10).

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 two pivotal clinical trials to demonstrate safety and effectiveness of Neutrolin would generally be required by the FDA to secure marketing approval in the U.S., based on the recently completed and unblinded topline results of the LOCK-IT-100 study, we have begun discussions with the FDA on the appropriate next steps to support regulatory approval for Neutrolin. We agreed to provide the FDA a detailed analysis of the full data set including secondary endpoints from the LOCK-IT-100 study to facilitate FDA's consideration of our request to file the New Drug Application ("NDA") for Neutrolin on the basis of the LOCK-IT-100 study results. These data became available following the locking and unblinding of the study data in late January 2019. The analysis is planned to be completed over the next several weeks. We can provide no assurances that the FDA will not require a second clinical trial prior to NDA submission for Neutrolin.

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 of drug products which 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.

Neutrolin – International

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 European Union ("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

We are evaluating opportunities for the possible expansion of taurolidine as a platform compound. Patent applications have been filed in wound closure, surgical meshes, wound management, and osteoarthritis, including visco-supplementation. We have had dialogue with the FDA on the regulatory pathway for these indications. The FDA has recently informed us that because taurolidine is an unapproved drug, there is 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, or PMA, for marketing authorization for these indications. In the event that the NDA for Neutrolin is approved by the FDA, the regulatory pathway for these other indications may 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. We believe taurolidine can also provide benefits not currently available in marketed antimicrobial medical devices, devices for burn victims and use in less sterile environments.

We are also involved in a pre-clinical research collaboration for the use of taurolidine in combination with certain anti-cancer drugs 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.

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 decontamination of the internal surface of the catheter to prevent the systemic dissemination of organisms contained within the biofilm as well as an anticoagulant to retain patency. 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 1,000 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 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 dialysis center operators. 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 under the ESRD PPS, or reimbursement as a drug used with a DMEPOS infusion pump. We cannot fully anticipate changes in reimbursement requirements and mechanisms in the coming years, however, and we cannot be certain that Neutrolin will be granted separate reimbursement under any of these mechanisms. Furthermore, we anticipate that the U.S. Centers for Medicare & Medicaid Services (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, Tauro_lock Heparin 100, TauroLock Heparin 500 and TauroLock Urokinase 2500IU. 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.

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

All of 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.

In April 2015, we entered into a Preliminary Services Agreement with [RC]2 Pharma Connect LLC (“RC2”), pursuant to which RC2 coordinates certain manufacturing services related to taurolidine, which is a key ingredient in Neutrolin. Specifically, RC2 undertook a critical parameters evaluation for our manufacturing needs and to coordinate the cGMP processes set forth in the agreement that we believe are necessary for the submission of our planned new drug application for Neutrolin to the FDA, as well as any foreign regulatory applications. The total cost for RC2’s services under the preliminary services agreement was approximately $1.8 million and the agreement was completed during

the first quarter of 2017. The active pharmaceutical ingredient, or API, produced under this agreement has been manufactured for future commercial sales in the EU, Middle East and the U.S. The API was used for the U.S. Phase 3 clinical trial. Further, CorMedix has a Drug Master File filed with FDA for taurolidine.

We are confident 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 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 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 Federal Food, Drug, and Cosmetic Act, or 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 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, or PDUFA, as amended, the FDA receives fees for reviewing an NDA, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. Fee waivers or reductions are available in certain circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an 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 of 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 of 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 21st 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 of 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. 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 are developing other products that may be regulated as medical devices in the United States. 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, or 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.

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. 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, technical and other information, including at least one adequate and well-controlled clinical investigation. 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 drug. Consequently, there is 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, 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 our collaborative partners 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 365,534 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 145,543 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, 2018. 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 125,000 shares of our common stock at an exercise price of $1.50 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 50,000 Series C-3 non-voting preferred stock and 250,000 warrants at an exercise price of $1.50 per share. During the year ended December 31, 2014, a certain milestone was achieved resulting in the release of 36,386 shares held in escrow. The number of shares held in escrow as of December 31, 2018 is 109,157 shares of common stock. There were no milestones achieved in 2017 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 problems discussed previously when using taurolidine in clinical applications, and specifically in hemodialysis applications. The patent portfolio licensed from NDP consists of 11 issued U.S. patents, 1 pending U.S. patent application, 14 issued foreign patents and 1 pending foreign patent application. We intend to file additional patent applications to cover any additional related subject matter we develop. We currently have 12 U.S. non-provisional patent applications, 3 U.S. provisional patent applications, 6 international (PCT) patent applications, and 34 foreign patent applications pending which cover additional applications using taurolidine in, among others, sutures, hydrogels, meshes, transdermal and biofilm products.

Employees

As of March 10, 2019, we had twenty-two 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.

We have announced our intention to effect a 1-for-5 reverse stock split to be effective on March 26, 2019 and we have not given effect to the proposed reverse stock split in this Report.

We maintain a website at www.cormedix.com; however, the information on, or that can be accessed through, 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.

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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 $26.8 million and $33.0 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of approximately $179.0 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 FDA and launched in the 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 hemodialysis catheters; 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, 2018 we had an accumulated deficit of $179.0 million, and incurred net losses from operations of $26.8 million for the year then ended. Based on the current development plans for Neutrolin in both the U.S. and foreign markets (including the recently concluded hemodialysis Phase 3 clinical trial in the U.S.) and our other operating requirements, management believes that the existing cash at December 31, 2018 plus funding raised through March 8, 2019, will be sufficient to fund operations into the second quarter of 2020. We will need additional funding for the 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, 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, 2018 plus funding raised through March 8, 2019, will be sufficient to fund operations into the second quarter of 2020. We will need additional funding thereafter to prepare for Neutrolin's commercial launch, or if required by the FDA, to undertake a second Phase 3 study prior to filing an NDA. If we are unable to raise additional funds when needed, we may not be able to complete the Neutrolin development program or commercialize Neutrolin and we could be required to delay, scale back or eliminate some or all of our research and development programs. 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.

