CorMedix Inc.
Form 10-K
March 16, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

_____

FORM 10-K

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

For the fiscal year ended: December 31, 2016

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.)

1430 US Highway 206, Suite 200, Bedminster, NJ	07921
(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 MKT 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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 or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

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 and non-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 $72.6 million. Solely for the purpose of this calculation, shares held by directors and executive officers of the registrant have been excluded. Such exclusion should not be deemed a determination or an admission by the registrant that such individuals are, in fact, affiliates of the registrant.

The number of outstanding shares of the registrant's common stock was 40,720,838 as of March 14, 2017.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2017 Annual Meeting of Stockholders are incorporated herein by reference, as indicated in Part III.

CORMEDIX INC.

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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® (also known as CRMD003), 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®. Neutrolin is a novel anti-infective solution (a formulation of taurolidine, citrate and heparin 1000 u/ml) 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, 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 an additional 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, pursuant to the Food and Drug Administration Safety Innovation Act, or FDASIA, 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. Based on those discussions, we determined to conduct two pivotal trials to demonstrate safety and effectiveness of Neutrolin to secure marketing approval in the U.S. We initiated a Phase 3 clinical trial in hemodialysis patients with a central venous catheter in December 2015 and are currently planning to initiate a Phase 3 trial in oncology patients with catheters.

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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, is a prospective, multicenter, randomized, double-blind, placebo-controlled, active control trial which aims 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 is time to CRBSI. The trial will evaluate whether Neutrolin is superior to the active control heparin by documenting the incidence of CRBSI and the time until the occurrence of CRBSI. Key secondary endpoints are catheter patency which is defined as required use of tissue plasminogen activating factor (tPA) or removal of catheter due to dysfunction or for any reason. We now project to complete enrollment in the fourth quarter of 2017, subject to funding requirements.

We are in discussions with the FDA to develop the design of a Phase 3 clinical trial in oncology patients with catheters, or LOCK-IT-200. This trial also is subject to funding requirements (see “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Funding and Capital Requirements” in Part II, Item 7 of this report).

Neutrolin – International

In July 2013, we received CE Mark approval for Neutrolin. As a result, in December 2013, we commercially launched Neutrolin in Germany for the prevention of catheter-related bloodstream infections (“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 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 for taurolidine as a platform. Patent applications have been filed in: wound closure, surgical meshes, wound management, and osteoarthritis, including visco-supplementation. There exists a need to control and protect against surgical site infections upon wound closure. We believe taurolidine can also offer benefits not currently available in marketed antimicrobial medical devices. It can also provide a significant advantage in 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 as a possible treatment for rare orphan pediatric tumors.

Neutrolin

Market Opportunity

Central venous catheters and peripherally inserted 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.

The treatment of patients undergoing hemodialysis requires access to their vascular system on a recurring basis. According to the 2015 United States Renal Disease System, there were 660,000 patients on hemodialysis. It has been reported by Hemodialysis National Kidney Foundation that patients requiring a catheter represent over 63 million catheter/dialysis treatment days per year. In the United States, 5.7 million intensive care patients were admitted annually according to the Society of Critical Care Medicine, which is estimated to represent 28.5 million catheter days associated with ICU stays 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 a long-term central venous catheter. When stages of disease and types of chemotherapy regime are considered, the number of catheter days per year are 90 million. Infections and thrombosis represent key complications among cancer patients with central venous catheters. One of the major and common complications for all patients requiring central venous catheters is catheter related blood stream infections, or CRBSIs, and the clinical complications associated with them. There are an estimated 250,000 CRBSIs 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 CRBI episodes and their complications would amount to approximately $6 billion.

Biofilm build up is the pathogenesis of both infections and thrombotic complications in central venous catheters. Prevention of CRBIs 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 CRBIs in central venous catheters. As noted above, we received the CE Mark approval for Neutrolin from the Medical Evaluation Board, or MEB, at the EU in July 2013.

We believe there is a significant need for prevention of CRBIs 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 directly to hospitals and also to key dialysis center operators. We anticipate that Medicare reimbursement could be available for Neutrolin in 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 DME 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 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. Our studies might 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.

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.

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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.

Zuragen, being developed by Ash Access Technology (Lafayette,IN). It has antimicrobial and anticoagulant activity and contains methylene blue, parabens and 7% citrate.

B-Lock, being developed by Great Lakes Pharmaceuticals Inc. (Cleveland, OH). It has anti-microbial, anti-coagulant and anti-fungal activity and contains trimethoprim, EDTA and ethanol combinations. Initiated study in 2012 in Poland and Hungary to support CE Mark in European Union.

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.

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.

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.

Medical Devices:

Tego® Needlefree Connector, manufactured by ICU Medical Inc. (California, USA) 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 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. 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. 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. 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 is approximately $1.7 million which is expected to be incurred under the terms of this agreement through the first quarter of 2017. Since inception through December 31, 2016, RC2 completed and we recognized expense of approximately $1,505,000 for its services related to this agreement.

We are also working with RC2 under several service agreements for an aggregate amount of $7.6 million for the manufacture of clinical supplies to support our ongoing and planned Phase 3 clinical trials. During the years ended December 31, 2016 and 2015, we recognized research and development expense of approximately $2,359,000 and $1,348,000, respectively, related to these agreements. We may terminate these agreements upon 30 days written notice and are only obligated for project costs and reasonable project shut down costs provided through the date of termination.

Navinta LLC, a U.S.-based active pharmaceutical ingredient, or API, developer, provides API manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for Neutrolin, pursuant to a supply agreement dated December 7, 2009 (the "Navinta Agreement"). On March 24, 2015, we and Navinta LLC entered into an amendment to the Navinta Agreement to extend the term of the Navinta Agreement to March 31, 2016 and to lower the price per kilogram of API that we purchase from Navinta LLC under the Navinta Agreement. We also agreed to purchase a minimum amount of product from Navinta LLC during 2015, which replaced the prior minimum purchase requirement. The Navinta Agreement was terminable by either party upon 30 days written notice. The Navinta Agreement expired in accordance with its terms without delivery of the minimum purchase requirement and without any further obligations by either party.

We are confident that there exist 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 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 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:

preclinical 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 preclinical 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 also 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 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 IRBs 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, 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 preclinical 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 limited population pathway for antibacterial and antifungal drugs, which was passed as part of the recent enacted 21st Century Cures Act. Under this program, a sponsor can request drug approval under this new pathway for an antibacterial or antifungal drug if the drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs. Under this program, the FDA's determination of safety and effectiveness would 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. 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. Under this program, the FDA must provide prompt advice to sponsors seeking approval under this pathway to enable them to plan a development program. If approved under this pathway, 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 preclinical 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 infections 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 has 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 products may change significantly from the current descriptions provided herein in the time that it may take for any of our products 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.

Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations

Our business activities, including but not limited to research, sales, promotion, distribution, medical education, and other activities following product approval, if any, will be subject to regulation by numerous federal and state regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the Centers for Medicare & Medicaid Services, or CMS, and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Our business activities must comply with numerous healthcare laws, including but not limited to, anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations, which are described below.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, furnishing, or order of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs, in whole or in part. The term “remuneration” has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. There are certain statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, reimbursement, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Patient Protection and Affordable Care Act, or ACA, of 2010, as amended, modified the intent requirement under the Anti-Kickback Statute, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the FCA.

The federal FCA prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. The FCA authorizes imposition of treble damages and a civil penalty for each false claim submitted. For violations after November 2, 2015, the penalty has increased from a minimum of $5,500 to $10,781, and a maximum of $11,000 to $21,563. A claim includes “any request or demand” for money or property presented to the U.S. government, including an invoice. Accordingly, FCA penalties for high claim volume products like pharmaceuticals have frequently aggregated into millions of dollars. The FCA has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not expressly approved by the FDA in a drug’s label, and allegations as to misrepresentations with respect to product quality or services rendered. Several pharmaceutical and other healthcare companies have further been sued under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Intent to deceive is not required to establish liability under the FCA. Liability may be predicated on reckless disregard for the truth. FCA actions may be brought by the government or may be brought by private individuals on behalf of the government, called “qui tam” actions. If the government decides

to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to substantial civil and criminal settlements regarding certain sales practices and promoting off label drug uses. Further, liability may be predicated on non-compliance with federal laws and regulations under the theory of implied certification. However, the Supreme Court imposed a materiality standard for liability under this theory – the non-compliance must be material to the government's payment decision. FCA liability may also be imposed for Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act.

The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim.

The civil monetary penalties statute is another potential statute under which biopharmaceutical companies may be subject to enforcement. Among other things, the civil monetary penalties statute imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent. In 2016, the Department of Justice doubled the amount of these penalties, which are specified in the civil FCA.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; or require drug manufacturers to track and report information related to payments, gifts, and other items of value to physicians and other healthcare providers. These laws may affect our future sales, marketing, and other promotional activities by imposing administrative and compliance burdens.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws that apply to us, we may be subject to penalties or other enforcement actions, including criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, debarment from receiving government contracts or refusal of new orders under existing contracts, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Enforcement actions can be brought by federal or state governments, or as qui tam actions brought by individual whistleblowers in the name of the government under the civil False Claims Act if the violations are alleged to have caused the government to pay a false or fraudulent claim.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

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.

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

CRMD003 and CRMD004

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, 2016. 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 is

exercisable immediately upon issuance and has a term of five years. The warrant contains a cashless exercise feature and standard adjustment features in the event of a stock split, stock dividend, recapitalization or similar events.

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, 2016 is 109,157 shares of common stock. There were no milestones achieved in 2015 or 2016.

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.

On January 30, 2008, we also entered into an Exclusive License and Consulting Agreement with Dr. Polaschegg. Pursuant to the Polaschegg License Agreement, Dr. Polaschegg granted us an exclusive, worldwide license for a gel lock invention and certain taurolidine treatments and the corresponding United States patent applications (the "Polaschegg Technology"). The Polaschegg Technology served as a basis for CRMD004, which is the gel formation of Neutrolin. As consideration for the rights to the Polaschegg Technology, in addition to an initial fee of $5,000, we agreed to pay Dr. Polaschegg certain royalty payments ranging from 1% to 3% of the net sales of the Polaschegg Technology. The Polaschegg License Agreement also set forth certain minimum royalty payments (on an annual basis) to be made to Dr. Polaschegg in connection with the Polaschegg Technology, which payments range from $10,000 to $45,000. Additional minimum royalty payments would become payable to Dr. Polaschegg if he developed new intellectual property that was applied to the Polaschegg Technology. As of December 31, 2015, we recorded an aggregate of approximately $300,000 in licensing and minimum royalty payments under the Polaschegg License Agreement.

We had the right to terminate the Polaschegg License Agreement with respect to the gel lock invention or taurolidine treatments (individually or together) upon 60 days notice. Dr. Polaschegg had the right to terminate the Polaschegg License Agreement with respect to the gel lock invention and/or taurolidine treatments if no product based on the particular portion of Polaschegg Technology has been made available to the market by the later of eight years after (i) the date of the Polaschegg License Agreement, and (ii) the priority date of any new patent. If the Polaschegg License Agreement is terminated with respect to any piece of Polaschegg Technology by either party, all rights with respect to such portion of Polaschegg Technology will revert to Dr. Polaschegg. In November 2015, we terminated the Polaschegg License Agreement.

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. We intend to file additional patent applications to cover any additional related subject matter we develop. We currently have five non-provisional patent applications, five international (PCT) patent applications and four provisional patent applications pending which cover additional applications using taurolidine in, among others, sutures, hydrogels, meshes, transdermal and biofilm products.

Employees

As of March 10, 2017, we had fourteen 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

1430 US Highway 206, Suite 200, Bedminster, New Jersey 07921. Our telephone number is (908) 517-9500.

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.

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 $24.6 million, $18.2 million and $20.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of approximately $119.2 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. 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 until it is approved by the FDA and launched in the U.S. market, and 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: successfully marketing Neutrolin in Germany and other countries in which it is approved for sale; obtaining necessary regulatory approvals for Neutrolin from the other applicable European and Middle East agencies, other foreign agencies and the FDA and international regulatory agencies for any other products; 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.

We have received a going concern opinion from our registered public accounting firm.

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, 2016, we had an accumulated deficit of $119.2 million, and incurred net losses from operations of $24.6 million for the year then ended. Based on the current development plans for Neutrolin in both the U.S. and foreign markets (including the ongoing hemodialysis Phase 3 clinical trial in the U.S.) and our other operating requirements, management believes that the existing cash at December 31, 2016 will not be sufficient to fund operations for at least the next 12 months following the filing of this annual report on Form 10-K. These factors raise substantial doubt regarding our ability to continue as a going concern. Additionally, we will need additional funding to complete the hemodialysis clinical trial in the U.S. which commenced in December 2015 as well as to initiate the planned Phase 3 clinical trial in oncology patients with catheters.

As a result of the above matters, our independent auditors have indicated in their report on our December 31, 2016 financial statements that there is substantial doubt about our ability to continue as a going concern. A “going concern” opinion indicates that the financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets,

or the amounts and classification of liabilities that may result if we do not continue as a going concern. Therefore, you should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of our creditors, and potentially be available for distribution to our stockholders, in the event of liquidation.

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 our ongoing and planned Phase 3 clinical trials 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, 2016, will not be sufficient to enable us to fund our projected operating requirements for at least the next 12 months following the balance sheet date. We will need additional funding thereafter to complete our ongoing Phase 3 hemodialysis clinical trial in the U.S., as well initiate as our planned Phase 3 clinical trial in the U.S. in oncology patients with catheters. If we are unable to raise additional funds when needed, we may not be able to complete our ongoing Phase 3 clinical trial, commence and complete our planned Phase 3 clinical trial 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 incur increases in our cash used in operations as we continue to commercialize Neutrolin in Europe and other markets, conduct our ongoing Phase 3 clinical trial and prepare for our planned Phase 3 clinical trial in oncology patients, seek FDA approval of Neutrolin in the U.S., commercialize Neutrolin in Europe and other markets, pursue 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.

Our efforts to explore strategic alternatives aimed at accelerating Neutrolin's development and commercialization and maximizing shareholder value may not result in any definitive transaction or deliver the expected benefits, and may create a distraction for our management and uncertainty that may adversely affect our operating results and business.

Strategic alternatives we may pursue could include, but are not limited to, joint ventures or partnering or other collaboration agreements, licensing arrangements, or another transaction intended to maximize shareholder value, such as a merger, a sale of the Company or some or all of its assets, or another strategic transaction. In March 2015, the Board commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. The Board previously engaged the investment bank Evercore Group L.L.C. to provide financial advice and assist the Board with its evaluation process. After the process with Evercore, we announced in July 2015 that we expect to continue to pursue product development and commercialization opportunities as we move forward with the planned Phase 3 clinical trials, rather than pursuing a possible sale of our company at that time. No transaction materialized pursuant to the Evercore engagement. We terminated the arrangement with Evercore in July 2016. Although we will remain open to and consider strategic partnerships, there can be no assurance that any transaction will present itself.

There are various uncertainties and risks relating to our evaluation and negotiation of possible strategic alternatives and our ability to consummate a definitive transaction, including:

expected benefits may not be successfully achieved;

evaluation and negotiation of a proposed transaction may distract management from focusing our time and resources on execution of our operating plan, which could have a material adverse effect on our operating results and business;

the process of evaluating proposed transactions may be time consuming and expensive and may result in the loss of business opportunities;

perceived uncertainties as to our future direction may result in increased difficulties in retaining key employees and recruiting new employees, particularly senior management;

even if our Board of Directors negotiates a definitive agreement, successful integration or execution of the strategic alternative will be subject to additional risks;

the current market price of our common stock may reflect a market assumption that a transaction will occur, and during the period in which we are considering a transaction, the market price of our common stock could be highly volatile; and

a failure to complete a transaction could result in a negative perception by investors in the Company generally and could cause a decline in the market price of our common stock, as well as lead to greater volatility in the market price of our common stock, all of which could adversely affect our ability to access the equity and financial markets, as well as our ability to explore and enter into different strategic alternatives.

Risks Related to the Development and Commercialization of Our Product Candidates

Our only product 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. Neturolin 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, clinical trials, regulatory clearances and/or investment by us or our collaborators as we continue its commercialization, as will any of our other products. Specifically, we plan to expand marketing of Neutrolin in other foreign countries and to develop Neutrolin for sale in the U.S., which will take time and capital.

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 some 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 me 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 are 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 products for which we are directly conducting clinical trials 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.

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 and Kuwait.

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 products. None of our product candidates has been determined to be safe and effective in the United States, and we have not submitted an NDA or PMA to the FDA for any product. We have received approval from the FDA to proceed with our ongoing Phase 3 clinical trial for Neutrolin in hemodialysis catheters and our planned Phase 3 trial in oncology patients with catheters, which is subject to finalization of the protocol with the FDA. In December 2015, we initiated the Phase 3 trial in hemodialysis catheters; however, we will not initiate the Phase 3 trial in oncology patients with catheters until we receive sufficient funding. We are seeking one or more strategic partners or other sources of capital to complete the Phase 3 trial in hemodialysis and to start the Phase 3 trial for oncology patients with catheters. However, we might not obtain any commercial partner or financing and may never start the Phase 3 clinical trial for oncology patients with catheters.

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.

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 lead many European and other foreign countries to adopt healthcare reform proposals and medical cost containment measures. 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 U.S. Centers for Medicare & Medicaid Services (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

We might not be able to access any of the $40.0 million available to us under our new at-the-market common stock sales program.

In August 2016, we entered into a sales agreement with the FBR Capital Markets & Co. whereby we can sell up to $40 million of shares of our common stock. However, pursuant to a Consent and Exchange Agreement between us and Manchester, dated September 15, 2014 (and entered into as part of our removal of anti-dilution, price reset and change of control provisions in various securities that had caused those securities to be classified as derivative liabilities), (as amended in April 2015), Manchester has a right of participation in equity financings undertaken by us prior to September 15, 2017. The participation right extends to the at-the-market common stock sales program. Any common stock sold as part of our new at-the-market common stock sales program would be subject to Manchester's participation right, Manchester's waiver of its participation right or another arrangement with Manchester. In the event we are not able to obtain such a waiver or reach an agreement with Manchester, we would not be able to sell shares of common stock in our new at-the-market program, which could have a material adverse effect on our financial condition and operations.

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 revenues or income with certainty or even confidence.

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.

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 the United States, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Healthcare Reform Act, substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. We anticipate that if we obtain approval for our products, some of our revenue may be derived from U.S. government healthcare programs, including Medicare. Furthermore, beginning in 2011, the Healthcare Reform Act imposed a non-deductible excise tax on pharmaceutical manufacturers or importers who sell "branded prescription

drugs," which includes innovator drugs and biologics (excluding orphan drugs or generics) to U.S. government programs. We expect that the Healthcare Reform Act and other healthcare reform measures that may be adopted in the future could have an adverse effect on our industry generally and our products specifically.

In addition to the Healthcare Reform 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. While it is too early to predict what effect the Healthcare Reform Act or any future legislation or regulation will have on us, such laws 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, Judith Abrams, our Chief Medical Officer 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 Jersey 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 clinical testing, clinical research and testing, government regulation, formulation and manufacturing, and sales and marketing. 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.

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 (for CRMD003);

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 (for CRMD003); 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.

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, 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 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.

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland ("Geistlich") brought an action against the European Sodemann Patent covering our Neutrolin product candidate, which is owned by ND Partners, LLC ("NDP") and licensed to us pursuant to the License and Assignment Agreement between us and NDP. This action was brought at the Board of the European Patent Office ("EPO") opposition division (the "Opposition Board") based upon alleged lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions of the prior art. The Opposition Board rejected the opposition by Geistlich. In a letter dated September 30, 2013, we were notified that the opposition division of the EPO reopened the proceedings before the first instance and gave their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfills the requirements of clarity, novelty, and inventive step, and invited the parties to provide their comments and/or requests by February 10, 2014. We filed our response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not file a further statement within the required timeline. On November 5, 2014, the Opposition Division at the EPO issued the interlocutory decision to maintain the patent on the basis of the claims as amended during the appeal proceedings. This decision became final as no further appeal was lodged by Geistlich.

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. 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 recent decision of the German PTO on the invalidity of the utility model. The EPO has scheduled a further oral hearing for November 22 / 23, 2017. While we continue to believe that the referenced publication and instructions for use do not, in fact, constitute prior art and that the Prosl European Patent will be found to be valid by the EPO, there can be no assurance that we will prevail in this matter.

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.

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 was held on November 15, 2016. The court made no rulings from the bench, and indicated that it is prepared to further examine the underlying facts of our allegations. At this time, there are no further hearings scheduled. We intend to continue to pursue this matter, and to provide additional supplemental documentary and other evidence as may be necessary to support our claims.

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

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 entered into an agreement with a German company to market and sell Neutrolin in Germany and a distributor agreement with each of a Saudi Arabian and a South Korean company for sales and marketing in those two countries (upon receipt of approval to market in South Korea). In addition, we have an independent sales representative marketing and selling in the Middle East. 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.

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 and any other product we might develop. However, we may not be able to maintain current and future arrangements or enter into new arrangements with third parties to sell Neutrolin or any other product on favorable terms or at all. In that event, we would have to develop our own marketing and sales force. The establishment and development of our own sales force would be expensive and time consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capability. In addition, 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 Germany and in Saudi Arabia and, upon regulatory approval, South Korea. We also have an independent sales representative in the Middle East. We intend to seek a sales partner in the U.S. if Neutrolin receives FDA approval. Consequently, we will be dependent on

these firms and individuals for the success of sales in these and any other countries in which approval is granted. If these firms or individuals do not perform for whatever reason, our business, prospects and results of operations will 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 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 a sufficient supply of our product candidates. 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

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 assured 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.

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, 2017, 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. 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:

market acceptance of Neutrolin in those markets in which it is approved for sale;

our need for additional capital;

the receipt of or failure to obtain additional regulatory approvals for Neutrolin, including FDA approval in the U.S.;

results of clinical trials of our product candidates, including our planned Phase 3 trial for Neutrolin in the U.S., 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;

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;

future sales or anticipated sales of our securities by us or our stockholders; 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 invest only if you can withstand a significant loss and wide fluctuations in 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, 2016, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

warrants for 227,273 shares of common stock issued in July 2013 with an exercise price of $1.50 that expire on July 30, 2018;

warrants for 500,000 shares of common stock issued in May 2013 with an exercise price of $0.65 per share that expire on May 30, 2019;

warrants for 125,000 shares issued to ND Partners in April 2013 in connection with the amendment to the license and assignment agreement with an exercise price of $1.50 per share that expire on April 11, 2018;

options to purchase an aggregate of 130,000 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 $1.38 per share;

options to purchase an aggregate of 4,479,755 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 $2.31 per share;

warrants issued to investors in our 2012 private placement to purchase an aggregate of 312,500 shares of our common stock with an exercise price of $0.40 per share, which expire on September 20, 2017;

a warrant for 795 shares of our common stock issued to the placement agent for our 2012 private placement with an exercise price of $0.40 per share, which expires on September 20, 2017;

a warrant to purchase 400,000 shares of our common stock issued on February 19, 2013 with an exercise price of $1.50 that expire on February 19, 2018;

warrants for 750,000 shares of common stock with an exercise price of $0.90 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 1,365,000 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;

warrants for 682,500 shares of common stock issued in March 2014 with an exercise price of $2.50 per shares 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; and

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

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.

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, 2016, we had an accumulated deficit of $119.2 million, and incurred net losses from operations of $24.6 million for the year then ended. Based on the current development plans for Neutrolin in both the U.S. and foreign markets (including the ongoing hemodialysis Phase 3 clinical trial in the U.S.) and our other operating requirements, management believes that the existing cash at December 31, 2016 will not be sufficient to fund operations for at least the next 12 months following the balance sheet date. Additionally, we will need additional funding to complete the hemodialysis clinical trial in the U.S. which commenced in December 2015 as well as to initiate the planned Phase 3 clinical trial in oncology patients with catheters. Further, 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. We expect to seek equity or debt financings in the future to fund 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, 2016, options to purchase 130,000 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of $1.38 per share, and options to purchase 4,479,755 shares of common stock issued under our 2013 Stock Plan at a weighted average exercise price of $2.31 per share were outstanding. In addition, at December 31, 2016, there were outstanding warrants to purchase an aggregate of 4,006,468 shares of our common stock at prices ranging from $0.40 to $7.00, and shares of our outstanding Series C-2, C-3, D and E preferred stock convertible into an aggregate of 6,303,999 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.

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 MKT, it may result in a delisting of our common stock from the exchange.

Our common stock is currently listed for trading on the NYSE MKT, and the continued listing of our common stock on the NYSE MKT 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 2012 and 2014, we received notices from the NYSE MKT that we did not meet continued listing standards of the NYSE MKT as set forth in Part 10 of the Company Guide. Specifically, we were not in compliance with Section 1003(a)(i) and Section 1003(a)(ii) of the Company Guide because we reported stockholders' equity of less than the required amounts. As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide and were subject to possible delisting. In March 2015, we regained compliance with the NYSE MKT listing requirements due to our market capitalization, pursuant to Section 1003(a) of the Company Guide. However, there can be no assurance that we will continue to meet the continued listing standards of the NYSE MKT.

If our common stock were no longer listed on the NYSE MKT, investors might only be able to trade on 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.

Because the average daily trading volume of our common stock has been low historically, the ability to sell our shares in the secondary trading market may be limited.

Because the average daily trading volume of our common stock on the NYSE MKT has been low historically, the liquidity of our common stock may be impaired. As a result, prices for shares of our common stock may be lower than might otherwise prevail if the average daily trading volume of our common stock was higher. The average daily trading volume of our common stock may be low relative to the stocks of other exchange-listed companies, which could limit investors' ability to sell shares in the secondary trading market.

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 MKT and so is not considered a penny stock. However, if we fail to maintain our common stock's listing on the NYSE MKT, 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 and 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. 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 4,700 square feet of office space in Bedminster, New Jersey. We sublease this office space pursuant to a sublease agreement dated December 2014 which runs from April 1, 2015 until March 31, 2018. Rent is $5,000 per month plus occupancy costs such as utilities, maintenance and taxes. The total lease obligation is approximately $180,000. Our remaining sublease obligation is approximately $75,000 as of December 31, 2016.

Our subsidiary leases its offices in Fulda, Germany for a term of 36 months which commenced on September 1, 2013 for a base monthly payment of €498. The total 36 month lease obligation was approximately €17,900. The 36 month lease has terminated. A new three-month lease agreement commenced on November 1, 2016 which is renewable every three months for a base monthly payment of €461.

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

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland (“Geistlich”) brought an action against the European Sodemann Patent covering our Neutrolin product candidate, which is owned by ND Partners, LLC (“NDP”) and licensed to us pursuant to the License and Assignment Agreement between us and NDP. This action was brought at the Board of the European Patent Office (“EPO”) opposition division (the “Opposition Board”) based upon alleged lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions of the prior art. The Opposition Board rejected the opposition by Geistlich. In a letter dated September 30, 2013, we were notified that the opposition division of the EPO reopened the proceedings before the first instance and gave their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfills the requirements of clarity, novelty, and inventive step, and invited the parties to provide their comments and/or requests by February 10, 2014. We filed our response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not file a further statement within the required timeline. On November 5, 2014, the Opposition Division at the EPO issued the interlocutory decision to maintain the patent on the basis of the claims as amended during the appeal proceedings. This decision became final as no further appeal was lodged by Geistlich.

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, 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. 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 recent decision of the German PTO on the invalidity of the utility model. The EPO has scheduled a further oral hearing for November 22 / 23, 2017. While we continue to believe that the referenced publication and instructions for use do not, in fact, constitute prior art and that the Prosl European Patent will be found to be valid by the EPO, there can be no assurance that we will prevail in this matter.

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 of the validity and possible infringement of the Prosl European Patent by the EPO. We filed an appeal against the ruling on September 7, 2016.

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 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. At this time, there are no further hearings scheduled. The Company intends to continue to pursue this matter, and to provide additional supplemental documentary and other evidence as may be necessary to support its claims.

On July 7, 2015, a putative class action lawsuit was commenced against the Company and certain of its current and former officers in the United States District Court for the District of New Jersey, captioned Li v. Cormedix Inc., et al., Case 3:15-cv-05264 (the "Securities Class Action"). On September 4, 2015, two individuals, Shahm Martini and Paul Chretien (the "Martini Group"), filed a Motion to Appoint Lead Plaintiff. On that same date, another individual, Elaine Wood, filed a competing Motion to Appoint Lead Plaintiff. On September 18, 2015, the Martini Group withdrew its motion. Thereafter, on September 22, 2015, the Court appointed Elaine Wood as Lead Plaintiff and, on October 2, 2015, appointed the Rosen Law Firm as Lead Counsel.

On December 1, 2015, Lead Plaintiff filed an Amended Complaint asserting claims that the Company and Steven Lefkowitz, Randy Milby and Harry O'Grady (the "Cormedix Defendants") violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act. The Amended Complaint also named as defendants several unrelated entities that allegedly were paid stock promoters. Lead Plaintiff alleged generally that the Cormedix Defendants made materially false or misleading statements and omissions concerning, among other things, the competitive landscape for the Company's Neutrolin product and the alleged use of stock promoters. The Amended Complaint sought unspecified damages, interest, attorneys' fees, and other costs.

On February 1, 2016, the Cormedix Defendants filed a motion to dismiss all claims asserted against them in the Amended Complaint on the grounds, among others, that the Amended Complaint fails to adequately allege: (1) material misstatements or omissions; (2) scienter by any of the Cormedix Defendants; or (3) loss causation. The Court heard oral argument on this motion on July 18, 2016 and in an order dated October 27, 2016, the Court granted the Cormedix Defendants' Motion to Dismiss and dismissed with prejudice the Amended Complaint (the "Dismissal Order"). On December 16, 2016, the parties filed a stipulation with the Court in which the plaintiffs and their counsel agreed not to appeal, move for reconsideration or otherwise challenge the Dismissal Order. No settlement payment was made in exchange for the stipulation.

On May 13, 2016, a putative shareholder derivative action was filed in the Superior Court of New Jersey against the Company and certain present and former directors and officers captioned Raval v. Milby, et. al., Docket No. C-12034-6 (the "Derivative Action"). The factual allegations of the Derivative Action substantially overlap the factual allegations contained in the Amended Complaint in the Securities Class Action. The plaintiff purports to assert claims against the individual defendants on behalf of the Company for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement and waste of corporate assets. The complaint in the Derivative Action seeks unspecified damages, interest, attorneys' fees and other costs, and certain amendments to the Company's "corporate governance and internal procedures". On June 30, 2016, the Court entered a stipulated order, among other things, staying the Derivative Action until 30 days after either: (a) the entry of any order denying any motion to dismiss the Derivative Action in the Securities Class Action, or (b) the entry of a final order dismissing the Securities Class Action with prejudice. Following entry of the Dismissal Order in the Securities Class Action, the parties entered into a stipulation, among other things, staying the Derivative Action until 30 days after either (a) November 30, 2016, in the event plaintiffs in the Securities Class Action did not file an appeal of the Dismissal Order or (b) the final disposition of any appeal in the event the plaintiffs in the Securities Class Action filed a Notice of Appeal of the Dismissal Order. On January 6, 2017, the parties filed a Stipulation of Dismissal without Prejudice of the Derivative Action.

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 MKT 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 MKT:

	2016		2015	
	High	Low	High	Low
First Quarter	$ 2.88	$1.15	$ 9.90	$1.63
Second Quarter	$ 4.54	$1.72	$10.40	$3.20
Third Quarter	$ 3.12	$1.35	$ 4.31	$1.72
Fourth Quarter	$ 3.26	$1.46	$ 2.96	$1.72

Based upon information furnished by our transfer agent, at March 14, 2017, we had approximately 63 holders of record of our common stock.

Stock Performance Graph

The following performance graph shall not be deemed to be “soliciting material” or “filed” or incorporated by reference in future filings with the SEC, or subject to the liabilities of Section 18 of the Exchange Act except as shall be expressly set forth by specific reference in such filing. The performance graph compares the performance of our common stock to the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph covers the most recent five-year period ended December 31, 2016. The graph assumes that the value of the investment in our common stock and each index was $100.00 at December 31, 2011, and that all dividends are reinvested.

Cumulative Total Return

	12/2011	12/2012	12/2013	12/2014	12/2015	12/2016
CorMedix, Inc.	$100	$255.03	$439.09	$676.35	$718.84	$541.78
NASDAQ Composite	$100	$116.41	$165.47	$188.69	$200.32	$216.54
NASDAQ Biotechnology	$100	$134.68	$232.37	$307.67	$328.76	$262.08

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, 2016 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 security holders (1)	4,609,755	$2.29	5,682,790
Equity compensation plans not approved by security holders (2)	125,795	1.49	--
Total	4,735,550	$1.81	5,682,790

(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.

(2) Consists of 795 shares of common stock issuable pursuant to a warrant issued to the placement agent of our convertible note financing in 2012 (with an exercise price of $0.40 per share) and 125,000 shares of common stock issuable pursuant to a warrant issued to ND Partners in April 2013 as consideration for the amendment of the ND Partners License Agreement.

Item 6.
Selected Consolidated Financial Data

The consolidated statement of income data set forth below with respect to the years ended December 31, 2016, December 31, 2015, and December 31, 2014, and the consolidated balance sheet data at December 31, 2016, December 31, 2015 and December 31, 2014 are derived from the audited consolidated financial statements included in Item 8 of this report and should be read in conjunction with those financial statements and notes thereto. The consolidated statement of income data for the years ended December 31, 2013 and December 31, 2012 and the consolidated balance sheet data at December 31, 2013 and December 31, 2012 are derived from audited consolidated financial statements not included herein.

(amounts in thousands, except for per share amounts)	2016	2015	2014	2013	2012
RESULTS OF OPERATIONS					
Net sales	$224	$210	$189	$2	$-
Gross (loss)	(143)	(109)	(257)	(200)	-
(Loss) from operations	(24,761)	(16,654)	(8,903)	(4,915)	(3,000)
(Loss) before income taxes	(24,644)	(18,187)	(20,453)	(9,133)	(3,381)
Net (loss)	(24,644)	(18,187)	(20,453)	(9,133)	(3,381)
Comprehensive income (loss)	19	(37)	108	(9)	-
Comprehensive (loss)	(24,625)	(18,224)	(20,345)	(9,142)	(3,381)

(LOSS) PER SHARE					
Basic and diluted	$(0.65)	(0.58)	(0.96)	(0.69)	$(0.30)
BALANCE SHEET DATA					
Total cash and marketable securities	$20,165	$35,386	$4,340	$2,374	$835
Total assets	21,906	37,102	5,098	2,968	1,153
Total liabilities	4,092	3,090	1,463	6,990	1,489
Total stockholders' equity (deficiency)	17,815	34,011	3,634	(4,022)	(335)

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 on the development of our lead product candidate, Neutrolin, for potential commercialization in the 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, citrate and heparin 1000 u/ml) 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, 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.

We plan to conduct two pivotal trials to demonstrate safety and effectiveness of Neutrolin to secure marketing approval in the U.S. We initiated one Phase 3 clinical trial in hemodialysis patients with a central venous catheter in December 2015 and plan to initiate one Phase 3 trial in oncology patients with catheters, subject to funding requirements.

In July 2013, we received CE Mark approval for Neutrolin. As a result, in December 2013, we commercially launched Neutrolin in Germany for the prevention of catheter-related bloodstream infections ("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.

Since our inception, we have not generated sufficient revenue from product sales to be profitable. Our operations to date have been primarily limited to licensing product candidates, developing clinical trials for our product candidates, establishing manufacturing for our product candidates, performing business and financial planning, performing research and development, seeking regulatory approval for our products, initial commercialization activities for Neutrolin, 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 incur increases in our cash use in operations as we continue to commercialize Neutrolin in Europe and other markets, prepare for and undertake our ongoing and planned Phase 3 clinical trials, pursue business development activities, incur additional legal costs to defend our intellectual property, and seek FDA approval of Neutrolin in the U.S. As of December 31, 2016, we had an accumulated deficit of approximately $119.2 million. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

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Financial Operations Overview

Revenue

We have not generated substantial revenue since our inception. Through December 31, 2016, we have funded our operations primarily through debt and equity financings and our initial public offering, and to a lesser extent, the receipt from Federal grants under the Qualifying Therapeutic Discovery Project program and the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program.

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, 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 preclinical 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 plan to increase our R&D expenses for the foreseeable future in order to complete development of Neutrolin in the U.S., especially for the ongoing Phase 3 trial in hemodialysis patients and the planned Phase 3 trial in oncology.