Until the date that none of the preferred stock or warrants that we issued to Elliott Associates, L.P. and Elliott International, L.P in November 2017 as part of the backstop financing are outstanding, we are prohibited from issuing or selling any securities convertible into common stock at a conversion price of below $0.162 per share on terms more favorable than the backstop financing terms and with a conversion, exchange or exercise price that is based upon and/or varies with the trading prices of or quotations for the shares of our common stock or that is subject to being reset at some future date or upon the occurrence of specified or contingent events directly or indirectly related to our business (other than pursuant to a customary "weighted average" anti-dilution provision) or the market for our common stock or enter into any agreement to sell securities at a future determined price (other than standard and customary "preemptive" or "participation" rights and other than pursuant to an at-the-market offering through a registered broker-dealer). Under certain conditions, this restriction could make raising capital through the sale of equity securities difficult and could have a material adverse impact on our business, financial condition and prospects.

Risks Related to the Development and Commercialization of Our Product Candidates

If the FDA requires a second clinical trial for Neutrolin in order for us to submit the NDA, 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., in light of the interim analysis results and the DSMB recommendation,

we are in dialogue with the FDA on the appropriate next steps for the development of Neutrolin based on the results of the interim analysis of our recently terminated Phase 3 clinical trial, LOCK-IT-100. However, we can provide no assurances that the FDA will not require a second clinical trial prior to NDA submission 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. 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 U. S.

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 launched it 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 products 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 of our 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 a commercial presence in Germany and 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 materially 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.

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;

failure to receive 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; 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.

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 our 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 institutional review board 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.

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 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. 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. We have received regulatory approval in Saudi Arabia, Kuwait, Bahrain and United Arab Emirates.

In the United States, we have no current application for, and have not received the regulatory approvals required for, the commercial sale of any of our product candidates. We have not submitted an NDA, PMA or 510(k) to the FDA for any product candidate. We are preparing an NDA for Neutrolin in hemodialysis catheters based on our recently terminated Phase 3 trial, LOCK-IT-100. We may be required to conduct a second Phase 3 clinical trial before the NDA may be submitted. Financing will be required to conduct a second Phase 3 trial, if required. 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 wound closure, surgical meshes, wound management and osteoarthritis. The FDA recently informed us that it regards taurolidine as a new chemical entity and therefore an unapproved 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. 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.

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, including Medicare patients. All of these potential customers are healthcare providers who depend upon reimbursement by government and commercial insurance payors for dialysis and other treatments. Reimbursement is strictly governed by these insurance payors. We believe that Neutrolin would be eligible for coverage under various reimbursement programs, including hospital inpatient diagnosis-related groups (DRGs), outpatient ambulatory payment classification (APCs) and the End-Stage Renal Disease Prospective Payment System (ESRD PPS) or under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule, depending on the treatment setting. 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, including those we intend to address such as dialysis and ESRD PPS. 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 have incorporated health economic evaluations into our ongoing clinical studies to support this review in the context of the prospective use of Neutrolin in dialysis, the 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;

cost-effectiveness of our product relative to competing products;

availability of reimbursement for our product from government or other healthcare payors; and

effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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 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.

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 United States and abroad. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, 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 United States 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 United States 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.

Health administration authorities in countries other than the United States 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 United States, 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, Robert Cook, our Chief Financial Officer, Paul Chew, our Acting Chief Medical Officer, Elizabeth Masson, 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. 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 that covers our clinical trials. 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. This coverage 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 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.

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, our 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 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 in November 2024) (the “Prosl Patent”) - use of Neutrolin for preventing infection and maintenance of catheter patency in hemodialysis catheters;

U.S. Patent No. 6,166,007 (expiring May 2019) (the “Sodemann Patent”) - a method of inhibiting or preventing infection and blood coagulation at a medical prosthetic device; 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.

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, or 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.

The above mentioned patents and patent applications 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.

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. 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.

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.

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 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.

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.

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 decision is subject to appeal and has only a declaratory effect, as the Utility Model had expired in November 2015. Furthermore, it has no bearing on the ongoing consideration of the validity and possible infringement of the Prosl Patent by the EPO. We filed an appeal against the ruling on September 7, 2016.

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, which we have appealed. 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 with either the German PTO or the EPO. 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 therefore filed an appeal in January 2019.

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 and sell Neutrolin. 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 establish our own marketing and sales capabilities, we may not be able to generate significant or any product revenues.

We do not have an internal sales organization. To date we have relied, and intend to continue to rely, on third parties for the marketing, sales and distribution of Neutrolin outside of the U.S. The use of third parties to commercialize our approved products reduces the revenues that we would receive if we commercialized these products ourselves.

We have entered into agreements with independent companies to market Neutrolin in Saudi Arabia, the United Arab Emirates and France, and, upon regulatory approval, South Korea. 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. 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. 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.

If we undertake the marketing and sales of Neutrolin in the U.S. on our own, we will need to hire and create our own marketing and sales infrastructure. The establishment and development of our own marketing and sales force would be expensive and time consuming and we could face delays in such undertaking, which would adversely affect the product launch. We cannot be certain that we would be able to successfully develop this capability. 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 are not able to develop and maintain collaborative marketing relationships with licensees or partners, or create an effective sales, marketing, and distribution capability, we may be unable to market our products or market them successfully.

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. 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. 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. We currently have no sales, marketing, or distribution infrastructure. 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.

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, or 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.

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, 2018, we had an accumulated deficit of $179.0 million, and incurred net losses from operations of $26.8 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, 2018 plus funding raised through March 8, 2019, will be sufficient to fund operations into the second quarter of 2020. Further, we will need additional funding to prepare for Neutrolin’s commercial launch, or if required by the FDA, to undertake a second Phase 3 study prior to filing an NDA. 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. The issuance of additional equity securities, or convertible debt or other derivative securities, likely will dilute some if not all of our then existing stockholders, depending on the financing terms.

Future sales and issuances of our equity securities or rights to purchase our equity securities, including pursuant to equity incentive plans, would result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

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.

Pursuant to our 2013 Stock Plan, our Board of Directors is authorized to award up to a total of 11,000,000 shares of common stock or options to purchase shares of common stock to our officers, directors, employees and non-employee consultants. As of December 31, 2018, options to purchase 120,000 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of $1.44 per share, and options to purchase 4,936,326 shares of common stock issued under our 2013 Stock Plan at a weighted average exercise price of $1.87 per share were outstanding. In addition, at December 31, 2018, there were outstanding warrants to purchase an aggregate of 16,595,016 shares of our common stock at prices ranging from $0.001 to $7.00, and shares of our outstanding Series C-2, C-3, D, E and F preferred stock convertible into an aggregate of 18,324,678 shares of our common stock. Stockholders will experience dilution in the event that additional shares of common stock are issued under our 2006 Stock Plan or 2013 Stock Plan, or options issued under our 2006 Stock Plan or 2013 Stock Plan are exercised, or any warrants are exercised for, or preferred stock shares are converted to, common stock.