The following table summarizes the percentages of our R&D payments related to our sole product candidate Neutrolin and our former product candidate CRMD0004 (we ceased development of and returned the rights to CRMD004 in late 2015). The percentages summarized in the following table reflect payments directly attributable to each development candidate, which are tracked on a project basis. A portion of our internal costs, including indirect costs relating to our product candidates, are not tracked on a project basis and are allocated based on management's estimate.

	Year EndedDecember 31,		
	2016	2015	2014
CRMD003	100%	98%	98%
CRMD004	-	2%	2%

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. Our current focus is on clinical development efforts in the U.S. and optimization of sales in markets where Neutrolin is approved. We are seeking to develop Neutrolin in the U.S. Based on our discussions with the FDA, we are conducting a Phase 3 clinical trial in hemodialysis catheters and, subject to finalization of the protocol, plan to conduct one Phase 3 clinical trial in oncology. We plan to initiate the Phase 3 trial in oncology depending on our ability to raise additional capital and our ability to complete the hemodialysis catheters trial within our expected budget. We expect that the ongoing Phase 3 trial for hemodialysis catheters will cost approximately $26 million to $30 million and will take 30 months to complete after initiation. We are still finalizing the details of the protocol for the planned second Phase 3 trial for oncology/total parenteral nutrition and are unable to provide a cost estimate at this time. We are seeking one or more strategic partners or other sources of capital to help complete the development of Neutrolin in the U.S.

On July 5, 2013, we received CE Mark approval for Neutrolin. As a result, in late 2013, we commercially launched Neutrolin in Germany for the prevention of catheter-related bloodstream infections, or CRBI, 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 East countries for such treatment.

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.

Loss on Issuance of Preferred Stock, Convertible Notes and Warrants

We issued preferred stock and related warrants during the year ended December 31, 2014. The loss on the issuance of preferred stock and related warrants represents the difference on the issuance date between the combined derivative related fair value of the conversion option and the warrants, and the proceeds that were received net of all fees and expenses related to the issuance.

Change in Fair Value of Derivative Liabilities

As previously disclosed in our December 31, 2014 Form 10-K, we entered into consent and exchange agreements with investors holding our outstanding Series C-2, Series C-3, Series D, and Series E non-voting convertible preferred stock. We modified certain terms within the preferred stock which resulted in the reclassification of the remaining derivative liability to equity in September 2014.

The change in the fair value of derivative liabilities represents the change in the fair value of the Series C, D and E preferred stock conversion options and the change in the fair value of warrants that were recorded at fair value on a recurring basis under accounting principles generally accepted in the United States (“GAAP”). This includes any changes in fair value resulting from the re-measurement of the derivative liabilities in connection with the redemption or conversion of the preferred stock and the exercise of warrants.

Loss on Modification of Equity Instruments and Extinguishment of Derivative Liabilities

As discussed in Note 7 to the financial statements included in this Report, the loss on modification of equity instruments and extinguishment of derivative liabilities represents the change in the fair value of the preferred stock hybrid instruments and liability classified warrants resulting from the modifications made to those instruments during the year ended December 31, 2014.

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). In 2014, foreign currency exchange transaction gain (loss) consists of foreign exchange transaction gains and losses on intercompany loans that are in place between our company, which is based in New Jersey, and our German subsidiary. Effective October 1, 2014, we determined that 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, beginning October 1, 2014, 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, 2016, 2015 and 2014

The following is a tabular presentation of our consolidated operating results (in thousands):

	For the Year Ended December 31,			% of Change Increase (Decrease)	
	2016	2015	2014	2016 versus 2015	2015 versus 2014
Revenue	$224	$210	$189	7%	11%
Cost of sales	(367)	(319)	(446)	15%	(29)%
Gross profit (loss)	(143)	(109)	(257)	31%	(58)%
Operating Expenses:					
Research and development	(15,735)	(6,282)	(1,319)	150%	376%
Selling, general and administrative	(8,883)	(10,263)	(7,327)	(13)%	40%
Total operating expenses	(24,618)	(16,545)	(8,646)	49%	91%
Loss from operations	(24,761)	(16,654)	(8,903)	49%	87%
Interest income	127	61	3	108%	1933%
Foreign exchange transaction loss	(8)	(7)	(151)	14%	(96)%
Value of warrants issued in connection with backstop financing	-	(1,583)	-	(100%)	(100)%
Loss on issuance of preferred stock, convertible notes and warrants	-	-	(89)	-	(100)%
Change in fair value of derivative liabilities	-	-	(8,849)	-	(100)%
Loss on modification of equity instruments and extinguishment of derivative liabilities	-	-	(2,462)	-	(100)%
Interest expense	(1)	(4)	(2)	(75)%	90%
Net loss	(24,643)	(18,187)	(20,453)	35%	(12)%
Other comprehensive income gain (loss)	19	(37)	108	(152)%	(134)%
Comprehensive loss	$(24,624)	$(18,224)	$(20,345)	35%	(11)%

Revenue. Revenue for the year ended December 31, 2016 was $224,000 as compared to $210,000 for the same period in 2015, an increase of $14,000. The increase was due to the recognition of deferred revenue of $106,000 for the products sold with warranty, substantially offset by a decrease in sales of Neutrolin in Germany and the Middle East of $92,000.

Revenue for the year ended December 31, 2015 was $210,000 as compared to $189,000 for the same period in 2014, an increase of $21,000. The majority of the revenue is from sales of Neutrolin in Germany and Middle East markets. In addition, we realized $8,000 associated with the amortization of deferred revenue from a non-refundable payment received from a distribution agreement in 2015 as compared to $4,000 in 2014.

Cost of Sales. Cost of sales for the year ended December 31, 2016 was $367,000 as compared to $319,000 for the same period in 2015, an increase of $48,000. The increase was primarily due to the $63,000 recognition of cost of sales associated with deferred revenue, an increase in write-off of expired raw materials of $58,000, and an increase of inventory reserve of $5,000, offset by decreases in ongoing stability studies of $35,000 and decreased cost of

materials of $43,000 due to lower sales in 2016 excluding deferred revenue.

Cost of sales for the year ended December 31, 2015 was $319,000 as compared to $446,000 for the same period in 2014, a decrease of $127,000. The decrease was primarily due to decreases in ongoing stability studies and services performed in the management of manufacturing of $131,000 and other manufacturing expenses mainly due to costs in transitioning Neutrolin to new labels and packaging of $13,000, offset by an increase in direct cost of materials of $67,000 due to the use of new commercial batches as compared to the use of old previously expensed research and development batches in 2014. In addition, we recorded a charge of $125,000 associated with pre-launch inventory build-up and start-up related manufacturing inefficiencies in 2015 as compared to $175,000 in 2014, a decrease of $50,000.

Research and Development Expense. R&D expense for the year ended December 31, 2016 was $15,735,000, an increase of $9,453,000 from $6,282,000 for the same period in 2015. The increase was primarily attributable to $5,317,000 of expenses related to the ongoing Phase 3 clinical trial in hemodialysis catheters in the U.S.; cost of new studies related to antimicrobial sutures, nanofiber webs, wound management and osteoarthritis and visco-supplementation of $2,438,000; costs to support the U.S. clinical trial drug supply consisting of manufacturing process development activities of $1,928,000; personnel cost of $627,000, mainly due to hiring employees and consulting fees of $290,000. These increases were partially offset by decreases in pharmacoeconomics and pricing and market research studies conducted in 2015 of $401,000 and decreased non-cash stock based compensation of $758,000.

R&D expense for the year ended December 31, 2015 was $6,282,000, an increase of $4,963,000 from $1,319,000 for the same period in 2014. The increase was primarily attributable to $1,020,000 for the initiation of the Phase 3 clinical trial in hemodialysis catheters in the U.S.; higher costs to support the U.S. clinical trial drug supply consisting of manufacturing process development activities of $1,718,000 and pharmacoeconomics, and pricing and market research studies of $203,000. Additionally, increases in non-cash stock based compensation of $871,000, consulting fees pertaining mainly to the clinical supply manufacturing development process and regulatory activities of $996,000, and personnel costs of $120,000 were recognized.

Selling, General and Administrative Expense. SG&A expense for the year ended December 31, 2016 was $8,883,000, a decrease of $1,380,000 from $10,263,000 for the same period in 2015. The decrease was primarily attributable to a $1,133,000 decrease in non-cash stock-based compensation expense, mainly due to the modification of our former CEO’s stock options recorded in 2015; a decrease in selling expenses in the EU of $666,000, mainly due to reduction in sales force and a decrease in expenses related to business development activities of $430,000. These decreases, among others of lesser significance, were partially offset by increased consulting fees of $587,000, primarily due to interim CFO and executive search fees; increased legal fees of $159,000; increased personnel expenses of $56,000 and increased investor relations activities of $50,000.

SG&A expense for the year ended December 31, 2015 was $10,263,000, an increase of $2,936,000 from $7,327,000 for the same period in 2014. The increase was attributable to increases in personnel expenses of $650,000 due to employee benefits and the Release of Claims and Severance Modification with our CEO; legal fees due mainly to ongoing intellectual property and securities litigation, increased SEC and clinical activities of $784,000; expenses related to business development activities of $292,000 and marketing research studies of $248,000; consulting fees of $554,000 primarily due to an executive search fee, increased investor relations activities of $193,000; and a non-cash charge of $187,000 for stock-based compensation expense due to the modification of the stock options of our CEO and $113,000 for modification of warrants. These increases, among others of lesser significance, were partially offset by a decrease in selling costs related to commercialization of Neutrolin in the EU of $268,000.

Loss on Issuance of Preferred Stock, Convertible Notes and Warrants. The loss on the issuance of preferred stock and warrants of $90,000 for the year ended December 31, 2014 represents the difference on the issuance date between the combined fair value of the conversion option and the warrants of $2,054,000, and the combined proceeds received and liabilities settled, net of all issuance-related fees and expenses of $1,965,000. Due to the elimination of the downround protection of these derivative liabilities through an agreement modification in September 2014, which resulted in the reclassification of derivative liabilities to equity, there was no charge to earnings during the years ended December 31, 2016 and 2015.

Change in Fair Value of Derivative Liabilities. The change in the value of derivative liabilities for the year ended December 31, 2014 of $8,849,000 consists of increases in the fair value of preferred stock conversion options and warrants between December 31, 2013 and September 15, 2014 of $7,138,000 and $1,711,000, respectively. Due to the modification of certain terms within the preferred stock which resulted in the reclassification of the remaining derivative liability to equity in September 2014, there was no charge to earnings during the years ended December 31,

2016 and 2015.

Loss on Modification of Equity Instruments and Extinguishment of Derivative Liabilities. The loss on extinguishment of derivative liabilities for the year ended December 31, 2014 of $2,463,000 represents the change in the fair value of the preferred stock hybrid instruments of $2,119,000 and liability classified warrants of $344,000 resulting from the modifications made to those instruments on September 15, 2014 for the purpose of changing the balance sheet classification from liability to equity.

Foreign Exchange Transaction Gain (Loss). Foreign exchange transaction losses for the years ended December 31, 2016 and 2015 of $8,000 and $7,000, respectively, were due to the foreign exchange rate fluctuations for the payment of invoices paid in foreign currency. Foreign exchange transaction loss for the year ended December 31, 2014 was $151,000 due to additional funding to our German subsidiary through September 30, 2014 and the corresponding fluctuation in the exchange rates. Effective October 1, 2014, we considered the intercompany loans to be of long-term investment nature. Foreign exchange gains or losses subsequent to October 1, 2014 have been recorded in other comprehensive income.

Interest Income. Interest income for the year ended December 31, 2016 was $126,800, an increase of $66,400 from $60,400 for the same period in 2015. The increase was attributable to recording higher interest income on short-term investments during 2016 as compared to the same period in 2015.

Interest income for the year ended December 31, 2015 was $60,400, an increase of $57,700 from $2,700 for the same period in 2014. The increase was attributable to higher average interest-bearing cash balances during the year ended December 31, 2015 as compared to the same period in 2014.

Interest Expense. Interest expense for the year ended December 31, 2016 was $1,300 as compared to $4,000 for the same period in 2015, a decrease of $2,700.

Interest expense for the year ended December 31, 2015 was $4,000 as compared to $2,000 for the same period in 2014, an increase of $2,000.

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 $19,000 gain in 2016, $37,000 loss in 2015 and $108,000 gain in 2014.

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 were incorporated in July 2006. We received the following proceeds from the issuance of our common stock during the years ended:

	December 31,					
	2016			2015		
	Shares Issued	Net Proceeds	Wtd. Ave. Price	Shares Issued	Net Proceeds	Wtd. Ave. Price
At-the-market program	3,360,037	$6,229,351	$1.92	5,310,037	$28,451,848	$5.55
Exercise of stock options	1,087,500	863,101	$0.79	499,955	492,960	$0.99
Exercise of warrants	-	-	$-	4,581,783	14,658,161	$3.20
Totals	4,447,537	$7,092,452		10,391,775	$43,602,969	

During the year ended December 31, 2014, we sold the following:

200,000 shares of our Series C-3 non-voting convertible preferred stock and warrants to purchase up to 1,000,000 shares of our common stock for net cash proceeds of $1,319,000 and the settlement of accounts payable and accrued expenses of $645,000; and

2,960,000 units, each unit consisted of one share of our common stock and 0.35 of a warrant to purchase one share of our common stock, for gross proceeds of $7,400,000. We received net proceeds of approximately $6,723,000.

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2016 was $22,265,000 as compared to $12,527,000 in 2015, an increase in net cash use of $9,738,000. The increase was primarily attributable to an increase in net loss of $6,456,000 driven by increased research and development expenses. The net loss of $24,644,000 for the year ended December 31, 2016 was higher than cash used in operating activities by $2,379,000. The difference is primarily attributable to non-cash stock-based compensation of $1,335,000, increase in accrued expenses of $1,122,000 and decreases in trade receivables and inventory of $308,000 and $80,000, respectively, offset by an increase in prepaid expenses of $505,000 due to expenses associated with the Phase 3 clinical trial in hemodialysis catheters in the U.S and decrease in accounts payable of $64,000.

Net cash used in operating activities for the year ended December 31, 2015 was $12,527,000 as compared to $6,321,000 in 2014. The net loss of $18,187,000 for the year ended December 31, 2015 was higher than cash used in operating activities by $5,660,000. The difference is attributable primarily to a non-cash stock-based compensation of $3,226,000, non-cash charge for warrants issued in connection with the March 2015 backstop agreement of $1,583,000 and value of warrants related to the extension of the expiration date of $113,000. In comparison for the same period last year, the net loss of $20,453,000 for the year ended December 31, 2014 was higher than cash used in operating activities by $14,132,000. The difference is attributable primarily to revaluation of derivative liabilities of $8,849,000, non-cash loss on extinguishment of derivative liabilities of $2,463,000, non-cash stock-based compensation of $2,168,000, and losses on foreign currency transactions and issuance of preferred stock of $151,000 and $90,000, respectively.

Net Cash Provided by (Used in) Investing Activities

Cash provided by (used in) investing activities for the year ended December 31, 2016 was $11,420,000, attributable to the proceeds on the sale of short-term investments as compared to cash used in investing activities of $23,608,000 for the same period in 2015 due to the purchase of short-term investments.

Cash used in investing activities for the year ended December 31, 2015 was $23,608,000 attributable to the purchase of short-term investments as compared to $25,000 for the same period in 2014 due to the purchase of software for our German subsidiary.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2016 was $7,092,000 as compared to $43,629,000 for the same period in 2015. During 2016, we generated net proceeds of $6,229,000 from the sale of our common stock in the at-the-market program and received net proceeds of $863,000 from the exercise of stock options.

Net cash provided by financing activities for the year ended December 31, 2015 was $43,629,000 as compared to $8,358,000 for the same period in 2014. During 2015, we generated $28,452,000 net proceeds from the sale of our common stock in an at-the-market program; received $14,658,000 and $493,000 net proceeds from the exercise of warrants and stock options, respectively. In comparison to the same period in 2014, we generated net proceeds of $6,723,000 and $1,319,000 from the sale of our common stock and Series C-3 preferred stock, respectively, and received net proceeds of $318,000 from the exercise of stock options.

Funding Requirements and Liquidity

Our total cash on hand and short-term investments as of December 31, 2016 was $20.2 million, excluding restricted cash of $0.2 million, compared with $35.4 million and $4.3 million at December 31, 2015 and 2014, respectively. In addition, we have approximately $4.1 million available under our current at-the-market program at December 31,

2016. In August 2016, we entered into a new At-the-Market Issuance Sales Agreement (the "ATM program") with FBR Capital Markets & Co. (“FBR”), the successor in interest to MLV, on terms identical to the Sales Agreement for our current at-the-market program. This new agreement allows us to sell up to $40 million of shares of our common stock; however, we cannot access the at-the-market program under the new sales agreement unless and until (i) we and Manchester Securities Corp. (“Manchester”) agree as to the exercise or waiver of Manchester’s participation rights in the new ATM program, which rights were granted in a Consent and Exchange Agreement dated September 15, 2014, and apply to any equity financing we undertake until September 15, 2017, and (ii) we amend our existing shelf registration statement or file a new registration statement that includes the prospectus for the new at-the-market program. (See Note 4).

Because our business has not currently generated positive operating cash flow, we will need to raise additional capital in order to continue to fund our research and development activities and our business development activities, as well as to fund operations generally. Our continued operations and completion of our ongoing Phase 3 clinical trial for Neutrolin in hemodialysis catheters in the U.S., which was initiated in December 2015, will depend on our ability to raise sufficient additional funds through various potential sources, such as equity, debt financings, and/or strategic relationships. We plan to conduct a Phase 3 clinical trial in oncology patients with catheters in the U.S., for which additional funds over and above the funds needed for the ongoing hemodialysis Phase 3 clinical trial will be required before such trial can commence. We can provide no assurances that financing or strategic relationships will be available on acceptable terms, or at all, that may enable us to complete our hemodialysis study and commence our oncology study.

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. At December 31, 2016, we have approximately $4.1 million available under our current at-the market program. We also have $60.0 million available under our current shelf registration for the issuance of equity, debt or equity-linked securities. We may utilize our ATM program, if conditions allow, to support our ongoing Phase 3 clinical trial for Neutrolin in hemodialysis catheters in the U.S. 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 in connection with a debt financing 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 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 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 expect to incur increases in our cash used in operations as we continue our ongoing and planned Phase 3 clinical trials, pursue business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S.