The anticipated benefits of our recently announced reverse stock split might not materialize.

We have announced our intention to effect a 1-for-5 reverse stock split to be effective on March 26, 2019. The reverse stock split is intended to reduce the number of outstanding shares of our common stock and thereby, absent other factors, to increase the per share market price of our common stock. However, other factors, such as the status of our development program for Neutrolin and other potential products, operating and financial results, market conditions and the market perception of our business may adversely affect the market price of our common stock. As a result, we cannot assure you that the reverse stock split, if completed, will result in the intended benefit of an increase in the market price per share of our common stock after the reverse stock split. Additionally, we cannot assure you that an increase, if any, in the market price of our common stock as a result of the reverse stock split will be in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split. Further, we cannot assure you that the market price of our common stock will not decrease in the future. Accordingly, the total market capitalization of our common stock after the reverse stock split may be lower than the total market capitalization before the reverse stock split.

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, or IPO, on March 30, 2010 through February 28, 2019, the high and low sales prices for our common stock were $10.40 and $0.15, 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;

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, 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;

market conditions in the pharmaceutical and medical device sectors and issuance of new or changed securities analysts' reports or recommendations;

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. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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, 2018, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

options to purchase an aggregate of 120,000 shares of our common stock issued to our officers, directors, employees and non-employee consultants under our Amended and Restated 2006 Stock Incentive Plan, or the 2006 Stock Plan, with a weighted average exercise price of $1.44 per share;

options to purchase an aggregate of 4,936,326 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 $1.87 per share;

warrants for 500,000 shares of common stock issued in May 2013 with an exercise price of $0.001 per share that expire on May 30, 2019;

warrants for 750,000 shares of common stock with an exercise price of $0.001 that expire on October 22, 2019;

warrants for 725,000 shares of common stock with an exercise price of $0.90 that expire on January 8, 2020;

Series C-2 Preferred Stock convertible into 1,500,000 shares of common;

Series C-3 Preferred Stock convertible into 1,040,000 shares of common stock;

Series D Preferred Stock convertible into 1,479,240 shares of common stock;

Series E Preferred Stock convertible into 1,959,759 shares of common stock;

Series F Preferred Stock convertible into 12,345,679 shares of common stock, subject to adjustment;

warrants for 682,500 shares of common stock issued in March 2014 with an exercise price of $2.50 per share that expire on September 10, 2019;

warrants for 200,000 shares of common stock with an exercise price of $7.00 that expire on March 3, 2020;

warrants for 83,400 shares of common stock with an exercise price of $7.00 that expire on March 25, 2020;

Series B warrants for 11,974,839 shares of common stock with an exercise price of $1.05 that expire on August 10, 2022;

underwriter warrants for 664,419 shares of common stock with an exercise price of $0.9375 that expire on August 10, 2022;

warrants for 564,858 shares of common stock with an exercise price of $0.001 that expire on November 16, 2020;

warrants for 450,000 shares of common stock with an exercise price of $1.50 that expire on December 31, 2023;

Senior convertible note convertible into 5,000,000 shares of common stock; and

restricted stock units for 29,087 shares of common stock with an average grant date fair value of $2.08 per share.

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 are 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). The notice noted that we reported stockholders' equity of $0.8 million as of March 31, 2018, and net losses in our five most recent fiscal years ended December 31, 2017. As a result, we have become subject to the procedures and requirements of Section 1009 of the Company Guide. We had to submit to the NYSE American no later than July 16, 2018 a plan of compliance to address how we intend to regain compliance with Section 1003(a)(i), Section 1003(a)(ii) or Section 1003(a)(iii) of the Company Guide by December 16, 2019 (the "Sections 1003(a)(i)-(iii) Plan Period"). The plan was submitted on time and was accepted by the NYSE American. As a result, we are able to continue our listing during the Sections 1003(a)(i)-(iii) Plan Period, during which time we will be subject to periodic review to determine whether we are making progress consistent with the plan. If we are not in compliance with the NYSE American's continued listing standards of Section 1003(a)(i), Section 1003(a)(ii) or Section 1003(a)(iii) within the timeframe provided, or do not make progress consistent with the plan during the Sections 1003(a)(i)-(iii) Plan Period, the NYSE American will initiate delisting proceedings.

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.

Prior to fiscal 2015, we had identified a material weakness in our internal control over financial reporting, and our current internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur.

In the several years prior to fiscal 2015, we had identified a material weakness in our internal control over financial reporting that was related to our limited finance staff and the resulting ineffective management review over financial reporting, coupled with increasingly complex accounting treatments associated with our financing activities and European expansion. While we remediated this material weakness in 2015, we cannot be certain that material weaknesses will not arise again.

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.

Penny stock regulations may impose certain restrictions on marketability of our securities.

The SEC has adopted regulations which generally define a "penny stock" to be any equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. A security listed on a national securities exchange is exempt from the definition of a penny stock. Our common stock is listed on the NYSE American and so is not considered a penny stock. However, if we fail to maintain our common stock's listing on the NYSE American, our common stock would be considered a penny stock. In that event, our common stock would be subject to rules that impose additional sales practice requirements on broker-dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of $1,000,000 or annual income exceeding $200,000, or $300,000 together with their spouse). For transactions covered by such rules, the broker-dealer must make a special suitability determination for the purchase of such securities and have received the purchaser's written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the transaction, of a risk disclosure document mandated by the SEC relating to the penny stock market. The broker-dealer must also disclose the commission payable to both the broker-dealer and the registered representative, current quotations for the securities and, if the broker-dealer is the sole market maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Broker-dealers must wait two business days after providing buyers with disclosure materials regarding a security before effecting a transaction in such security. Consequently, the "penny stock" rules restrict the ability of broker-dealers to sell our securities and affect the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

Stockholders should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;

manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;

"boiler room" practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;

excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

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 D, E and F 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. 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 the Company.

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 (the "Defendants") claiming infringement of our European Patent EP 1 814 562 B1, which was granted by 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.

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 made a final decision on the underlying validity of the Prosl European Patent and the Utility Model.

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, had 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 decision has only a declaratory effect, as the Utility Model had expired in November 2015. Furthermore, it has no bearing on the ongoing consideration by the EPO of the validity and possible infringement of the Prosl European Patent. We filed an appeal against the ruling on September 7, 2016.

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, which we have appealed. 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 with either the German PTO or the EPO. 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 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 prepared the requested reply and produced the respective documentation. TauroPharm also filed another writ within the same deadline and both parties 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 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 firmly that our claims are well-founded. We therefore filed an appeal in January 2019.

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." The following table sets forth the high and low sales prices for our common stock for the periods indicated as reported by NYSE American:

	2018		2017	
	High	Low	High	Low
First Quarter	$0.59	$0.17	$2.48	$1.44
Second Quarter	$0.40	$0.17	$1.64	$0.36
Third Quarter	$1.03	$0.23	$0.54	$0.32
Fourth Quarter	$2.40	$0.84	$0.77	$0.45

Based upon information furnished by our transfer agent, at March 7, 2019, we had approximately 66 holders of record of our common stock.

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 D and Series E 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, 2018 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 ofsecurities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by	5,056,326	$1.86	5,025,305

security holders (1)

(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.

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. 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

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 to develop our lead product candidate, Neutrolin®, for potential commercialization in the United States ("U.S.") and other key markets. We have in-licensed the worldwide rights to develop and commercialize Neutrolin, which is a novel anti-infective solution (a formulation of taurolidine, citrate and heparin 1000 u/ml) under development in the U.S. for the reduction and prevention of catheter-related infections and thrombosis in patients requiring central venous catheters in clinical settings such as dialysis, critical/intensive care, and oncology. Infection and thrombosis represent key complications among 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, the 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 has the potential to address a significant unmet medical need and represents a significant market opportunity.

In July 2013, we received CE Mark approval for Neutrolin. To date, Neutrolin is registered and may be sold in certain European Union ("EU") and Middle Eastern countries for the prevention of catheter-related bloodstream infections and maintenance of catheter patency in hemodialysis patients.

In December 2015, we initiated a multicenter, double-blind, randomized, active control Phase 3 clinical trial in the U.S. in hemodialysis patients with a central venous catheter ("LOCK-IT-100"). In April 2017, a safety review by our independent Data Safety Monitoring Board, or DSMB, was completed. The DSMB unanimously concluded that it was safe to continue the LOCK-IT-100 clinical trial as designed based on its evaluation of data from the first 279 patients randomized into the trial. On July 25, 2018, the DSMB completed its review of the interim analysis of the data from the LOCK-IT-100 study and, because the pre-specified level of statistical significance was reached and efficacy had been demonstrated, the DSMB recommended the study be terminated early. The DSMB also reported that there were no safety concerns.

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., based on the recently completed and unblinded topline results of the LOCK-IT-100 study, we have begun discussions with the FDA on the appropriate next steps to support regulatory approval for Neutrolin. We agreed to provide the FDA a detailed analysis of the full data set including secondary endpoints from the LOCK-IT-100 study to facilitate FDA's consideration of our request to file the New Drug Application ("NDA") for Neutrolin on the basis of the LOCK-IT-100 study results. These data became available following the locking and unblinding of the study data in late January 2019. The analysis is planned to be completed over the next several weeks.

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 of drug products which 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.

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. We are seeking one or more strategic partners or other sources of capital to help us develop and commercialize taurolidine for the treatment of neuroblastoma. 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 wound closure, surgical meshes, wound management, and osteoarthritis, including visco-supplementation. 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 has informed us that it regards taurolidine as a new chemical entity and therefore an unapproved drug. Consequently, there is 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, or PMA, for marketing authorization for these indications. In the event that an NDA for Neutrolin is approved by the FDA, the regulatory pathway for these 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 August 2017, we secured a research grant from the National Institutes of Health (NIH) to expand our antimicrobial hydrogel medical device program. In addition to our ongoing development of taurolidine-incorporated hydrogels to reduce infections in common burns, this funding will finance the development of an advanced hydrogel formulation that is designed to reduce the risk of potentially life-threatening infection and promote healing of more severe burn injuries, for which there is significant need.

As previously announced, the New Jersey Economic Development Authority ("NJEDA") has approved our application to participate in the New Jersey Technology Business Tax Certificate Transfer ("NOL") program for State Fiscal Year 2018. The approval will allow us to sell approximately $5.4 million of the total $6.1 million in available tax benefits to an unrelated, profitable New Jersey corporation in return for approximately $5.0 million in cash. Closing is subject to NJEDA's typical closing conditions, which are in process.

Since our inception, our operations to date 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 close out our LOCK-IT-100 Phase 3 clinical trial in hemodialysis patients with catheters, possibly plan a second Phase 3 clinical trial for Neutrolin, if required by the FDA, prepare and submit a NDA for Neutrolin to the FDA, 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, 2018, we had an accumulated deficit of approximately $179.0 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, 2018, 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., especially closing out the LOCK-IT-100 clinical trial, preparing an NDA for Neutrolin and possibly planning a second Phase 3 trial, if required.

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 clinical development of Neutrolin in the U.S. and optimization of sales in foreign markets where Neutrolin is approved. In December 2015, we contracted with our contract research organization, or 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 2017, we modified the original contract to cover various changes in cost due to timeline extensions, protocol changes, and additional activities related to the collection of retrospective data outside the treatment centers. In 2018, we brought in-house and assumed direct responsibility for several aspects of the study, among them site management and review of severe adverse events, or SAEs, for the remainder of the study. At December 31, 2018, approximately $28.5 million of clinical trial expense has been recorded in connection with the Master Service Agreement and work orders. Approximately $24.0 million has been paid. 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 confidential settlement agreement with the CRO in which we received cash and other consideration in return for agreeing to make cumulative net payments of approximately $6.2 million, plus investigator fees and third-party costs that had not been invoiced as of September 30, 2018. Among other benefits, the settlement agreement resulted in full satisfaction of all outstanding accounts payable and accrued expenses related to the period through June 30, 2018. Additionally, 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 us related to the closeout of the study. The budgeted amount of the new work order is approximately $1.4 million.