Based on our cash resources at December 31, 2016 and the expected cost of the Phase 3 clinical trial in hemodialysis catheters in the U.S., we believe that our existing cash and short-term investments will be insufficient to fund our operations through 2017 and will not be sufficient to complete the ongoing Phase 3 trial for hemodialysis catheters in the U.S. or to begin the planned Phase 3 trial for oncology patients with catheters. If we are unable to raise additional funds when needed, we may be forced to slow or discontinue our ongoing Phase 3 clinical trial, and will be unable to commence our planned Phase 3 clinical trial for oncology patients with catheters. We could also be required to delay, scale back or eliminate some or all of our research and development programs. Each of these alternatives would likely have a material adverse effect on our business.

Contractual Obligations

We entered into a sublease for 4,700 square feet of office space in Bedminster, New Jersey, which runs from April 1, 2015 until March 31, 2018. Rent is $5,000 per month plus occupancy costs such as utilities, maintenance and taxes. In accordance with the lease agreement, we deposited $5,000 with the landlord, the equivalent of one month rent.

Our German subsidiary entered into a lease agreement for its offices in Fulda, Germany. The lease initially had a term of 36 months which commenced on September 1, 2013 for a base monthly payment of €498. A new lease agreement commenced on November 1, 2016 which is renewable every three months for a base monthly payment of €461.

Under our current lease agreements, the total estimated remaining lease obligation as of December 31, 2016 is set forth below:

2017	$62,237
2018	15,000
Total	$77,237

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 and a Monte Carlo option pricing model for options with market vesting conditions. Stock-based compensation cost is recognized as expense, over the employee's requisite service period on a straight-line basis.

Effective October 1, 2016, we adopted Accounting Standards Update ("ASU") 2016-09, Improvements to Employee Share-Based Payment Accounting, which was applied retroactively effective January 1, 2016, to account for forfeitures as they occur. Under ASU 2016-09, all share-based awards will be recognized on a straight-line method, assuming all awards granted will vest. Forfeitures of share-based awards will be recognized in the period in which they occur. Prior to the adoption of ASU 2016-09, share-based compensation cost was measured at grant date, based on the estimated fair value of the award, and was recognized as expense net of expected forfeitures, 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. Prior to 2015, the expected volatility used in the valuation of our stock options was based on the historical volatility of publicly traded peer group companies due to the limited trading history of our common stock. Beginning in the first quarter of 2015, the expected stock price volatility for our stock options is calculated based on the historical volatility since the initial public offering of our common stock in March 2010, weighted pre and post CE Mark approval in the European Union. 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.

Revenue Recognition

We recognize revenue in accordance with SEC SAB No. 101, “Revenue Recognition in Financial Statements” (“SAB 101”), as amended by SAB No. 104, “Revenue Recognition” (“SAB 104”) and FASB ASC 605, “Revenue Recognition” (“ASC 605”). Our product Neutrolin received its CE Mark in Europe in July 2013 and shipment of product to the dialysis centers began in December 2013. In accordance with SAB 101 and SAB 104, we recognize revenue from product sales when the following four revenue recognition criteria are met: persuasive evidence of an arrangement exists, delivery has occurred, the selling price is fixed or determinable, and collectability is reasonably assured. We recognize revenue upon shipment of product to the dialysis centers because the four revenue recognition criteria are met at that time. For an upfront payment related to an exclusive distribution agreement, we record it as deferred revenue and recognize revenue on a straight-line basis over the contractual term of the agreement

In October 2015, we shipped product with less than 75% of its remaining shelf life to a customer and issued a guarantee that any product shipped with less than 75% of its shelf life remaining 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. Due to limited sales experience with the customer, we were unable to estimate the amount of the warranty obligation that may be incurred as a result of this shipment. Therefore, we deferred the revenue and related cost of sales associated with the original shipment of this product. Since we will be unable to resell the expired product if returned by the customer, the deferred revenue and related cost of sales is presented net as "Deferred revenue" on the consolidated balance sheet. During the year ended December 31, 2016, we recognized 35.6% of deferred revenue and related cost of sales amounting to $106,000 and $63,000, respectively. At December 31, 2016 and 2015, deferred revenue on shipment to distributor was $75,000 and $121,000, respectively.

During the year ended December 31, 2014, we entered into a distribution 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 of the agreement, Wonik paid to 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. Revenue associated with the non-refundable up-front payment under this arrangement is deferred and recognized as revenue on a straight-line basis over the contractual term of our agreement. Deferred revenue related to this agreement at December 31, 2016 and 2015 amounted to approximately $29,000 and $38,000, 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 market price 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.

Embedded Derivative Liabilities:

We have previously had several series of preferred stock and warrants that contained embedded derivatives. We evaluate all our financial instruments to determine if those instruments or any embedded components of those instruments qualify as derivatives that need to be separately accounted for in accordance with FASB ASC 815, "Derivatives and Hedging". Embedded derivatives satisfying certain criteria are recorded at fair value at issuance and marked-to-market at each balance sheet date with the change in the fair value recorded as income or expense. In addition, upon the occurrence of an event that requires the derivative liability to be reclassified to equity, the derivative liability is revalued to fair value at that date.

We account for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants that allow for cash settlement or provide for certain modifications of the warrant exercise price are accounted for as derivative liabilities. For those liability-classified warrants that have down-round provisions which allow the exercise price to be adjusted as a result of certain future financing transactions, we use level 3 inputs to value those warrants. The estimated fair values of the warrant liabilities with downround protection were determined using a Monte Carlo option pricing model which takes into account the probabilities of certain events occurring over the life of the warrants. The derivative liabilities are adjusted to their estimated fair values at each reporting period, with any decrease or increase in the estimated fair value being recorded in other income (expense).

Recent Authoritative Pronouncements:

In May 2014, the FASB issued new guidance related to how an entity should recognize revenue. The guidance specifies that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. In addition, the guidance expands the required disclosures related to revenue and cash flows from contracts with customers. The guidance is effective for us beginning in the first quarter of 2017. Early adoption is not permitted

and retrospective application is required. We are currently evaluating the impact of adopting this guidance on our consolidated financial statements.

In July 2015, the FASB issued an accounting standard that requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. The standard defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation and is effective for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The guidance should be applied prospectively. We are evaluating the impact the adoption of this guidance will have on the determination or reporting of our consolidated financial statements.

In November 2015, the FASB issued guidance that requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this amendment. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. We are evaluating the impact the adoption of this guidance will have on the determination or reporting of our consolidated financial statements.

In January 2016, the FASB issued a new standard that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. We are currently assessing the impact that adopting this new accounting guidance will have on our consolidated financial statements.

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. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In April 2016, the FASB issued an update which clarifies two aspects of the new revenue guidance by providing guidance on how to identify performance obligations and providing implementation guidance surrounding licensing. The amendments in this update do not change the core principle of the new revenue guidance. The guidance is effective for us beginning in the first quarter of 2017. Early adoption is not permitted and retrospective application is required. We are currently evaluating the impact of adopting this guidance 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 August 2016, the FASB issued new guidance which clarifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows in order to reduce diversity in practice. The guidance is effective for us beginning in the first quarter of fiscal year 2018. Early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In November 2016, the FASB issued new guidance which clarifies how restricted cash is presented and classified in the statement of cash flows. The guidance is effective for us beginning in the first quarter of fiscal year 2018. Early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In January 2017, the FASB issued new guidance which clarifies the definition of a business in a business combination. The guidance is effective for us beginning in the first quarter of fiscal year 2018. Early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In January 2017, the FASB issued new guidance which simplifies the test for goodwill impairment. The guidance is effective for us beginning in the first quarter of fiscal year 2020. Early adoption is permitted for interim or annual

goodwill impairments tests after January 1, 2017. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

Recently Adopted Authoritative Pronouncements:

In June 2014, the FASB issued an accounting standard that clarifies the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The standard requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The amendments are effective for interim and annual reporting periods beginning after December 15, 2015. This adoption did not have a material impact on our consolidated financial statements.

In August 2014, the FASB issued new guidance related to disclosures of uncertainties about an entity's ability to continue as a going concern. The ASU requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued and if management's plans will alleviate that doubt. Management will be required to make this evaluation for both annual and interim reporting periods. We adopted this guidance as of the fiscal year ended December 31, 2016.

In April 2015, the FASB issued new guidance which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance requires retrospective adoption and was effective for us beginning in the first quarter of 2016. This adoption did not have a material impact on our consolidated financial statements.

In March 2016, the FASB issued new guidance which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. We adopted this guidance in the fourth quarter of fiscal year 2016. This adoption did not have a material impact 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, 2016, 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, 2016, 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, 2016.

Friedman LLP, the independent registered public accounting firm that audited our consolidated financial statements included in this report, has issued their report on the effectiveness of internal control over financial reporting as of December 31, 2016, a copy of which is included herein.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of CorMedix, Inc.

We have audited CorMedix, Inc. and subsidiary's (the "Company") internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, CorMedix, Inc. and subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control-Integrated Framework issued by COSO in 2013.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of CorMedix, Inc. and subsidiary as of December 31, 2016, and 2015, and the related consolidated statements of operations, comprehensive income (loss), cash flows, and stockholder's equity for each of the years in the three-year period ended December 31, 2016, and our report dated March 16, 2017 expressed an unqualified opinion thereon that included an explanatory paragraph regarding CorMedix, Inc.'s ability to continue as a going concern.

/s/ Friedman LLP
East Hanover, NJ
March 16, 2017

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Item 9B.
Other Information

None.

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.

The other information required by this Item concerning our directors and executive officers is incorporated by reference from the section captioned “Proposal No. 1—Election of Directors” and “Corporate Governance” contained in our proxy statement related to the 2017 Annual Meeting of Stockholders scheduled to be held on June 6, 2017 which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K. The information required by this Item concerning compliance with Section 16(a) of the Exchange Act by our directors, executive officers and persons who own more than 10% of our outstanding common stock is incorporated by reference from the section captioned “Section 16(a) Beneficial Ownership Reporting Compliance” contained in the proxy statement.

Item 11.
Executive Compensation

The information required by this Item concerning directors and executive compensation is incorporated by reference from the section captioned “Director Compensation,” “Executive Compensation – Summary Compensation Table” “Executive Compensation – Compensation Discussion and Analysis,” “Executive Compensation – Grants of Plan Based Awards,” “Executive Compensation – Option Exercises and Stock Vested,” “Executive Compensation – Outstanding Equity Awards at Fiscal Year End 2015” “Executive Compensation – Compensation Committee Interlocks and Insider Participation,” and “Executive Compensation – Compensation Committee Report” contained in the proxy statement.

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

The information regarding our equity compensation plans required by this Item is found in Item 5 of this report. The other information required by this Item is incorporated by reference to the information under the section captioned “Security Ownership of Certain Beneficial Owners and Management” contained in the proxy statement.

Item 13.
Certain Relationships and Related Transactions and Director Independence

The information required by this Item is incorporated by reference to the information under the section captioned “Certain Relationships and Related Transactions” and “Proposal No. 1—Election of Directors” contained in the proxy statement.

Item 14.
Principal Accountant Fees and Services

The information required by this Item is incorporated by reference to the information under the section captioned "Auditor and Audit Committee Matters" contained in the proxy statement.

PART IV

Item 15.
Exhibits and Financial Statement Schedules

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

1.
Financial Statements:

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

2.
Financial Statement Schedules:

None.

3.
Exhibit Index

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

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
3.1	Form of Amended and Restated Certificate of Incorporation.	S-1/A	3/01/2010	3.3	
3.2	Form of Amended and Restated Bylaws.	S-1/A	3/01/2010	3.4	
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated December 3, 2012.	10-K	3/27/2013	3.3	
3.4	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on February 18, 2013, as corrected on February 19, 2013.	8-K	2/19/2013	3.3	
3.5	Certificate of Designation of Series B Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on July 26, 2013.	8-K	7/26/2013	3.4	
3.6	Certificate of Designation of Series C-1 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.5	
3.7	Certificate of Amendment to Certificate of Designation of Series C-1 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.10	
3.8	Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.6	
3.9	Certificate of Amendment to Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of	8-K	1/09/2014	3.11	

	CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.			
3.10	Certificate of Designation of Series C-3 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.9
3.11	Certificate of Designation of Series D Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.7
3.12	Certificate of Amendment to Certificate of Designation of Series D Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.12

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
3.13	Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.8	
3.14	Certificate of Amendment to Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.13	
4.1	Specimen of Common Stock Certificate.	S-1/A	3/19/2010	4.1	
4.2	Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC.	S-1	11/25/2009	4.7	
4.3	Form of Warrant Issued in September/November 2012.	10-Q	11/13/2012	4.2	
4.4	Form of Sales Agent Warrant issued in September 2012.	10-Q	11/13/2012	4.3	
4.5	Warrant issued to ND Partners in April 2013.	10-Q	5/15/2013	4.18	
4.6	Form of Warrant issued on February 19, 2013.	8-K	2/19/2013	4.13	
4.7	Form of Warrant issued on July 30, 2013.	8-K	7/26/2013	4.21	
4.8	Form of Warrant issued on October 22, 2013.	8-K	10/18/2013	4.22	
4.9	Form of Warrant issued on January 8, 2014.	8-K	1/09/2014	4.23	
4.10	Form of Warrant issued on March 10, 2014.	8-K	3/05/2014	4.24	
4.11	Form of Warrant issued on March 3, 2015.	8-K	3/04/2015	4.1	
4.12	Amended and Restated Warrant originally issued May 30, 2013.	8-K	3/04/2015	4.3	
4.13	Amended and Restated Warrant originally issued March 24, 2010.	8-K	3/04/2015	4.2	
4.14	Registration Rights Agreement, dated March 3, 2015, by and between CorMedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	4.5	
10.1*	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC.	S-1/A	12/312009	10.5	
10.2	Escrow Agreement, dated as of January 30, 2008, among the Company, ND Partners LLC and the Secretary of the Company, as Escrow Agent.	S-1	11/25/2009	10.6	
10.3	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl.	S-1	11/25/2009	10.12	
10.4*	Manufacture and Development Agreement, dated as of March 5, 2007, by and between the Company and Emcure Pharmaceuticals USA, Inc.	S-1/A	12/31/2009	10.14	
10.5	Amended and Restated 2006 Stock Incentive Plan.	S-1/A	3/01/2010	10.8	
10.6	Form of Indemnification Agreement between the Company and each of its directors and executive officers.	S-1/A	3/01/2010	10.17	
10.7	Agreement for Work on Pharmaceutical Advertising dated January 10, 2013 by and between MKM Co-Pharma GmbH and CorMedix Inc.	8-K	1/16/2013	10.22	
10.8	2013 Stock Incentive Plan	10-K	3/27/2013	10.27	
10.9	Form of Securities Purchase Agreement, dated January 7, 2014, between CorMedix Inc. and the investors named therein.	8-K	1/09/2014	10.36	
10.10		10-Q	8/06/2015	10.1	

	Preliminary Services Agreement dated April 8, 2015, between CorMedix Inc. and [RC]2 Pharma Connect LLC.	
10.11	Release of Claims and Severance Modification, dated July 17, 2015, between Randy Milby and CorMedix Inc.	X

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Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.12	Employment Agreement, effective February 1, 2017, between CorMedix Inc. and Robert Cook.**				X
10.13	Employment Agreement, effective February 1, 2017, between CorMedix Inc. and Judith Abrams.**				X
10.14	Employment Agreement, effective March 1, 2017, between CorMedix Inc. and John Armstrong.				X
21.1	List of Subsidiaries	10-K	3/27/2013	21.1	
23.1	Consent of Independent Registered Public Accounting Firm.				X
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following materials from CorMedix Inc. Form 10-K for the year ended December 31, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2016 and 2015, (ii) Statements of Operations for the years ended December 31, 2016, 2015 and 2014, (iii) Statements of Changes in Stockholders' Equity for the years ended December 31, 2016, 2015 and 2014, (iv) Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014 and (v) Notes to the Financial Statements.***				X

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

** Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

*** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

SIGNATURES

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

CORMEDIX INC.

March 16, 2017 By: /s/ Khoso Baluch
Khoso Baluch
Chief Executive Officer
(Principal Executive Officer)

March 16, 2017 By: /s/ Robert Cook
Robert Cook
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ Khoso Baluch Khoso Baluch	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2017
/s/ Robert Cook Robert Cook	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2017
/s/ Cora Tellez Cora Tellez	Chairman of the Board and Director	March 16, 2017
/s/ Janet Dillione Janet Dillione	Director	March 16, 2017
/s/ Michael George Michael George	Director	March 16, 2017
/s/ Myron Kaplan Myron Kaplan	Director	March 16, 2017
/s/ Taunia Markvicka Taunia Markvicka	Director	March 16, 2017

CORMEDIX INC. AND SUBSIDIARY

FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
CorMedix, Inc.

We have audited the accompanying consolidated balance sheets of CorMedix, Inc. and Subsidiary (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended 2016. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of 2016 and 2015, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As described in Note 2, the Company has an accumulated deficit of $119.2 million as of December 31, 2016, has recurring losses, and negative cash flow from operations. These conditions, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty. If the Company is unable to obtain additional financing, there could be a material adverse effect on the Company.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of the year ended December 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 16, 2017, expressed an unqualified opinion.