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 will 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. We are seeking one or more strategic partners or other sources of capital to help us develop and commercialize taurolidine for the treatment of neuroblastoma.

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.

Change in Fair Value of Derivative Liabilities

In November 2017, we entered into a backstop agreement with an existing long-term institutional investor to purchase 2,000 additional Series F convertible preferred stock at $1,000 per share, at our sole discretion, beginning January 15, 2018 through March 31, 2018. As consideration for the backstop agreement, we issued 564,858 warrants, exercisable for three years, to purchase shares of our common stock at a per share exercise price of $0.001. These warrants were initially classified as derivative liability as we had a conditional obligation to settle these warrants by issuing a variable number of shares with variations of the obligation based on inputs other than the fair value of our shares (i.e. the amount subject to the backstop agreement). In November 2017, we initially recorded a derivative liability of $270,592 and a corresponding reduction to additional paid in capital based on the initial Black Scholes valuation. In December 2017, the number of warrants issued was determined and, as a result, the derivative liability was reclassified to equity. Prior to the reclassification to equity, an expense of $56,487 for the change in fair value of

derivative liability was recorded on our consolidated statement of operations and comprehensive income (loss) during the fourth quarter of 2017.

As previously disclosed, at the time we issued the warrants in our May 2017 public offering, we did not have a sufficient number of authorized shares of common stock to cover the shares issuable upon exercise of the warrants and therefore recorded and classified the fair value of the warrants as a derivative liability at the issuance date and marked-to-market at each balance sheet date. The change in the fair value of derivative liability is the difference between the fair value of the warrants recorded on issuance date and the fair value of warrants at the balance sheet date, with any decrease or increase in the estimated fair value being recorded in other income (expense). On August 9, 2017, we amended our certificate of incorporation to increase our authorized shares and we, as of that date, have sufficient authorized shares to cover shares issuable upon the conversion of the warrants. The fair value of these warrants was re-measured on August 10, 2017, the date the warrants became exercisable and were reclassified from liability to equity, which resulted in a loss of $121,000, recorded on our consolidated statement of operations and comprehensive income (loss) for the year ended December 31, 2017.

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 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 and cash equivalents and short-term investments.

Interest Expense

Interest expense consists of interest incurred on financing of expenditures.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

The following is a tabular presentation of our consolidated operating results for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017	% of Change Increase (Decrease)
Revenue	$430	$329	31%
Cost of sales	(397)	(115)	245%
Gross profit (loss)	33	214	(85)%
Operating Expenses:			
Research and development	(18,822)	(24,486)	(23)%
Selling, general and administrative	(8,075)	(8,652)	(7)%
Total operating expenses	(26,897)	(33,138)	(19)%
Loss from operations	(26,864)	(32,924)	(18)%
Interest income	37	111	(67)%
Foreign exchange transaction loss	(1)	(14)	(93)%
Change in fair value of derivative liabilities	-	(177)	(100)%
Interest expense	(2)	(6)	(67)%
Total other income (expense)	34	(86)	(140)%
Net loss	(26,830)	(33,010)	(19)%
Other comprehensive income gain (loss)	(2)	17	(112)%
Comprehensive loss	$(26,832)	$(32,993)	(19)%

Revenue. Revenue for the year ended December 31, 2018 was $430,000 as compared to $329,000 for the same period in 2017, an increase of $101,000. The increase was primarily attributable to higher sales in the Middle East and Germany of $190,000 and $14,000, respectively, offset by a decrease of sales of Neutrolin in other areas of the EU in the amount of $103,000.

Cost of Sales. Cost of sales for the year ended December 31, 2018 was $397,000 as compared to $115,000 for the same period in 2017, an increase of $282,000. The increase was primarily due to the recognition of additional cost of goods sold for the year ended December 31, 2018 of $43,000 related to products shipped under warranty in addition to the reduction of the inventory reserve during the year ended December 31, 2017 in the amount of $327,000, mainly due to longer shelf life of the products manufactured. The increase was partially offset by decreases in packaging and stability studies of $55,000 and cost of materials of $33,000, respectively.

Research and Development Expense. R&D expense for the year ended December 31, 2018 was $18,822,000, a decrease of $5,664,000 from $24,486,000 for the same period in 2017. The decrease was primarily attributable to a net decrease in expenses related to the LOCK-IT-100 clinical trial in the U.S. of $3,734,000, mainly due to the confidential settlement agreement with our CRO. Additionally, there were also decreases in costs related to manufacturing process development activities of $2,359,000, due to the completion or cancelation of majority of the projects, and reduced activity related to antimicrobial sutures, nanofiber webs, wound management and osteoarthritis and visco-supplementation of $566,000. These decreases were partially offset by a $1,001,000 increase in personnel expenses, mainly due to the hiring of new staff supporting the LOCK-IT-100 trial.

Selling, General and Administrative Expense. SG&A expense for the year ended December 31, 2018 was $8,075,000, a decrease of $577,000 from $8,652,000 for the same period in 2017. The decrease was primarily attributable to a decrease in non-cash charge for stock-based compensation expense of $511,000, due to non-achievement of performance conditions related to certain stock options which resulted in a reversal of expense of $306,000; and a reduction of consulting fees of $437,000, mainly due to executive search fees that were incurred in 2017. These decreases, among others of lesser significance, were partially offset by a $162,000 increase in legal fees, mainly due to fees related to the settlement agreement with our CRO, a $138,000 increase in costs related to marketing research studies, a $44,000 increase in personnel expenses, and an increase in business development activities of $30,000.

Interest Income. Interest income for the year ended December 31, 2018 was $37,000, a decrease of $74,000 from $111,000 for the same period in 2017. The decrease was attributable to lower average interest-bearing cash balances and short-term investments during 2018 as compared to the same period in 2017.

Foreign Exchange Transaction Gain (Loss). Foreign exchange transaction loss for the year ended December 31, 2017 of $14,000 was due to the foreign exchange rate fluctuations for the payment of invoices paid in foreign currency. There was minimal foreign exchange transaction loss for the year ended December 31, 2018.

Change in Fair Value of Derivative Liabilities. The change in the value of derivative liabilities for the year ended December 31, 2017 of $177,000 represented the $121,000 net change in the fair value of the warrants issued at issuance date (May 3, 2017 public offering) of $3,733,000 and the estimated fair value of the warrants of $3,854,000 at August 10, 2017, the date that the warrants were reclassified from liability to equity; and the $56,000 increase in fair value of the warrants issued related to the backstop agreement at November 16, 2017 issuance date of $271,000 and the estimated fair value of the warrants of $327,000 at December 24, 2017, the date that the number of warrants to be issued was determined and were reclassified from liability to equity.

Interest Expense. Interest expense for the year ended December 31, 2018 was $2,000 as compared to $6,000 for the same period in 2017, a decrease of $4,000 due to fees incurred for financing some of 2017 expenditures.

Other Comprehensive Income (Loss). Unrealized foreign exchange movements related to long-term intercompany loans and the translation of the foreign affiliate financial statements to U.S. dollars and unrealized movements related to short-term investment are recorded in other comprehensive income resulting in a $2,000 loss in 2018 and a $17,000 gain in 2017.

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, 2018, we received net proceeds of $21,968,000 from the issuance of 35,888,772 shares of common

stock under our at-the-market-issuance sales agreement; $7,391,000 from the issuance of a 10% convertible note; $26,000 from the exercise of 25,000 warrants; and $11,600 from the exercise of 40,000 stock options.

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2018 was $23,700,000 as compared to $28,587,000 in 2017, a decrease in net cash use of $4,887,000. The decrease was primarily attributable to a decrease in net loss of $6,180,000 driven by decreased research and development expenses due to the benefits received from the settlement agreement with our CRO. The net loss of $26,830,000 for the year ended December 31, 2018 was higher than cash used in operating activities by $3,130,000. The difference is primarily attributable to non-cash stock-based compensation of $1,111,000, and increases in accrued expenses and accounts payable of $998,000 and $782,000, respectively, primarily due to the schedule of payments agreed with our CRO in the confidential settlement agreement signed in November 2018.

Net Cash Provided by Investing Activities

Cash provided by investing activities for the year ended December 31, 2018 was $1,555,000 attributable to the proceeds on the sale of short-term investments of $1,604,000, offset by the purchase of equipment of $49,000. In the same period in 2017, net cash provided by investing activities of $10,358,000 was attributable to the proceeds from the sale of short-term investments used to fund operations of $23,584,000 offset by $13,074,000 purchases of short-term investments.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2018 was $29,397,000 as compared to $20,525,000 for the same period in 2017. During 2018, we generated 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; $26,000 from the exercise of warrants; and $12,000 from the exercise of stock options. In comparison to the same period in 2017, we generated net proceeds of $12,798,000 from the public offering of our common stock and warrants; $5,543,000 from the sale of our common stock in our at-the-market program; $1,877,000 from the sale of our Series F non-voting preferred stock; $300,000 from the sale of our common stock from our directors, executive officers and certain employees; and $7,000 from the exercise of stock options.

Funding Requirements and Liquidity

Our total cash on hand and short-term investments as of December 31, 2018 was $17,624,000, excluding restricted cash of $172,000, compared with $11,984,000 at December 31, 2017. At December 31, 2018, we have approximately $20.3 million available under our current at-the-market program 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 expect to utilize our ATM program, if conditions allow, to support our ongoing development of Neutrolin in hemodialysis catheters in the U.S.

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. 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, including the potential necessity to fund an additional Phase 3 clinical trial, if required by the FDA, 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.

While we expect to grow product sales, we do not anticipate that we will generate significant product revenues in the foreseeable future. In the absence of such revenue, we are likely to continue generating operating cash flow deficits. We will continue to use cash as we close out our Phase 3 clinical trial, and increase other activities leading to the preparation and submission of an NDA to seek marketing approval of Neutrolin in the U.S., and, if required, fund an additional Phase 3 clinical trial for Neutrolin, pursue business development activities, and incur additional legal costs to defend our intellectual property.

Based on the current development plans for Neutrolin and our other operating requirements, we believe that the existing cash and cash equivalents at December 31, 2018, plus the funds raised under our ATM program through the filing date of this report, will be adequate to fund the costs of our operations into the second quarter 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, or if required by the FDA, to undertake a second Phase 3 study prior to filing an NDA. 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.

Until the date that none of the preferred stock or warrants that we issued to Elliott Associates, L.P. and Elliott International, L.P in November 2017 as part of the backstop financing are outstanding, we are prohibited from issuing or selling any securities convertible into common stock at a conversion price of below $0.162 per share on terms more favorable than the backstop financing terms and with a conversion, exchange or exercise price that is based upon and/or varies with the trading prices of or quotations for the shares of our common stock or that is subject to being reset at some future date or upon the occurrence of specified or contingent events directly or indirectly related to our business (other than pursuant to a customary “weighted average” anti-dilution provision) or the market for our common stock or enter into any agreement to sell securities at a future determined price (other than standard and customary “preemptive” or “participation” rights and other than pursuant to an at-the-market offering through a registered broker-dealer). Under certain conditions, this restriction could make raising capital through the sale of equity securities difficult and could have a material adverse impact on our business, financial condition and prospects.

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.

As of December 31, 2018, 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 employee's requisite service period on a straight-line basis.

We account for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing model in accordance with ASC 718 and ASC No. 505-50, "Equity-Based Payments to Non-Employees" ("ASC 505"). The non-cash charge to operations for non-employee options with time-based vesting provisions is based on the fair value of the options remeasured each reporting period and amortized to expense over the related vesting period. The non-cash charge to operations for non-employee options with performance based vesting provisions is recorded when the achievement of the performance condition is probable and remeasured each reporting period until the performance condition is achieved.

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.

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

In October 2015, we shipped product with less than 75% of its remaining shelf life to a customer and issued a guarantee that the specific product shipped would be replaced by us if the customer was not able to sell the product before it expired. As a result of this warranty, we may have an additional performance obligation (i.e. accept returned product and deliver new product to the customer) if the customer is unable to sell the short-dated product. As a result of the adoption of ASC 606, we accelerated the recognition of the deferred revenue and related cost of sales in the net amount of $70,500 and recorded the warranty obligation in the amount of $52,900 upon adoption.

Deferred Revenue

In August 2014, we 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 Korea. Upon execution, Wonik paid us a non-refundable $50,000 payment and will pay an additional $50,000 upon receipt of the product registration necessary to sell Neutrolin in the Republic of 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 the Wonik agreement at December 31, 2018 and 2017 amounted to approximately $11,000 and $20,000, respectively.