/s/ Friedman LLP
East Hanover, NJ
March 16, 2017

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
December 31, 2016 and 2015

	December 31,	
	2016	2015
ASSETS		
Current assets		
Cash and cash equivalents	$8,064,490	$11,817,418
Restricted cash	171,553	171,553
Short-term investments	12,100,920	23,568,386
Trade receivables	12,014	315,771
Inventories, net	166,733	376,569
Prepaid research and development expenses	943,924	430,162
Other prepaid expenses and current assets	372,057	379,004
Total current assets	21,831,691	37,058,863
Property and equipment, net	69,695	37,866
Other assets	5,000	5,000
TOTAL ASSETS	$21,906,386	$37,101,729
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$1,645,298	$1,709,397
Accrued expenses	2,342,352	1,221,557
Deferred revenue	104,210	130,409
Total current liabilities	4,091,860	3,061,363
Deferred revenue, long term	-	28,878
TOTAL LIABILITIES	4,091,860	3,090,241
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 450,085 shares issued and outstanding at December 31, 2016 and 2015, respectively	450	450
Common stock - $0.001 par value: 80,000,000 shares authorized; 40,432,339 and 35,963,348 shares issued and outstanding at December 31, 2016 and 2015, respectively	40,433	35,964
Accumulated other comprehensive gain	81,186	62,130
Additional paid-in capital	136,857,409	128,304,539
Accumulated deficit	(119,164,952)	(94,391,595)
TOTAL STOCKHOLDERS' EQUITY	17,814,526	34,011,488

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$21,906,386	$37,101,729

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
Years Ended December 31, 2016, 2015 and 2014

	December 31,		
	2016	2015	2014
Revenue			
Net sales	$224,105	$210,130	$189,274
Cost of sales	(366,673)	(318,718)	(445,799)
Gross loss	(142,568)	(108,588)	(256,525)
Operating Expenses			
Research and development	(15,735,300)	(6,281,823)	(1,318,734)
Selling, general and administrative	(8,883,050)	(10,263,560)	(7,326,861)
Total operating expenses	(24,618,350)	(16,545,383)	(8,645,595)
Loss From Operations	(24,760,918)	(16,653,971)	(8,902,120)
Other Income (Expense)			
Interest income	126,774	60,393	2,714
Foreign exchange transaction loss	(8,172)	(6,735)	(150,803)
Loss on issuance of preferred stock, convertible notes and warrants	-	-	(89,590)
Value of warrants issued in connection with backstop financing	-	(1,583,252)	-
Change in fair value of derivative liabilities	-	-	(8,848,953)
Loss on modification of equity instruments and extinguishment of derivative liabilities	-	-	(2,462,588)
Interest expense	(1,311)	(3,964)	(2,087)
Total income (expense)	117,291	(1,533,558)	(11,551,307)
Net Loss	(24,643,627)	(18,187,529)	(20,453,427)
Other Comprehensive Income Gain (Loss)			
Unrealized gain (loss) from investments	11,027	(24,239)	-
Foreign currency translation gain (loss)	8,029	(12,603)	108,295
Total other comprehensive income gain (loss)	19,056	(36,842)	108,295
Comprehensive Loss	$(24,624,571)	$(18,224,371)	$(20,345,132)
Net Loss	$(24,643,627)	$(18,187,529)	$(20,453,427)
Dividends, including deemed dividends	-	(33,121)	(82,899)
Net Loss Attributable To Common Shareholders	$(24,643,627)	$(18,220,650)	$(20,536,326)
Net Loss Per Common Share – Basic and Diluted	$(0.65)	$(0.58)	$(0.96)
Weighted Average Common Shares Outstanding – Basic and Diluted	37,967,373	31,343,545	21,441,906

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERSí EQUITY
Years Ended December 31, 2016, 2015 and 2014

	Common Stock		Non-Voting Preferred Stock – Series A, Series B, Series C-1, Series C-2, C-3, Series D and Series E		Accumulated Other Comprehen-sive Gain (Loss)	AdditionalPaid-inCapital	Accumulated Deficit	Total Stock Equit (Defi
	Shares	Amount	Shares	Amount				
Balance at December 31, 2013	16,606,695	$16,606	857,160	$857	$(9,323)	$51,720,156	$(55,750,639)	$(4,0
Series C-3 non-voting preferred stock issued in January 2014 financing at $10 per share, net	-	-	200,000	200	-	-	-	200
Conversion of Series C-1 non-voting preferred stock to common stock	1,400,000	1,400	(140,000)	(140)	-	2,446,124	-	2,44
Stock issued in connection with March 2014 public offering at $2.50 per unit, net	2,960,000	2,960	-	-	-	4,991,838	-	4,99
Reclassification of Series C-2 and Series C-3 preferred stock conversion option derivative liability to equity	-	-	-	-	-	6,235,398	-	6,23
Reclassification of derivative liabilities to equity from modification of various equity	-	-	53,788	54	-	11,740,809	-	11,7

instruments including payment-in-kind dividends								
Shares held in escrow upon achievement of certain milestone	-	-	-	-	-	(36)	-	-
Stock-based compensation	-	-	-	-	-	2,168,303	-	2,16
Stock issued in connection with warrants cashless exercised	772,589	773	-	-	-	(773)	-	-
Stock issued in connection with stock options exercised	455,000	455	-	-	-	317,695	-	318,
Conversion of wages and fees to common stock	57,384	57	-	-	-	96,794	-	96,8
Conversion of Series C-3 non-voting preferred stock to common stock	210,000	210	(21,000)	(21)	-	(189)	-	-
Other comprehensive gain	-	-	-	-	108,295	-	-	108,
Net loss	-	-	-	-	-	-	(20,453,427)	(20,
Balance at December 31, 2014	22,461,668	22,461	949,948	950	98,972	79,716,155	(76,204,066)	3,63
Conversion of Series B non-voting preferred stock to common stock	454,546	455	(454,546)	(455)	-	-	-	-
Conversion of Series C-3 non-voting preferred stock to common stock	425,000	425	(42,500)	(42)	-	(383)	-	-
Conversion of Series E non-voting preferred stock to common stock	61,598	62	(2,817)	(3)	-	(59)	-	-
Stock issued in connection with warrants	4,581,783	4,582	-	-	-	14,653,579	-	14,6

exercised								
Stock issued in connection with warrants cashless exercised	2,158,033	2,158	-	-	-	(2,158)	-	-
Stock issued in connection with stock options exercised	499,955	500	-	-	-	492,460	-	492,
Stock issued in connection with sale of common stock	5,310,037	5,310	-	-	-	28,446,538	-	28,4
Stock issued in connection with conversion of wages	10,728	11	-	-	-	49,989	-	50,0
Value of warrants in connection with backstop financing	-	-	-	-	-	1,583,252	-	1,58
Modification of warrant agreement	-	-	-	-	-	112,982	-	112,
Short swing profit recovery	-	-	-	-	-	26,525	-	26,5
Stock-based compensation	-	-	-	-	-	3,225,659	-	3,22
Other comprehensive loss	-	-	-	-	(36,842)	-	-	(36,
Net loss	-	-	-	-	-	-	(18,187,529)	(18,
Balance at December 31, 2015	35,963,348	35,964	450,085	450	62,130	128,304,539	(94,391,595)	34,0
Cumulative effect of change in accounting principle (Note 8)	-	-	-	-	-	129,730	(129,730)	-
Stock issued in connection with sale of common stock, net	3,360,037	3,360	-	-	-	6,225,991	-	6,22
Stock issued in connection with warrants cashless exercised	21,454	21	-	-	-	(21)	-	-
Stock issued in connection with	1,087,500	1,088	-	-	-	862,013	-	863,

stock options exercised								
Stock-based compensation	-	-	-	-	-	1,335,157	-	1,33
Other comprehensive gain	-	-	-	-	19,056	-	-	19,0
Net loss	-	-	-	-	-	-	(24,643,627)	(24,
Balance at December 31, 2016	40,432,339	$40,433	450,085	$450	$81,186	$136,857,409	$(119,164,952)	$17,8

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2016, 2015 and 2014

	December 31,		
	2016	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(24,643,627)	$(18,187,529)	$(20,453,427)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	1,335,157	3,225,659	2,168,303
Value of warrants issued in connection with backstop financing	-	1,583,252	-
Modification of warrant agreement	-	112,982	-
Loss on foreign exchange transactions	-	-	150,803
Loss on issuance of preferred stock, convertible notes and warrants	-	-	89,590
Loss on modification of equity instruments and extinguishment of derivative liabilities	-	-	2,462,588
Inventory reserve	130,000	125,000	175,000
Revaluation of derivative liabilities	-	-	8,848,953
Depreciation	25,596	15,076	15,074
Changes in operating assets and liabilities:			
Restricted cash	-	(171,553)	220,586
Trade receivables	307,774	(248,186)	(85,412)
Inventory	79,836	(38,540)	(558,008)
Prepaid expenses and other current assets	(505,492)	(645,356)	72,958
Accounts payable	(63,586)	825,105	8,055
Accrued expenses	1,121,863	764,114	522,995
Deferred revenue	(52,916)	113,078	41,123
Net cash used in operating activities	(22,265,395)	(12,526,898)	(6,320,819)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Sale (purchase) of short-term investments	11,478,493	(23,592,625)	-
Purchase of equipment	(58,723)	(15,446)	(25,402)
Net cash provided by (used in) investing activities	11,419,770	(23,608,071)	(25,402)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from sale of common stock from at-the-market program	6,229,351	28,451,848	-
Proceeds from Series C-3 preferred stock, net	-	-	743,884
Proceeds from Series C-3 preferred stock, related party	-	-	575,000
Proceeds from exercise of warrants	-	14,658,161	-
Proceeds from exercise of stock options	863,101	492,960	318,150
Payment of deferred financing costs	-	-	(2,366)
Proceeds from sale of equity securities	-	-	6,723,248
Proceeds from short swing profit recovery	-	26,525	-

Net cash provided by financing activities	7,092,452	43,629,494	8,357,916
Foreign exchange effects on cash	245	(16,647)	(46,048)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(3,752,928)	7,477,878	1,965,647
CASH AND CASH EQUIVALENTS – BEGINNING OF YEAR	11,817,418	4,339,540	2,373,893
CASH AND CASH EQUIVALENTS – END OF YEAR	$8,064,490	$11,817,418	$4,339,540

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2016, 2015 and 2014

	December 31,		
	2016	2015	2014
Cash paid for interest	$1,197	$3,964	$2,074
Supplemental Disclosure of Non Cash Financing Activities:			
Unrealized gain (loss) from investments	$11,027	$(24,239)	$-
Conversion of preferred stock to common stock	$-	$500	$2,447,384
Conversion of accounts payable and accrued expenses to preferred stock	$-	$-	$645,458
Reclassification of derivative liabilities to equity	$-	$-	$17,955,143
Settlement of accrued dividends with issuance of preferred stock	$-	$-	$102,845
Conversion of wages and fees to common stock	$-	$50,000	$96,851
Dividend, including deemed dividends	$-	$33,121	$82,899

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

CORMEDIX INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business:

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

The Company’s primary activities have been acquiring licenses for its pharmaceutical product candidates, performing research and development, seeking regulatory approval for its products and developing its lead product Neutrolin® (also known as CRMD003) for potential commercialization in the United States and other key markets. The Company has in-licensed the worldwide rights to develop and commercialize Neutrolin®. The Company had also previously in-licensed CRMD004 which ceased development in late 2015.

The Company received CE Mark approval for Neutrolin in 2013 and commercially launched Neutrolin in Germany for the prevention of catheter-related bloodstream infections 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 granted labeling for expanded indications for Neutrolin in the European Union (“EU”). In December 2014, the Company received approval from the Hessian District President in Germany to expand the label to include use in oncology patients receiving chemotherapy, intravenous (“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, or IV, nutrition was also approved.

The Company launched its Phase 3 clinical trial in hemodialysis catheters in the U.S. in December 2015 and is currently planning to conduct a Phase 3 clinical trial in oncology, subject to funding requirements.

Note 2 — Liquidity, Going Concern and Uncertainties:

The financial statements have been prepared in conformity with generally accepted accounting principles which contemplate continuation of the Company as a going concern. To date, the Company’s commercial operations have not generated sufficient revenues to enable profitability. As of December 31, 2016, the Company had an accumulated deficit of $119.2 million, and incurred losses from operations of $24.8 million, $16.7 million and $8.9 million for the years ended December 31, 2016, 2015 and 2014, respectively. Based on the current development plans for Neutrolin in both the U.S. and foreign markets (including the ongoing hemodialysis Phase 3 clinical trial in the U.S.) and the Company’s other operating requirements, management believes that the existing cash at December 31, 2016 will not be sufficient to fund operations for at least the next twelve months following the filing date of the Company’s Annual Report on Form 10-K for the year ended December 31, 2016 (the “Form 10-K”). These factors raise substantial doubt regarding the Company’s ability to continue as a going concern.

The Company’s continued operations will depend on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products in order to complete its ongoing and planned Phase 3 clinical trials and until it achieves profitability, if ever. Management is actively pursuing financing plans but can provide no assurances that such financing or strategic relationships will be

available on acceptable terms, or at all. Without this funding, the Company could be required to delay, scale back or eliminate some or all of its research and development programs which would likely have a material adverse effect on the Company.

CORMEDIX INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

At December 31, 2016, approximately $4.1 million remained available for sale under an April 2015 At-the-Market Issuance Sales Agreement (the "ATM program") with MLV & Co. LLC, now a subsidiary of FBR Capital Markets & Co. ("FBR"), pursuant to which the Company is able to issue and sell up to $40 million of shares of its common stock from time to time (See Note 8). In August 2016, the Company entered into a new ATM program with FBR, which allows the Company to sell up to another $40 million of shares of its common stock. However, the Company cannot access the August 2016 ATM program unless and until (i) the Company and Manchester Securities Corp. ("Manchester") agree as to the exercise or waiver of Manchester's participation rights in the new ATM program, which rights were granted in a Consent and Exchange Agreement dated September 15, 2014, and apply to any equity financing we undertake until September 15, 2017 (See Note 4), and (ii) the registration statement that includes the prospectus for the new ATM program that the Company filed with the Securities and Exchange Commission is declared effective. As of the filing date of the Form 10-K, Manchester has not agreed to exercise or waive its rights nor has the registration statement that the Company filed in August 2016 been declared effective.

The financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

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

Note 3 — Summary of Significant Accounting Policies:

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Basis of Consolidation

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

Financial Instruments

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

The appropriate classification of marketable securities is determined at the time of purchase and reevaluated as of each balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair value is determined using quoted market prices in active markets for identical assets or liabilities or

quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in other comprehensive income (loss). Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in income (expense). For declines in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other (income) expense, net. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. There were no deemed permanent impairments at December 31, 2016 or 2015.

CORMEDIX INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company's marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with original maturities of more than 90 days. As of December 31, 2016 and 2015, all of the Company's investments had contractual maturities which were less than one year. The following table summarizes the amortized cost, unrealized gains and losses and the fair value at December 31, 2016 and 2015:

December 31, 2016:	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Fair Value
Money Market Funds included in Cash Equivalents	$95,949	$-	$-	$95,949
Corporate Securities	10,619,583	(13,212)	-	10,606,371
Commercial Paper	1,494,549	-	-	1,494,549
Subtotal	12,114,132	(13,212)	-	12,100,920
Total December 31, 2016	$12,210,081	$(13,212)	$-	$12,196,869
December 31, 2015:				
Money Market Funds included in Cash Equivalents	$3,353,067	$-	$-	$3,353,067
U.S. Government Agency Securities	6,531,914	(3,014)	-	6,528,900
Corporate Securities	15,065,595	(21,637)	412	15,044,370
Commercial Paper	1,995,116	-	-	1,995,116
Subtotal	23,592,625	(24,651)	412	23,568,386
Total December 31, 2015	$26,945,692	$(24,651)	$412	$26,921,453

Fair Value Measurements

The Company's financial instruments recorded in the consolidated balance sheets include cash and cash equivalents, accounts receivable, investment securities, accounts payable and accrued expenses. The carrying value of certain financial instruments, primarily cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their estimated fair values based upon the short-term nature of their maturity dates.

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

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

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

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

CORMEDIX INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table provides the carrying value and fair value of the Company's financial assets measured at fair value as of December 31, 2016 and 2015:

December 31, 2016:	Carrying Value	Level 1	Level 2	Level 3
Money Market Funds	$95,949	$95,949	$-	$-
Available for sale securities:				
Corporate Securities	10,606,371	-	10,606,371	-
Commercial Paper	1,494,549	-	1,494,549	-
Subtotal	12,100,920	-	12,100,920	-
Total December 31, 2016	$12,196,869	$95,949	$12,100,920	$-
December 31, 2015:				
Money Market Funds	$3,353,067	$3,353,067	$-	$-
Available for sale securities:				
US Government Agency Securities	6,528,900	-	6,528,900	-
Corporate Securities	15,044,370	-	15,044,370	-
Commercial Paper	1,995,116	-	1,995,116	-
Subtotal	23,568,386	-	23,568,386	-
Total December 31, 2015	$26,921,453	$3,353,067	$23,568,386	$-

Foreign Currency Translation and Transactions

The consolidated financial statements are presented in U.S. Dollars (USD), the reporting currency of the Company. For the financial statements of the Company's foreign subsidiary, whose functional currency is the EURO, foreign currency asset and liability amounts, if any, are translated into USD at end-of-period exchange rates. Foreign currency income and expenses are translated at average exchange rates in effect during the year. Translation gains and losses are included in other comprehensive loss. The Company had foreign currency translation gain of $8,029 in 2016, a loss of $12,603 in 2015 and a gain of $108,295 in 2014.

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

Segment and Geographic Information

The Company reported revenues of $224,105, $210,130 and $189,274 for the years ended December 31, 2016, 2015 and 2014, respectively. Of the Company's 2016, 2015 and 2014 revenues, $215,282, $201,306 and $185,598, respectively, were attributable to its European and Mideast operations, which are based in Germany. Total assets at December 31, 2016 and 2015 were $22,643,953 and $37,101,729, respectively, of which $22,333,139 and $36,190,835 were located in the United States at December 31, 2016 and 2015, respectively, with the remainder in Germany.

Restricted Cash

As of December 31, 2016 and 2015, the Company's restricted cash is in connection with the patent and utility model infringement proceedings against TauroPharm (see Note 6). The Company was required by the District Court Mannheim to provide a security deposit of approximately $132,000 to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The Company furthermore had to provide a deposit in the amount of

$40,000 in connection with the unfair competition proceedings in Cologne.

Prepaid Research and Development and Other Prepaid Expenses

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

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Inventories, net

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

	December 31,	
	2016	2015
Raw materials	$79,900	$244,459
Work in process	463,897	424,622
Finished goods	52,936	7,488
Inventory reserve	(430,000)	(300,000)
Total	$166,733	$376,569

Property and Equipment

Property and equipment consist primarily of furnishings, fixtures, leasehold improvements, office equipment and computer equipment which are recorded at cost. Depreciation is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. Property and equipment, as of December 31, 2016 and 2015 were 69,695 and $37,866, respectively, net of accumulated depreciation of $117,949 and $92,353, respectively. Depreciation and amortization of property and equipment is included in selling, general and administrative expenses.

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

Accrued Expenses

Accrued expenses consist of the following at December 31:

	2016	2015
Professional and consulting fees	$335,198	$282,975
Accrued payroll and payroll taxes	737,607	532,084
Clinical trial and manufacturing development	875,500	226,042
Product development	374,839	-
Monitoring program fees	-	65,076
Statutory taxes	1,833	67,236
Other	17,375	48,144

Total	$2,342,352	$1,221,557

Revenue Recognition

Revenue is recognized from product sales when the following four revenue recognition criteria are met: persuasive evidence of an arrangement exists, delivery has occurred, the selling price is fixed or determinable, and collectability is reasonably assured.