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 condensed 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 condensed 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 February 2016, the FASB issued new guidance related to how an entity should 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. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for us beginning in the first quarter of 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This adoption on January 1, 2019 did not have a material impact on our consolidated financial statements.

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 guidance is effective for us beginning in the first quarter of fiscal year 2020. Early adoption is permitted beginning in the first quarter of fiscal year 2019. We are evaluating the impact of adopting this guidance on our 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. The guidance is effective for us beginning in the first quarter of fiscal year 2019. Early adoption is permitted. This adoption on January 1, 2019 did not have a material impact on our consolidated financial statements.

In June 2018, the FASB issued a new guidance which expands the scope of ASC 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for the Company beginning in the first quarter of fiscal year 2019. Early adoption is permitted. This adoption on January 1, 2019 did not have a material 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 the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted. We are assessing the impact of adopting this guidance 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 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, 2018, 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 Chief Executive Officer and Chief Financial Officer, have undertaken an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2018, 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, 2018.

This annual report does not include an attestation report of our independent registered public accounting firm regarding the effectiveness of our internal control over financial reporting because we are a smaller reporting company.

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.

Section 16(a) Beneficial Ownership Reporting Compliance

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, 2018, with the exception of: a Form 4 for Janet Dillione to report the grant on February 21, 2018 of 15,357 restricted stock units that was due on February 23, 2018 and was filed on March 22, 2018; a Form 4 for Myron Kaplan to report the grant of 10,000 restricted stock units on February 21, 2018 that was due on February 23, 2018 and was filed on March 22, 2018 and a Form 4 for Mr. Kaplan to report the grant of 5,000 restricted stock units on November 6, 2018 that was due on November 8, 2018 and was filed on November 27, 2018 ; a Form 4 for John Armstrong to report the vesting of 18,028 restricted stock units on December 31, 2017 that was due on January 2, 2018 and was filed on March 22, 2018 and a Form 4 for Mr. Armstrong to report the vesting of 18,029 restricted stock units on December 31, 2018 that was due on January 2, 2019 and was filed on January 3, 2019; and a Form 3 for Elizbeth Masson to report her hiring as an executive officer on March 19, 2018 that was due on March 29, 2018 and was filed on April 9, 2018 and a Form 4 for Ms. Masson to report the grant on March 19, 2018 of options to purchase 310,000 shares of common stock that was due on March 21, 2018 and was filed on April 9, 2018.

Directors

The following table sets forth the name, age and position of each of our directors as of December 31, 2018:

Name	Age	Director Since	Position(s) with CorMedix
Khoso Baluch	60	October 2016	Director and Chief Executive Officer
Janet M. Dillione	58	August 2015	Director
Gary Gelbfish (1)	59	August 2017	Director
Myron Kaplan	73	April 2016	Chairman of the Board
Mehmood Khan	60	June 2017	Director
Steven Lefkowitz	62	June 2017	Director

(1)
Dr. Gelbfish resigned as a director on January 14, 2019.

Khoso Baluch joined our Board in October 2016 upon his appointment as our Chief Executive Officer. Mr. Baluch previously served as Senior Vice President and President Europe, Middle East & Africa EMEA of UCB, SA, or UCB, from January 2015 to early 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 & Co 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. 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 M. Dillione has been a director of CorMedix since August 2015. Ms. Dillione has served as the Chief Executive Officer of Bernoulli (formerly known as Cardiopulmonary Corp.), a leader in medical device connectivity for EMR integration, and integrated clinical applications and workflows for over 20 years, since 2014. 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 May 2010 until March 2014. From June 2000 to April 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 1995. She has over 25 years of experience leading global teams in the development and delivery of healthcare technology and services. 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.

Myron Kaplan became a director of CorMedix in April 2016. On August 3, 2017, he was elected as our Chairman of the Board. Mr. Kaplan 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. Dr. Khan currently serves as the Chief Executive Officer of Life BioSciences Inc., a private company focused on age-related decline, a position he has held since March 2019. Prior to that, Dr. Khan served as Vice Chairman (from January 2015 to March 2019) and Chief Scientific Officer of Global Research and Development (from December 2007 to March 2019) for PepsiCo, where he led global R&D and oversees the company's 2025 sustainability agenda, which included 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 for HemoShear Therapeutics, a biotechnology company focused on discovering novel biological targets and developing drugs to treat rare juvenile metabolic disorders, and Reckett Benckhiser Group, a British private company. 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. He has served as a director AIS, RE., a privately held reinsurance company since 2001. 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.

On February 27, 2019, our Board of Directors appointed Alan W. Dunton, M.D., as a director, effective March 1, 2019, to serve until the 2019 annual meeting or until his respective successor is duly elected and qualified. In 2006, Dr. Duncan founded Danerius, LLC, a biotechnology and pharmaceutical consulting business. Prior to starting Danerius, he was Chief Executive Officer of Panacos Pharmaceuticals, Inc., as well as Metaphore Pharmaceuticals, Inc., both biotechnology companies. 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 and 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. Dr. Dunton currently serves on the boards of two public companies, Palatin Technologies, Inc. and Oragenics, Inc. He chairs the audit and compensation committees of each of these companies. He is also a member of the board of Cytogel Pharma LLC, a private bio-pharmaceutical development company focused on acquiring promising early-stage programs. 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.

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), Mr. Kaplan and Ms. Dillione. Our Compensation Committee currently consists of Ms. Dillione (Chair), Mr. Lefkowitz and Dr. Khan. Our Nominating and Governance Committee currently consists of Dr. Khan (Chair) and Mr. Kaplan.

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 Steven Lefkowitz (Chair) and Janet 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 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.

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 Code of 1986, as amended (the "Internal Revenue 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	61	Chief Executive Officer
Robert Cook	63	Chief Financial Officer
John Armstrong	75	Executive Vice President for Technical Operations
Elizabeth Masson	40	Executive Vice President and Head of Clinical Operations

See the biography for Khoso Baluch under "Directors."