Neutrolin received its CE Mark in Europe in July 2013 and product shipments to dialysis centers began in December 2013. Orders are processed through a distributor; however, Neutrolin is drop-shipped via a pharmacy directly to the Company's customer, the dialysis center. The Company recognizes net sales upon shipment of product to the dialysis centers.

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Deferred Revenue

In October 2015, the Company 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 the Company if the customer was not able to sell the product before it expired. As a result of this warranty, the Company 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. Due to limited sales experience with the customer, the Company is unable to estimate the amount of the warranty obligation that may be incurred as a result of this shipment. Therefore, the Company has deferred the revenue and related cost of sales associated with the shipment of this product. During the year ended December 31, 2016, the Company recognized 35.6% of deferred revenue and related cost of sales amounting to $106,000 and $63,000, respectively. Deferred revenue at December 31, 2016 and 2015 amounted to approximately $75,000 and $121,000, respectively.

In August 2014, the Company entered into an exclusive distribution agreement (the “Wonik Agreement”) with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis and oncolytic patients upon receipt of regulatory approval in Korea. Upon execution, Wonik paid the Company a non-refundable $50,000 payment and will pay an additional $50,000 upon receipt of the product registration necessary to sell Neutrolin in 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 this agreement at December 31, 2016 and 2015 amounted to approximately $29,000 and $38,000, respectively.

Loss Per Common Share

Basic loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity. Since the Company has only incurred losses, basic and diluted loss per share are the same as potentially dilutive shares have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive.

The shares outstanding at the end of the respective periods presented below were excluded from the calculation of diluted net loss per shares due to their anti-dilutive effect:

	December 31,		
	2016	2015	2014
Series B non-voting preferred stock	-	-	454,546
Series C non-voting preferred stock	2,865,000	2,865,000	3,290,000
Series D non-voting preferred stock	1,479,240	1,479,240	1,479,240
Series E non-voting preferred stock	1,959,759	1,959,759	2,021,358
Shares underlying outstanding warrants	4,006,468	4,422,188	11,520,762
Shares underlying outstanding stock options	4,609,755	3,600,045	3,664,500
Total Potentially Dilutive Shares	14,920,222	14,326,232	22,430,406

Stock-Based Compensation

The Company accounts for stock options granted to employees, officers and directors according to 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 and a Monte Carlo option pricing model for options with market vesting conditions. Stock-based compensation cost is recognized as expense over the employee’s requisite service period on a straight-line basis.

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Effective October 1, 2016, the Company adopted Accounting Standards Update (“ASU”) 2016-09, Compensation — Stock Compensation (“Topic 718”), Improvements to Employee Share-Based Payment Accounting to account for forfeitures as they occur. All share-based awards will be recognized on a straight-line method, assuming all awards granted will vest. Forfeitures of share-based awards will be recognized in the period in which they occur. Prior to the adoption of ASU 2016-09, share-based compensation expense was recognized by applying the expected forfeiture rate during the vesting period to the fair value of the award. As of January 1, 2016, a cumulative effect adjustment of $129,730 was recognized to reflect the forfeiture rate that had been applied to unvested option awards prior to fiscal year 2016.

The Company accounts 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.

Research and Development

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

Income Taxes

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

Embedded Derivative Liabilities and Warrant Liabilities

The Company has several series of preferred stock and warrants and evaluates all its financial instruments to determine if those instruments or any potential embedded components of those instruments qualify as derivatives that need to be separately accounted for in accordance with FASB ASC 815, “Derivatives and Hedging”. Embedded derivatives satisfying certain criteria are recorded at fair value at issuance and marked-to-market at each balance sheet date with the change in the fair value recorded as income or expense. In addition, upon the occurrence of an event that requires the derivative liability to be reclassified to equity, the derivative liability is revalued to fair value at that date. (See Note 7).

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The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants that allow for cash settlement or provide for certain modifications of the warrant exercise price were accounted for as derivative liabilities. For those liability-classified warrants that have down-round provisions which allow the exercise price to be adjusted as a result of certain future financing transactions, the Company uses level 3 inputs to value those warrants. The estimated fair values of the warrant liabilities with downround protection were determined using a Monte Carlo option pricing model which takes into account the probabilities of certain events occurring over the life of the warrants. The derivative liabilities were adjusted to their estimated fair values at each reporting period, with any decrease or increase in the estimated fair value being recorded in other income (expense). The significant inputs and assumptions are as follows:

Stock price – Due to the historical volatility of the Company's common stock price, a one month volume-weighted average stock price was used as of each valuation date.

Conversion/redemption strike price – These assumptions incorporate both the initial contractual conversion price as well as subsequent downward adjustments (wherever applicable) based on management's estimate of the probabilities of additional future financings that would include a stock price or conversion price that is lower than the then existing conversion price.

Volatility – The Company used a weighted average of (i) the historical volatility of the Company's common stock for approximately five years, (ii) the volatility used for prior period valuations, and (iii) the volatilities of comparable companies (provided by the Company's management) from the date product approval is received to the various valuation dates. Then, appropriate weights were applied to these data points to arrive at the weighted average historical volatility.

Term – Although the Series C, D and E preferred stocks do not have a specified contracted life, the Company has assumed a five year life from the date of inception for the purpose of the valuations.

Risk-free Rate – The U.S. Treasury Bond Rate with a term approximating the term of the instrument was used as the risk-free interest rate in the valuation.

Credit adjusted discount rate – Management believes that its debt, if rated, would be equivalent to Moody's C rated bonds or lower.

Dividend rate - Management does not expect to pay any dividends during the term of the hybrid instrument.

Recently Adopted Authoritative Pronouncements

In June 2014, the FASB issued an accounting standard that clarifies the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The standard requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The amendments are effective for interim and annual reporting periods beginning after December 15, 2015. This adoption did not have a material impact on the Company's consolidated financial statements.

In August 2014, the FASB issued new guidance related to disclosures of uncertainties about an entity's ability to continue as a going concern. The ASU requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued and if management's plans will alleviate that doubt. Management will be required to make this

evaluation for both annual and interim reporting periods. The Company adopted this guidance for the fiscal year ended December 31, 2016. This adoption did not have a material impact on the Company's consolidated financial statements.

In April 2015, the FASB issued new guidance which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance was effective for the Company beginning in the first quarter of 2016. This adoption did not have a material impact on the Company's consolidated financial statements.

In March 2016, the FASB issued new guidance which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company adopted this guidance in the fourth quarter of fiscal year 2016, which was applied retroactively effective January 1, 2016. This adoption did not have a material impact on the Company's consolidated financial statements.

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Recent Authoritative Pronouncements

In May 2014, the FASB issued new guidance related to how an entity should recognize revenue. The guidance specifies that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. In addition, the guidance expands the required disclosures related to revenue and cash flows from contracts with customers. The guidance is effective for the Company beginning in the first quarter of 2017. Early adoption is not permitted and retrospective application is required. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial statements.

In July 2015, the FASB issued an accounting standard that requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. The standard defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation and is effective for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The guidance should be applied prospectively. The Company is evaluating the impact the adoption of this guidance will have on the determination or reporting of its consolidated financial statements.

In November 2015, the FASB issued guidance that requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this amendment. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. The Company is evaluating the impact the adoption of this guidance will have on the determination or reporting of its consolidated financial statements.

In January 2016, the FASB issued a new standard that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements.

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 the Company 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. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

In April 2016, the FASB issued an update which clarifies two aspects of the new revenue guidance by providing guidance on how to identify performance obligations and providing implementation guidance surrounding licensing. The amendments in this update do not change the core principle of the new revenue guidance. The guidance is effective for the Company beginning in the first quarter of 2017. Early adoption is not permitted and retrospective application is required. The Company is currently evaluating the impact of adopting this guidance on its 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 the Company beginning in the first quarter of fiscal year 2020. Early adoption is permitted beginning in the first quarter of fiscal year 2019. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

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In August 2016, the FASB issued new guidance which clarifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows in order to reduce diversity in practice. The guidance is effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

In November 2016, the FASB issued new guidance which clarifies how restricted cash is presented and classified in the statement of cash flows. The guidance is effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

Note 4 — Related Party Transactions:

In September 2014, as part of the removal of anti-dilution, price reset and change of control provisions in various securities that had caused those securities to be classified as derivative liabilities, the Company entered into a Consent and Exchange Agreement dated September 15, 2014, with Manchester Securities Corp., or Manchester, pursuant to which Manchester has a right of participation in equity financings undertaken by the Company prior to September 15, 2017.

On March 3, 2015, the Company entered into a backstop agreement with an existing institutional investor, Manchester Securities Corp., a wholly owned subsidiary of Elliott Associates, L.P., and a beneficial holder of more than 5% of the Company's outstanding common stock. Pursuant to the backstop agreement, Manchester agreed to lend the Company, at its request, up to $4,500,000 on or before April 30, 2015, provided that the loan could not exceed $3,000,000. The Company issued two warrants exercisable for an aggregate of up to 283,400 common shares with an exercise price of $7.00 per share and a term of five years as a result of entering into the backstop agreement. The Company did not access the loan and the loan expired on April 30, 2015. Additionally, the Company granted Manchester the right for as long as it or its affiliates hold any of the Company's common stock or securities convertible into its common stock the right to appoint up to two members to the Company's board of directors and/or to have up to two observers attend board meetings in a non-voting capacity. As of December 31, 2016, two board members had been appointed to the Company's board of directors under this provision.

On April 7, 2015, the Company entered into a one year agreement with a consultant to advise management with their investment banking relationships and assist in the negotiations with potential external parties, if applicable. The consultant is a member of the board of directors of Sterling HSA which was founded by the Chairman of the Board of Directors of the Company. The arrangement called for a $30,000 retainer, a monthly fee of $6,000, and a multiple of the price per share upon a merger or acquisition or a percentage of any strategic partnership. This agreement was terminated at the end of August 2015.

In January 2014, the following related parties participated in the private placement of Series C-3 preferred stock and warrants to purchase the Company's common stock at an exercise price of $1.25 per share, which was reduced to $0.90 in September 2014. Each share of Series C-3 preferred stock is convertible into 10 shares of common stock. All terms were the same as the Series C-1 and C-2 preferred stock issued in the October 2013 private placement:

		Amount	Number of Series C-3 Preferred Stock	Number of Warrants
Gary A. Gelbfish (1)	Former Chairman of the Board	$500,000	50,000	250,000

Randy Milby and affiliate	CEO and Director	$250,000	25,000	125,000
Steven W. Lefkowitz and affiliate	Director and Former Interim CFO	$75,000	7,500	37,500

(1) Gary A. Gelbfish resigned effective June 13, 2014 and ceased to be a related party 90 days thereafter.

In each instance, the purchase was on the same terms as all other purchasers in the offerings. The Audit Committee of the Board of Directors approved the purchase by these insiders.

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Note 5 — Income Taxes:

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

	December 31,		
	2016	2015	2014
United States	$(23,743,682)	$(16,690,084)	$(18,653,576)
Foreign	(899,945)	(1,497,445)	(1,799,851)
Total	$(24,643,627)	$(18,187,529)	$(20,453,427)

There were no current or deferred income tax provision for the years ended December 31, 2016, 2015 or 2014 because the Company has incurred operating losses since inception.

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

	December 31,	
	2016	2015
Net operating loss carryforwards – Federal	$27,798,000	$18,282,000
Net operating loss carryforwards – State	4,082,000	2,522,000
Net operating loss carryforwards – Foreign	1,373,000	1,103,000
Capitalized licensing fees	1,734,000	1,915,000
Stock-based compensation	2,511,000	2,349,000
Accrued compensation	132,000	206,000
Other	181,000	150,000
Totals	37,811,000	26,527,000
Less valuation allowance	(37,811,000)	(26,527,000)
Deferred tax assets	$-	$-

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

	December 31,		
	2016	2015	2014
Federal	$81,759,000	$56,429,000	$38,023,000
State	$68,713,000	$45,113,000	$25,772,000
Foreign	$4,577,000	$3,678,000	$2,183,000

The net operating loss tax carryforwards will start to expire in 2026 for Federal purposes and 2016 for state purposes. The foreign net operating loss tax carryforwards do not expire. Our federal and state operating loss carryforwards include windfall tax deductions from stock option exercises.

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

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

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The effective tax rate varied from the statutory rate as follows:

	December 31,		
	2016	2015	2014
Statutory Federal tax rate	(34.0)%	(34.0)%	(34.0)%
State income tax rate (net of Federal)	(5.7)%	(6.2)%	(0.6)%
Effect of foreign operations	(1.1)%	(2.5)%	0.4%
Non-deductible expenses associated with derivative liabilities	0.0%	0.0%	23.5%
Warrant related expenses	0.0%	3.2%	0.0%
Prior year return to provision adjustment	0.0%	(3.1)%	0.0%
Other permanent differences	(0.7)%	(0.1)%	(0.1)%
Effect of valuation allowance	41.5%	42.7%	10.8%
Effective tax rate	0.0%	0.0%	0.0%

In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income of the appropriate character during the periods in which those temporary differences become deductible and the loss carryforwards are available to reduce taxable income. In making its assessment, the Company considered all sources of taxable income including carryback potential, future reversals of existing deferred tax liabilities, prudent and feasible tax planning strategies, and lastly, objectively verifiable projections of future taxable income exclusive of reversing temporary differences and carryforwards. At December 31, 2016 and 2015, the Company maintained a full valuation allowance against its net deferred tax assets. The Company will continue to assess all available evidence during future periods to evaluate the realization of its deferred tax assets.

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

Year Ended	Balance at Beginning of Year	Increase (Decrease) Charged (Credited) to Income Taxes (Benefit)	Increase (Decrease) Charged (Credited) to OCI	Balance at End of Year
December 31, 2016	$26,527,000	$11,309,800	$(25,800)	$37,811,000
December 31, 2015	$18,744,000	$7,770,000	$13,000	$26,527,000
December 31, 2014	$16,564,000	$2,212,000	$(32,000)	$18,744,000

Accounting for uncertainty in income taxes requires uncertain tax positions to be classified as non-current income tax liabilities unless they are expected to be paid within one year. The Company has concluded that there are no uncertain tax positions requiring recognition in its consolidated financial statements as of December 31, 2016, 2015 and 2014. The Company recognizes interest and penalties related to uncertain tax positions if any as a component of income tax expense.

The Company files income tax returns in the U.S. federal, state and foreign jurisdictions. Tax years 2012 to 2016 remain open to examination for both the U.S. federal and state jurisdictions. Tax years 2013 to 2015 remain open for Germany.

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Note 6 — Commitments and Contingencies:

Contingency Matters

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland ("Geistlich") brought an action against the European Sodemann Patent covering the Company's Neutrolin product candidate, which is owned by ND Partners, LLC ("NDP") and licensed to the Company pursuant to the License and Assignment Agreement between the Company and NDP. This action was brought at the Board of the European Patent Office ("EPO") opposition division (the "Opposition Board") based upon alleged lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions of the prior art. The Opposition Board rejected the opposition by Geistlich. In a letter dated September 30, 2013, the Company was notified that the opposition division of the EPO reopened the proceedings before the first instance and gave their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfills the requirements of clarity, novelty, and inventive step, and invited the parties to provide their comments and/or requests by February 10, 2014. The Company filed its response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not file a further statement within the required timeline. On November 5, 2014, the Opposition Division at the EPO issued the interlocutory decision to maintain the patent on the basis of the claims as amended during the appeal proceedings. This decision became final as no further appeal was lodged by Geistlich.

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

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

On March 27, 2015, the District Court held a hearing to evaluate whether the Utility Model has been infringed by TauroPharm in connection with the manufacture, sale and distribution of its TauroLock-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 the Company that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the EPO, in the case of the Prosl European Patent, or the German PTO, in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by the Company for injunctive and other relief until such time as the EPO or the German PTO has 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. The EPO held a hearing in the opposition proceeding on November 25, 2015. In its preliminary consideration of the matter, the EPO (and the German PTO) had regarded the patent as not inventive or novel due to publication of prior art. However, the EPO did not issue a decision at the end of the hearing but adjourned the matter due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in a further hearing in order to close some gaps in the documentation presented by TauroPharm as regards the publication of the prior art. 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 recent decision of the German PTO on the invalidity of the utility model. The EPO has issued a further oral hearing for November 22 / 23, 2017. While the Company continues to believe that the referenced publication and instructions for use do not, in fact, constitute prior art and that the Prosl European Patent will be found to be valid by the EPO, there can be no assurance that the Company will prevail in this matter.

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 of the validity and possible infringement of the Prosl European Patent by the EPO. The Company filed an appeal against the ruling on September 7, 2016.

On January 16, 2015, the Company filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, the Company alleges violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. The Company alleges that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. The Company seeks a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider the Company's claims. In this hearing, the presiding judge explained that the court needed more information with regard to several aspects of the case. As a consequence, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to the court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. The Company's legal team has prepared the requested reply and produced the respective documentation. TauroPharm has also filed another writ within the same deadline and both parties have filed further writs at the end of April setting out their respective argumentation in more detail. A further oral hearing in this matter was held 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. At this time, there are no further hearings scheduled. The Company intends to continue to pursue this matter, and to provide additional supplemental documentary and other evidence as may be necessary to support its claims.

In connection with the aforementioned patent and utility model infringement proceedings against TauroPharm, the Company was required by the District Court Mannheim to provide a security deposit of approximately $132,000 to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The Company recorded the deposit as restricted cash for the year ended December 31, 2015. The Company furthermore had to provide a deposit in the amount of $40,000 in connection with the unfair competition proceedings in Cologne.

On July 7, 2015, a putative class action lawsuit was commenced against the Company and certain of its current and former officers in the United States District Court for the District of New Jersey, captioned Li v. Cormedix Inc., et al., Case 3:15-cv-05264 (the “Securities Class Action”). On September 4, 2015, two individuals, Shahm Martini and Paul Chretien (the “Martini Group”), filed a Motion to Appoint Lead Plaintiff. On that same date, another individual, Elaine Wood, filed a competing Motion to Appoint Lead Plaintiff. On September 18, 2015, the Martini Group withdrew its motion. Thereafter, on September 22, 2015, the Court appointed Elaine Wood as Lead Plaintiff and, on October 2, 2015, appointed the Rosen Law Firm as Lead Counsel.