Robert Cook most recently served as Chief Financial Officer of Bioblast Pharma Ltd. from January 2016 to July 2016. His prior pharma experience includes: Executive Vice President and Chief Financial Officer at Strata Skin Sciences, Inc. from April 2014 to January 2016; Senior Vice President and Chief Financial Officer at Immune Pharmaceuticals, Inc. from August 2013 to March 2014, and its predecessor EpiCept Corporation from April 2004 to August 2013, including one year as Interim President and CEO of EpiCept in which he completed the reverse merger of EpiCept into Immune. Previously he served as CFO of publicly-held Pharmos Corporation. Mr. Cook began his career in financial services at Chase Manhattan and he also held a position as a Vice President in the Healthcare Group at General Electric Capital Commercial Finance. Mr. Cook holds a B.S. in Finance, magna cum laude, from The American University, in Washington, DC.

John Armstrong became our Executive Vice President for Technical Operations in March 2017. Prior to that, he was been 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. John 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 held varied roles in Manufacturing, QA, Led Integrated business systems development for three companies as well as having expertise in business development. Mr. Armstrong holds an executive M.B.A. from Century University. He is also a CPIM (Certified in Production and Inventory Management).

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

Item 11. Executive Compensation

DIRECTOR COMPENSATION

Director Compensation in Fiscal 2018

The following table shows the compensation earned by each non-employee director of our company for the year ended December 31, 2018.

Name	Fees Earned ($)	Option Awards (1) (2) ($)	Restricted Units Awards (1) (3) ($)	Total ($)
Janet M. Dillione	30,000(4)	16,440	7,980	54,420
Gary Gelbfish (5)	235,000(5)	16,440	5,700	257,140
Myron Kaplan	30,000	16,440	24,440	70,880
Mehmood Khan	30,000	16,440	7,125	53,565
Steven Lefkowitz	30,000	16,440	21,020	67,460

(1)
The amounts included in this column are the dollar amounts representing the full grant date fair value of each stock option 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. For information on the valuation assumptions used in calculating this amount, see Note 8 to our audited financial statements included in this Annual Report on Form 10-K.

(2)
As of December 31, 2018, the number of shares underlying options held by each non-employee director was as follows: 225,000 shares for Ms. Dillione; 115,000 shares for Dr. Gelbfish; 130,000 shares for Mr. Kaplan; 115,000 shares for Dr. Khan; and 115,000 shares for Mr. Lefkowitz.

(3)
As of December 31, 2018, the number of restricted stock units held by each non-employee director was as follows: 2,334 shares for Ms. Dillione; 1,667 shares for Dr. Gelbfish; 12,001 shares for Mr. Kaplan; 2,084 shares for Dr. Khan; and 11,001 shares for Mr. Lefkowitz.

(4)
Includes fees of $30,000 for Ms. Dillione that were deferred. See “Directors Compensation Plan” below for a description of the deferral plan pursuant to which the deferrals were made.

(5)
Fees earned for 2018 include $25,000 as a director and $210,000 as a consultant. Also see “Related Party Transactions” below. Dr. Gelbfish resigned as a director on January 14, 2019.

Director Compensation Plan

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.

Based on the information presented by Frederic W. Cook & Co., in February 2017, we adopted the following cash and equity compensation plan for non-employee directors. In December 2018, we increased several elements of non-employee director compensation, effective January 1, 2019, as reflected below. Each director receives an annual cash fee of $25,000, the Board Chair and committee Chairs each receives an additional $5,000. Upon a director's first election to the Board, he or she will be granted an option to purchase 75,000 (increased to 100,000) shares of our common stock that vest one third each on the date of grant and the first and second anniversary of the date of grant, subject to continued service on the Board through the vesting date. In the next calendar year after his or her election to the Board and annually thereafter, each director will be granted (i) an option to purchase 40,000 (increased to 75,000) shares of our common stock that vest monthly over one year after the date of grant, subject to continued service on the Board through the vesting date, and (ii) restricted stock units in the amount of the lesser of 10,000 units or $25,000 divided by our stock price on the date of grant (increased to 12,500 and $25,000), with the Board chair receiving an additional number of restricted stock units in the amount of the lesser of 12,000 units or $24,000 divided by our stock price on the date of grant (increased to 15,000 and $30,000), the Audit Committee chair receiving an additional number of restricted stock units in the amount of the lesser of 6,000 units or $12,000 divided by our stock price on the date of grant (increased to 7,500 and $15,000), the Compensation Committee chair receiving an additional number of restricted stock units in the amount of the lesser of 4,000 units or $8,000 divided by our stock price on the date of grant (increased to 5,000 and $10,000), and the Nomination and Governance Committee chair receiving an additional number of restricted stock units in the amount of the lesser of 2,500 units or $5,000 divided by our stock price on the date of grant (increased to 3,000 and $6,000). In addition, in September 2018, we formed the Strategic Finance Committee, which has two co-chairs each of whom, beginning with fiscal year 2019, receives an annual cash fee of $5,000 and restricted stock units in the amount of the lesser of 5,000 units or $10,000 divided by our stock price on the date of grant. Restricted stock units vest monthly over one year after the grant date, 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.

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 to the designated beneficiaries, if any. If there are no designated beneficiaries, the account will be paid out the same as with any other termination of service. 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.

EXECUTIVE COMPENSATION

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.

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 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 2017 and 2018 is set forth in the Summary Compensation Table below. In October 2016, February 2017, 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, John Armstrong, our Executive Vice President for Technical Operations, and Elizabeth Masson, 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 target award for each Named Executive Officer based on a percentage of base salary, and based on 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, each Named Executive Officer, in conjunction with the Chief Executive Officer, establishes annual goals and objectives. Actual bonus awards are based on an assessment against the pre-established goals for each Named Executive Officer's individual performance, the performance of the business function for which he is responsible, the executive management team's overall performance, and/or our company's overall performance for the year. For any given performance year, proposed annual bonuses may range from 0% to 100% of target, or higher under certain circumstances, based on corporate, team and individual performance. Corporate, team and individual 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, Mr. Baluch, Mr. Cook, Mr. Armstrong and Ms. Masson are each eligible for an annual bonus, which may equal up to 80%, 30%, 35% 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, and specified personal objectives, predetermined by the Board and 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 Stock Plan and 2013 Stock 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 Stock Plan, we were no longer able to issue any award under the 2006 Stock Plan. 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 Stock Plan and our 2013 Stock Plan.

Stock Options

Our 2013 Stock Plan (and formerly our 2006 Stock Plan) 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 Internal Revenue Code of 1986.

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.