On December 1, 2015, Lead Plaintiff filed an Amended Complaint asserting claims that the Company and Steven Lefkowitz, Randy Milby and Harry O'Grady (the "Cormedix Defendants") violated Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act. The Amended Complaint also named as defendants several unrelated entities that allegedly were paid stock promoters. Lead Plaintiff alleged generally that the Cormedix Defendants made materially false or misleading statements and omissions concerning, among other things, the competitive landscape for the Company's Neutrolin product and the alleged use of stock promoters. The Amended Complaint sought unspecified damages, interest, attorneys' fees, and other costs. The Court heard oral argument on this motion on July 18, 2016 and in an order dated October 27, 2016, the Court granted the Cormedix Defendants' Motion to Dismiss and dismissed with prejudice the Amended Complaint (the "Dismissal Order"). On December 16, 2016, the parties filed a stipulation with the Court in which the plaintiffs and their counsel agreed not to appeal, move for reconsideration or otherwise challenge the Dismissal Order. No settlement payment was made in exchange for the stipulation.

On May 13, 2016, a putative shareholder derivative action was filed in the Superior Court of New Jersey against the Company and certain present and former directors and officers captioned Raval v. Milby, et. al., Docket No. C-12034-6 (the "Derivative Action"). The factual allegations of the Derivative Action substantially overlap the factual allegations contained in the Amended Complaint in the Securities Class Action. The complaint in the Derivative Action seeks unspecified damages, interest, attorneys' fees and other costs, and certain amendments to the Company's "corporate governance and internal procedures". On June 30, 2016, the Court entered a stipulated order, among other things, staying the Derivative Action until 30 days after either: (a) the entry of any order denying any motion to dismiss the Derivative Action in the Securities Class Action, or (b) the entry of a final order dismissing the Securities Class Action with prejudice. Following entry of the Dismissal Order in the Securities Class Action, the parties entered into a stipulation, among other things, staying the Derivative Action until 30 days after either (a) November 30, 2016, in the event plaintiffs in the Securities Class Action did not file an appeal of the Dismissal Order or (b) the final disposition of any appeal in the event the plaintiffs in the Securities Class Action filed a Notice of Appeal of the Dismissal Order. On January 6, 2017, the parties filed a Stipulation of Dismissal without Prejudice of the Derivative Action.

Commitments

Manufacturing

Navinta LLC, a U.S.-based API developer, provides API manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for CRMD003, pursuant to an original supply agreement dated December 7, 2009 (the "Navinta Agreement"). The Navinta Agreement provided that Navinta will supply taurolidine (the API for CRMD003) to the Company on an exclusive worldwide basis in the field of the prevention and treatment of human infection and/or dialysis so long as the Company purchases a minimum of $2,250,000 of product on an annual basis for five years following the Company's first commercial sale of a product incorporating taurolidine. The Company did not purchase the required amounts and as a result, lost its exclusive manufacturing rights. The Company is also required to make certain cash payments to Navinta upon the achievement of certain sales-based milestones which is based on a tiered approach and does not commence until the Company achieves a designated net sales threshold. The maximum aggregate amount of such payments, assuming achievement of all milestones, is $1,975,000 over five years. There were no milestones achieved in 2016, 2015 and 2014.

On March 24, 2015, the Company and Navinta LLC entered into an amendment to the Navinta Agreement to extend the term of the Navinta Agreement to March 31, 2016 and to lower the price per kilogram of API that the Company purchases from Navinta LLC under the Navinta Agreement. The Company also agreed to purchase a minimum amount of product from Navinta LLC during 2015, which replaced the prior minimum purchase requirement. The

Navinta Agreement expired on March 31, 2016, was not renewed and there are no further purchase obligations or milestone payments.

The Company has developed a program aimed at reducing the cost of goods of Neutrolin through a more efficient, custom synthesis of the active ingredient taurolidine. As part of that program, on April 8, 2015, the Company entered into a Preliminary Services Agreement with [RC]2 Pharma Connect LLC (“RC2”), pursuant to which RC2 will coordinate certain manufacturing services related to taurolidine that the Company believes are necessary for the submission of its 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 expected to approximate $1.7 million through the first quarter of 2017. During the years ended December 31, 2016 and 2015, the Company recognized research and development expense of $1,278,000 and $227,000, respectively, for its services related to the agreement.

The Company also has several service agreements with RC2 for the manufacture of clinical supplies to support its ongoing and planned Phase 3 clinical trials for an aggregate amount of $7.6 million. During the years ended December 31, 2016 and 2015, the Company recognized research and development expense of approximately $2,359,000 and $1,348,000, respectively, related to these agreements. The Company may terminate these agreements upon 30 days written notice and is only obligated for project costs and reasonable project shut down costs provided through the date of termination.

Clinical and Regulatory

On December 3, 2015 CorMedix signed a Master Service Agreement and Work Order (the "Master Service Agreement") with PPD Development, LP ("PPD") for a $19.5 million (originally, $19.2 million) Phase 3 multicenter, double-blind, randomized active control study (the "Phase 3 Clinical Trial") to demonstrate the safety and effectiveness of Neutrolin in preventing catheter-related bloodstream infections and blood clotting in subjects receiving hemodialysis therapy as treatment for end stage renal disease. The Phase 3 Clinical Trial is expected to accrue up to 632 patients in 70 sites in the US. Prior to the signing of the Master Service Agreement, CorMedix signed a Letter of Agreement ("LOA") with PPD in July 2015. During the years ended December 31, 2016 and 2015, the Company recognized $5,283,000 and $1,019,000 research and development expense related to this agreement, respectively.

In-Licensing

In 2008, the Company entered into a License and Assignment Agreement (the "NDP License Agreement") with NDP. Pursuant to the NDP License Agreement, NDP granted the Company exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the "NDP Technology"). The Company acquired such licenses and patents through its assignment and assumption of NDP's rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann and Dr. Johannes Reinmueller. As consideration in part for the rights to the NDP Technology, the Company paid NDP an initial licensing fee of $325,000 and granted NDP a 5% equity interest in the Company, consisting of 39,980 shares of the Company's common stock.

In addition, the Company is required to make payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The maximum aggregate number of shares issuable upon achievement of milestones is 145,543 shares. 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, 2016 and 2015 is 109,157 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, 2016 and 2015. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval and upon achieving certain worldwide net sales amounts. There were no milestones achieved in 2016 and 2015.

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

On January 30, 2008, the Company also entered into an Exclusive License and Consulting Agreement with Dr. Polaschegg (the "Polaschegg License Agreement"). Pursuant to the Polaschegg License Agreement, Dr. Polaschegg granted the Company an exclusive, worldwide license for a certain antimicrobial solution and certain taurolidine treatments and the corresponding United States patent applications (the "Polaschegg Technology"), and agreed to provide the Company with certain consulting services. As consideration for the rights to the Polaschegg Technology, the Company paid Dr. Polaschegg an initial payment of $5,000 and agreed to pay Dr. Polaschegg certain royalty payments ranging from 1% to 3% of the net sales of the Polaschegg Technology. The Polaschegg License Agreement also set forth certain minimum royalty payments (on an annual basis) to be made to Dr. Polaschegg in connection with the Polaschegg Technology, which payments range from $10,000 to $45,000. The Company could terminate the Polaschegg License Agreement with respect to any piece of the Polaschegg Technology upon 60 days notice. If the Polaschegg License Agreement is terminated with respect to any piece of the Polaschegg Technology by either party, all rights with respect to such portion of the Polaschegg Technology revert to Dr. Polaschegg. On November 5, 2015, the Company gave notice of its termination of the Polaschegg License Agreement. During the years ended December 31, 2015 and 2014, the Company expensed $30,000 and $40,000, respectively, in connection with the Polaschegg License Agreement.

Other

On September 27, 2016, the Company entered into an employment agreement, effective October 3, 2016, with Khoso Baluch, its Chief Executive Officer. Unless renewed pursuant to the terms thereof, the agreement will expire on October 3, 2019. After the initial three-year term of Mr. Baluch's employment agreement, the agreement will automatically renew for additional successive one-year periods, unless either party notifies the other in writing at least 90 days before the expiration of the then current term that the agreement will not be renewed. Mr. Baluch also was appointed to the Company's Board of Directors (the "Board") on October 3, 2016. Mr. Baluch was granted stock options to purchase 1,850,000 shares of common stock, subject to four-year vesting for some of these options and subject to performance and market based vesting requirements for the rest of the options.

If the Company terminates Mr. Baluch's employment other than for Cause (as defined in the agreement), death or disability, other than by notice of nonrenewal, or if Mr. Baluch resigns for Good Reason (as defined in the agreement), Mr. Baluch will receive his base salary and benefits for a period of 12 months following the effective date of the termination of his employment and all restricted shares and unvested stock options that are scheduled to vest on or before the next succeeding anniversary of the date of termination shall be accelerated and deemed to have vested as of the termination date.

On August 3, 2015, the Company entered into a Release of Claims and Severance Modification with Randy Milby, its former Chief Executive Officer, that Mr. Milby may not compete against the Company by engaging in any business involving the development or commercialization of (i) a preventive anti-infective product that would be a direct competitor of Neutrolin or (ii) a product containing taurolidine. The non-compete term did not change and remains at twelve months following termination of his employment. The employment agreement was also amended to allow Mr. Milby a period in which to exercise all vested options and warrants until the later of 60 months following the termination date of his employment, provided in no event shall he be able to exercise after the respective expiration date of any stock option or warrant. During the year ended December 31, 2015, the Company recorded non-cash expense of $507,341 as a result of this modification.

Mr. Milby resigned as the Company's Interim Chief Executive Officer on October 2, 2016. Pursuant to the terms of his employment agreement, Mr. Milby will be entitled to receive his base salary and benefits for a period of twelve months following the effective date of the termination of his employment.

The Company entered into a sublease for 4,700 square feet of office space in Bedminster, New Jersey, which sublease runs from April 1, 2015 until March 31, 2018. Rent is $5,000 per month plus occupancy costs such as utilities, maintenance and taxes. In accordance with the lease agreement, the Company has deposited $5,000 with the landlord, the equivalent of one month rent.

The Company's subsidiary entered into a lease agreement for its offices in Fulda, Germany. The lease has a term of 36 months which commenced on September 1, 2013 for a base monthly payment of €498. The total 36 month lease obligation is approximately €17,900 ($20,000). The 36 month lease has terminated. A new lease agreement commenced on November 1, 2017 which is renewable every three months for a base monthly payment of €461.

Rent expense for the years ended December 31, 2016, 2015 and 2014, was $68,096, $72,119 and $70,337, respectively.

Under the Company's current lease agreements, the total remaining lease obligation as of December 31, 2016 is set forth below:

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2017	$62,237
2018	15,000
Total	$77,237

Note 7 — Equity Instruments Modification and Fair Value Measurements:

The following table presents the fair value hierarchy and the change in fair values of the Company's derivative liabilities measured at fair value on a recurring basis during the year ended December 31, 2014.

	Fair Value Hierarchy Level	Change in Fair Value From Jan. 1 to Sept. 15, 2014 (Modification Date)
Series C-1, C-2 and C-3 non-voting preferred stock conversion option issued in October 2013 and January 2014	3	$599,814
Series D non-voting preferred stock conversion option issued in October 2013	3	2,017,960
Series E non-voting preferred stock conversion option issued in October 2013	3	1,786,902
Warrants issued in connection with convertible debt issued in May 2013	3	1,566,444
Warrants issued in connection with Series C-1, C-2 and C-3 non-voting preferred stock issued in October 2013 and January 2014	3	3,732,962
Warrants issued in March 2014 in connection with the private placement of common stock and warrants	3	(855,129)
Total		$8,848,953

On September 15, 2014, the Company entered into consent and exchange agreements with the investors holding its outstanding Series C-2 preferred stock and related warrants, Series C-3 preferred stock and related warrants, Series D preferred stock and Series E preferred stock, and the investors holding warrants issued in March 2014. Pursuant to those agreements, the Company and the investors agreed to amend and restate the Series C-2 preferred stock and related warrants, Series C-3 preferred stock and related warrants, Series D preferred stock and Series E preferred stock and the warrants, to remove anti-dilution, price reset, cash settlement features and certain change of control provisions that caused those instruments to be classified as derivative liabilities. The Company also eliminated the preferred dividends on the Series D preferred stock and Series E preferred stock.

In exchange for the removal of the anti-dilution, price reset, cash settlement, change of control and dividend provisions, the Company agreed to the following:

1. Decrease the exercise price of the warrants issued in May 2013 from $1.00 to $0.65, decrease the exercise price of the warrants issued in October 2013 from $1.25 to $0.90, decrease the exercise price of the warrants issued in January 2014 from $1.25 to $0.90, and decrease the exercise price of the warrants issued in March 2014 from $3.10 to $2.50;
2. Extend the existing right of the two institutional investors in our May and October 2013 financings to participate in future financings to the later of two years (subsequently extended by an additional year) after September 15, 2014 or

the date on which the respective holder holds less than 5% of the Company's common stock on a fully diluted basis;

3. Increase the conversion ratio of the Series E preferred stock from 20 shares to 21.8667 shares of common stock for every share of Series E preferred stock;

4. Issue 16,562 shares of the Company's Series D preferred stock to the investor holding all of the outstanding shares of the Series D preferred stock in satisfaction of the 9.0% payment-in-kind dividend on that stock; and

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5.
Issue an aggregate of 37,226 shares of Series E preferred stock to the two investors holding all of the outstanding shares of Series E preferred stock in satisfaction of the 8.0% payment-in-kind dividend on that stock.

As a result of these modifications, all of the outstanding derivative liabilities were reclassified to equity on September 15, 2014. The fair value was re-measured immediately prior to the modification date with the original terms and immediately after the modification date with the amended terms. The change in fair value resulting from the modifications made to those instruments on September 15, 2014 was recorded as loss on modification of equity instruments and extinguishment of derivative liabilities in the amount of approximately $2,463,000.

The table below sets forth a summary of changes in the fair value of the Company's Level 3 derivative liabilities related to the non-voting preferred stock embedded derivatives and the liability classified warrants.

	December 31, 2014
Balance at beginning of year	$5,308,804
Additions to derivative liabilities	3,782,182
Conversion of convertible preferred stock to common stock	(2,447,384)
Loss from modification of preferred stock and warrant instruments	2,462,588
Change in fair value of derivative liabilities	8,848,953
Reclassification of derivative liabilities to equity (excluding $21,117 dividends issued in 2013)	(17,955,143)
Balance at December 31, 2014	$-

Note 8 — Stockholders' Equity:

Common Stock:

During 2015 the Company entered into a Sales Agreement with MLV under which the Company may issue and sell up to $40.0 million of shares of its common stock from time to time through MLV acting as agent, subject to limitations imposed by the Company, such as the number or dollar amount of shares registered under the registration statement to which the offering relates. When the Company wishes to issue and sell common stock under the Sales Agreement, it notifies MLV of the number of shares to be issued, the dates on which such sales are anticipated to be made, any minimum price below which sales may not be made and other sales parameters as the Company deems appropriate. MLV is entitled to a commission of up to 3% of the gross proceeds from the sale of common stock sold under the Sales Agreement. The shares of common stock to be sold under the Sales Agreement are registered under an effective registration statement filed with the SEC. At December 31, 2016, approximately $4.1 million was available for sale under this Sales Agreement. During the years ended December 31, 2016 and 2015, the shares of common stock under the Sales Agreement issued by the Company were 3,360,037 and 5,310,037, respectively, and realized net proceeds of $6,229,000 in 2016 and $28,452,000 in 2015.

In August 2016, the Company entered into a new sales agreement with the same bank, which is identical in terms to the Sales Agreement for the Company's current ATM program and allows the Company to sell up to $40 million of shares of its common stock. The Company will not and cannot access the ATM program under the new sales agreement unless and until (i) the Company and Manchester agree as to the exercise or waiver of Manchester's participation rights in the new ATM program, which rights were granted in a Consent and Exchange Agreement dated September 15, 2014, and apply to any equity financing we undertake until September 15, 2017, and (ii) the

registration statement that includes the prospectus for the new ATM program that the Company filed with the Securities and Exchange Commission is declared effective. At such time, the Company will be able to access the new ATM program and will terminate the current ATM program and the related Sales Agreement. There is no assurance that conditions will allow the Company to raise additional funds available under its at-the-market program.

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During the year ended December 31, 2016, the Company also issued the following shares of common stock:

21,454 shares upon cashless exercise of 25,000 warrants;

1,087,500 shares upon exercise of stock options at a weighted average exercise price of $0.79 per share, resulting in gross proceeds of $863,101.

During the year ended December 31, 2015, the Company also issued the following shares of common stock:

4,581,783 shares of common stock upon exercise of warrants with a weighted average exercise price of $3.20 per share resulting in gross proceeds of $14,658,161;

2,158,033 shares upon cashless exercise of 2,597,591 warrants;

499,955 shares upon exercise of stock options at a weighted average exercise price of $0.99 per share, resulting in gross proceeds of $492,960;

454,546 shares upon conversion of 454,546 shares of the Series B non-voting preferred stock;

425,000 shares upon conversion of an aggregate of 42,500 shares of the Series C-3 non-voting preferred stock;

61,598 shares upon conversion of 2,817 shares of the Series E non-voting preferred stock; and

10,728 shares upon conversion of wages by an officer of the Company in an aggregate amount of $50,000 at prices per share of $3.10 - $8.55.

During the year ended December 31, 2014, the Company issued the following shares of common stock:

455,000 shares upon exercise of stock options resulting in gross proceeds of $318,150;

1,400,000 shares upon conversion of an aggregate of 140,000 shares of the Series C-1 non-voting preferred stock;

210,000 shares upon conversion of 21,000 shares of the Series C-3 non-voting preferred stock;

772,589 shares upon exercise of warrants to purchase 919,513 shares of the Company’s common stock on a cashless basis; and

57,384 shares upon conversion of wages and board fees by an officer and board member in an aggregate amount of $96,851 at prices of $1.32 - $2.00 per share.

In March 2014, the Company sold an aggregate of 2,960,000 units in a registered direct offering at a purchase price of $2.50 per unit, for net proceeds of $6,723,248. Each unit consisted of one share of the Company’s common stock and 0.35 of a warrant, each to purchase one share of the Company’s common stock. Upon issuance, the warrants had an exercise price of $3.10 per share, are exercisable commencing six months from the date of issuance, and have a term of five years from the date of exercisability. Under certain circumstances, the warrants may be settled in cash and

were therefore were initially classified as derivative liabilities (See Note 7). The Company used the Black Scholes option pricing model to value the warrants, of which $1,728,450 was the ascribed value calculated at the issuance date. These warrants were revalued at each balance sheet date and the resulting changes were recorded in other income (expense) in the statement of operations. On September 15, 2014, the exercise price of these warrants was decreased to $2.50 in exchange for the removal of the cash settlement provisions of the warrant. During 2014, the Company used the following assumptions in calculating the Black Scholes values of these warrants:

	At Issuance Date	At September 15, 2014
Expected term (years)	5.5	5
Volatility	75%	75%
Dividend yield	0.0%	0.0%
Risk-free interest rate	1.63%	1.8%

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Preferred Stock and Warrants

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

	As of December 31, 2016 and 2015			As of December 31, 2014		
	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference
Series B	-	$0.001	$-	454,546	$0.001	$455
Series C-2	150,000	10.000	1,500,000	150,000	10.000	1,500,000
Series C-3	136,500	10.000	1,365,000	179,000	10.000	1,790,000
Series D	73,962	21.000	1,553,202	73,962	21.000	1,553,202
Series E	89,623	49.200	4,409,452	92,440	49.200	4,548,048
Total	450,085		$8,827,654	949,948		$9,391,705

The following terms and conditions apply to all of the non-voting convertible preferred stock outstanding at December 31, 2016, 2015 and 2014:

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

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

Redemption – The Company is not obligated to redeem or repurchase any shares of Series B, Series C, Series D or Series E non-voting preferred stock. Shares of Series B, Series C, series D and Series E Preferred Stock are not

otherwise entitled to any redemption rights.

Listing- There is no established public trading market for the Series B, Series C, Series D or Series E non-voting preferred stock, and the Company does not expect a market to develop. In addition, the Company does not intend to apply for listing of the Series B, Series C, Series D or Series E non-voting preferred stock on any national securities exchange or trading system.

Series B Non-Voting Convertible Preferred Stock and Warrants

On July 30, 2013, the Company sold 454,546 shares of its Series B non-voting convertible preferred stock and a warrant to purchase up to 227,273 shares of the Company's common stock, for gross proceeds of $500,000. Each share of Series B stock was convertible into one share of the Company's common stock at any time at the holder's option. All shares of Series B stock were converted into 454,546 shares of common stock in 2015.

The warrant was exercisable immediately upon issuance and has an exercise price of $1.50 per share and a term of five years.

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Series C-1, Series C-2 and Series C-3 Non-Voting Convertible Preferred Stock and Warrants

On October 22, 2013, the Company issued 150,000 shares of Series C-1 non-voting convertible preferred stock and 150,000 shares of Series C-2 non-voting convertible preferred stock, together with warrants to purchase up to an aggregate of 1,500,000 shares of common stock. As a condition to the closing, the Company simultaneously exchanged a convertible note held by one of the investors in the principal amount of $400,000 for 57,400 shares of Series D non-voting convertible preferred stock and exchanged another convertible note held by the same investor in the principal amount of $750,000 for 53,537 shares of Series E non-voting convertible preferred stock. The Company also issued 1,677 shares of Series E preferred stock to the other investor in the offering.

In January 2014, the Company sold to various investors 200,000 shares of Series C-3 non-voting convertible preferred stock, together with warrants to purchase up to an aggregate of 1,000,000 shares of common stock, for aggregate gross proceeds of $2,000,000. The Series C-3 non-voting convertible preferred stock and the related warrants were sold together at a price of $10.00 per share. The warrants are exercisable one year after issuance, had an exercise price of $1.25 per share (decreased to $0.90 per share in September 2014 – See Note 7), subject to adjustment, and a term of five years from the date they are first exercisable. The Company received net proceeds of $1,318,884.

The Series C-1 non-voting preferred stock, Series C-2 non-voting preferred stock and Series C-3 non-voting preferred stock have identical rights, privileges and terms and are referred to collectively as the “Series C Stock.” Each share of Series C Stock is convertible into 10 shares of common stock at any time at the holder’s option at a conversion price of $1.00 per share. In the event of the Company’s liquidation, dissolution, or winding up, holders of the Series C Stock will receive a payment equal to $10.00 per share of Series C Stock, subject to adjustment, before any proceeds are distributed to the holders of common stock. Shares of the Series C Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company’s board of directors.

In January 2014, all 140,000 outstanding shares of Series C-1 non-voting preferred stock were converted into 1,400,000 shares of the Company’s common stock which resulted in the reclassification of the derivative liability to equity in the amount of $2,447,384 for the year ended December 31, 2014.

The Series C Preferred Stock ranks senior to the Company’s common stock; senior to any class or series of capital stock created after the issuance of the Series C Preferred Stock; and junior to the Series D non-voting convertible preferred stock and Series E non-voting convertible preferred stock. As long as any of the Series C-2 Preferred Stock is outstanding, the Company cannot incur any indebtedness other than indebtedness existing prior to September 15, 2014, trade payables incurred in the ordinary course of business consistent with past practice, and letters of credit incurred in an aggregate amount of $3.0 million at any point in time.

Due to the existence of downround provisions, the conversion features of the Series C-3 non-voting convertible preferred stock and the associated warrants were initially classified as derivative liabilities upon issuance and were valued using a Monte Carlo simulation model. On the issuance date, the estimated value of the conversion features and warrants was $1,398,158 and $655,574, respectively.

In February 2014, the downround protection of Series C-2 and Series C-3 non-voting convertible preferred stock was eliminated as, pursuant to their terms, the closing price of the Company’s common stock was greater than $2.00 for a period of twenty trading days for a consecutive thirty trading day period subsequent to the closing (See Note 7).

The Series C-1 non-voting convertible preferred stock, Series C-2 non-voting convertible preferred stock, Series D non-voting convertible preferred stock and Series E non-voting convertible preferred stock all contained a prohibition on its respective conversion (in the case of the Series C-1 and Series C-2, in the aggregate for both series) if, as a

result of such conversion, the Company would have issued in each case shares of its common stock in an aggregate amount equal to 3,190,221 shares, which is 20% of the shares of common stock outstanding on October 17, 2013, unless the Company received the approval of its stockholders for such overage. On February 28, 2014, the shareholders approved the issuance of such overage.

Series D Non-Voting Convertible Preferred Stock

Each share of Series D non-voting convertible preferred stock is convertible into 20 shares of common stock (subject to adjustment) at a per share price of $0.35 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series D non-voting convertible preferred stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding. In the event of the Company's liquidation, dissolution or winding up, holders of Series D non-voting convertible preferred stock originally were to receive a payment equal to $7.00 per share (increased to $21.00 per share in September 2014 – See Note 7) of Series D non-voting convertible preferred stock on parity with the payment of the liquidation preference due the Series E non-voting convertible preferred stock, but before any proceeds are distributed to the holders of common stock, the Series C-1 non-voting convertible preferred stock and the Series C-2 non-voting convertible preferred stock. Shares of Series D non-voting convertible preferred stock received a dividend of 9% per annum through September 15, 2014 (See Note 7).

The Series D non-voting convertible preferred stock ranks senior to the Company's common stock; senior to any class or series of capital stock created after the issuance of the Series D non-voting convertible preferred stock; senior to the Series C-2 non-voting convertible preferred stock and the Series C-3 non-voting convertible preferred stock; and on parity with the Series E non-voting convertible preferred stock. As long as any of the Series D non-voting convertible preferred stock is outstanding, the Company cannot incur any indebtedness other than indebtedness existing prior to September 15, 2014, trade payables incurred in the ordinary course of business consistent with past practice, and letters of credit incurred in an aggregate amount of $3.0 million at any point in time.

In addition to the debt restrictions above, as long as any shares of the Series D non-voting convertible preferred stock are outstanding, the Company cannot, among others things: create, incur, assume or suffer to exist any encumbrances on any of its assets or property; or redeem, purchase or otherwise acquire or pay or declare any dividend or other distribution on any junior securities.

Series E Non-Voting Convertible Preferred Stock

Each share of Series E non-voting convertible preferred stock was originally convertible into 20 shares (increased to 21.8667 per share in September 2014 – See Note 7) of the Company's common stock (subject to adjustment) at a per share price of $0.82 (reduced to $0.75 per share in September 2014 – See Note 7) at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series E non-voting convertible preferred stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding. In the event of the Company's liquidation, dissolution or winding up, holders of Series E preferred stock originally was to receive a payment equal to $16.40 per share (increased to $49.20 per share in September 2014 – See Note 7) of Series E non-voting convertible preferred stock on parity with the payment of the liquidation preference due the Series D non-voting convertible preferred stock, but before any proceeds are distributed to the holders of common stock, the Series C-2 non-voting convertible preferred stock. Shares of Series E non-voting convertible preferred stock received a dividend of 8% per annum through September 15, 2014 (See Note 7).

The Series E non-voting convertible preferred stock ranks senior to the Company's common stock; senior to any class or series of capital stock created after the issuance of the Series E non-voting preferred stock; senior to the Series C-2 and the Series C-3 non-voting convertible preferred stock; and on parity with the Series D non-voting convertible preferred stock. As long as any of the Series E non-voting convertible preferred stock is outstanding, the Company cannot incur any indebtedness other than indebtedness existing prior to September 15, 2014, trade payables incurred

in the ordinary course of business consistent with past practice, and letters of credit incurred in an aggregate amount of $3.0 million at any point in time.

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

In the event the Company issues any options, convertible securities or rights to purchase stock or other securities pro rata to the holders of common stock, then holders of Series E non-voting convertible preferred stock will be entitled to acquire, upon the same terms a pro rata amount of such stock or securities as if the Series E non-voting convertible preferred stock had been converted to common stock.

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The Company used a Monte Carlo model to separately value the Series C-1, C-2, C-3, D and E preferred stock, the conversion options associated with the those preferred stock instruments and the warrants issued in connection with the Series C-1 and C-2 preferred stock. A summary of the key assumptions used in the Monte Carlo models are as follows:

Stock price – Due to the historical volatility of the stock price, a 30-day volume-weighted average stock price was used as of each valuation date.

Conversion/redemption strike price – These assumptions incorporate both the initial contractual conversion price as well as subsequent downward adjustments based on management's estimate of the probabilities of additional future financings that would include a stock price or conversion price that is lower than the then existing conversion price.

Volatility – The Company used a weighted average of 1) the historical volatility of the stock of CorMedix for approximately three years, 2) the volatility of the stock of CorMedix after receiving product approval and 3) the volatilities of comparable companies (provided by the management) from the date product approval is received to the various valuation dates. Then, appropriate weights were applied to these data points to arrive at the weighted average historical volatility. The concluded volatility is assumed to remain constant for all the valuation dates.

Term – Although the preferred Series C, D and E instruments do not have a specified contracted life, the Company has assumed a five year life from the date of inception for the purpose of the valuations, indicating that these instruments would expire in October 2018 at which point the holder would convert the investments into equity.

Risk-free Rate – The U.S. Treasury Bond Rate with a term approximating the term of the instrument was used as the risk-free interest rate in the valuation.

Credit adjusted discount rate – Management believes that its debt, if rated, would be equivalent to Moody's C rated bonds or lower.

Dividend rate - Management does not expect to pay any dividends during the term of the hybrid instrument.

A summary of the assumptions used in the Monte Carlo models are as follows:

	At September 15, 2014	At Issuance Date
Expected term (months)	49 - 64	56 - 60
Volatility	75%	75%
Dividend yield	0.0%	0.0%
Risk-free interest rate	1.63 - 1.8%	1.3 - 1.5%

Stock Options:

In 2013, the Company's board of directors approved the 2013 Stock Incentive Plan (the "2013 Plan"). The 2013 Plan provides for the issuance of equity grants in the form of options, restricted stock, stock awards and other forms of equity compensation. Awards may be made to directors, officers, employees and consultants under the 2013 Plan. An aggregate of 5,000,000 shares of the Company's common stock is reserved for issuance under the 2013 Plan. On January 19, 2016, the shareholders approved the increase of the shares issuable under the 2013 Plan from 5,000,000 to 8,000,000 and on June 13, 2016 from 8,000,000 to 11,000,000.

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During the year ended December 31, 2016, the Company granted ten-year non-qualified stock options under the 2013 Plan covering an aggregate of 2,891,000 shares of the Company's common stock to its officers, directors, employees and consultants. Of these options, 1,850,000 were granted on September 30, 2016 to the Company's new CEO in connection with his employment. 1,250,000 of the options will vest in four equal annual installments on the first four anniversaries of the grant date. Of the remaining options, 300,000, split into three equal tranches, become exercisable upon the achievement of specified performance milestones, provided that these options will be forfeited if the milestones are not achieved within four years of grant date and provided further that these options will not vest before December 18, 2018. The remaining 300,000 options become exercisable upon the achievement of a specified average closing stock price, provided that these options will not vest before December 31, 2018 and if the closing price per share of the Company's common stock is below the specified average closing stock price on December 31, 2018, the options will be forfeited. In each case, the new CEO must be an employee of the Company or consultant to the Company on the applicable vesting date. The total fair value of the 1,850,000 stock options issued to the Company's CEO on the date of grant was $3,186,450 which will be amortized to expense over the related vesting periods.

During the year ended December 31, 2015, the Company granted ten-year service based non-qualified stock options under the 2013 Plan covering an aggregate of 640,000 shares of the Company's common stock to its officers, directors and consultants.

During the years ended December 31, 2016, 2015 and 2014, total compensation expense for stock options issued to employees, directors, officers and consultants was $1,335,157, $3,225,659 and $2,168,303, respectively.

As of December 31, 2016, there was $3,375,165 total unrecognized compensation expense related to stock options granted which expense will be recognized over an expected remaining weighted average period of 1.8 years.

Effective October 1, 2016, the Company adopted Accounting Standards Update ("ASU") 2016-09, Compensation — Stock Compensation ("Topic 718"), Improvements to Employee Share-Based Payment Accounting to account for forfeitures as they occur. All share-based awards will be recognized on a straight-line method, assuming all awards granted will vest. Forfeitures of share-based awards will be recognized in the period in which they occur. Prior to the adoption of ASU 2016-09, share-based compensation expense was recognized by applying the expected forfeiture rate during the vesting period to the fair value of the award. As of January 1, 2016, a cumulative effect adjustment of $129,730 was recognized to reflect the forfeiture rate that had been applied to unvested option awards prior to fiscal year 2016.

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

	Year Ended December 31,		
	2016	2015	2014
Risk-free interest rate	1.14% - 1.94%	1.47% - 2.26%	1.5% - 2.9%
Expected volatility	96% - 98%	93% - 94%	74% - 113%
Expected term (years)	5 - 10 years	5 - 10 years	5 - 10 years
Expected dividend yield	0.0%	0.0%	0.0%
Weighted-average grant date fair value of options granted during the period	$ 1.76	$ 3.46	$ 1.50

The Company estimated the expected term of the stock options granted to employees based on anticipated exercises in future periods. The expected term of the stock options granted to consultants is based upon the full term of the respective option agreements. The expected volatility is calculated based on the historical volatility since the initial public offering of the Company's common stock in March 2010, weighted pre and post CE Mark approval in the

European Union. The expected dividend yield of 0.0% reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards.

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The fair value of the grant issued subject to a market based vesting condition was determined using the onte Carlo option pricing model which values financial instruments whose value is dependent on share price by sampling random paths for share price. The key inputs for the simulation included the closing stock price of the Company on the date of grant, the expected term of the stock options granted was based on anticipated exercises in future periods, the expected stock price volatility for the Company's stock options was calculated based on the historical volatility since the initial public offering of the Company's common stock in March 2010, weighted pre and post CE Mark, the expected dividend yield of 0.0% reflects the Company's current and expected future policy for dividends on the Company's common stock and the risk-free interest rate which was determined by utilizing the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The table below summarizes the key inputs used in the Monte Carlo simulation:

Expected Term	5 years
Volatility	97%
Dividend yield	0.0%
Risk-free interest rate	1.13%
Weighted-average grant date fair value of options granted during the period	$1.12

The following table summarizes the Company's stock options activity and related information for the year ended December 31, 2016:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at beginning of year	3,600,045	$1.82	7.6	$2,405,321
Granted	2,891,000	$2.38		
Exercised	(1,087,500)	$0.79		
Expired/Cancelled	(510,000)	$2.73		
Forfeited	(283,790)	$2.28		
Outstanding at end of year	4,609,755	$2.29	8.2	$581,823
Vested at end of year	2,136,458	$2.13	6.6	$581,823
Expected to vest in the future	2,462,797	$2.42	9.6	$-

The total intrinsic value of stock options exercised during the years ended December 31, 2016, 2015 and 2014 was $1,497,506, $3,260,728 and $636,250, respectively. The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying options and the quoted closing price of the common stock of the Company at the end of the reporting period for those options that have an exercise price below the quoted closing price.

In July 2015, the Company entered into a Release of Claims and Severance Modification Agreement with Randy Milby (See Note 6), the Company's CEO, due to Mr. Milby's anticipated termination of employment. As a result, the Company recorded a total of $507,341 compensation expense for the incremental value of an aggregate of 762,500 options during the year ended December 31, 2015 using the Black-Scholes option pricing model with the following

assumptions:

Expected term (years)	0.25 – 5
Volatility	94% - 97%
Dividend yield	0.0%
Risk-free interest rate	0.05% - 1.61%

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Warrants:

The following table is the summary of warrant activities:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at December 31, 2015	4,422,188	$1.80	3.07
Expired	(390,720)	$3.44	-
Exercised	(25,000)	$0.40	-
Outstanding at December 31, 2016	4,006,468	$1.65	2.36

During the year ended December 31, 2015, the Company extended the expiration date for an aggregate of 38,400 warrants with an exercise price of $3.4375. The Company accounted for this transaction as a modification of warrants and recorded additional paid in capital and non-cash general and administrative expense in the amount of $112,982. The warrants were valued using the Black-Scholes option pricing model with the following assumptions:

Expected term (days)	5
Volatility	88.17%
Dividend yield	0.0%
Risk-free interest rate	.003%

On March 2, 2015, the Company's board of directors approved an extension to April 30, 2015 of the expiration date of the Company's publicly traded warrants which resulted in deemed dividend of $33,121.

In March 2015, the Company issued two warrants exercisable for an aggregate of up to 283,400 common shares with an exercise price of $7.00 per share and a term of five years as a result of entering into a backstop agreement with Manchester Securities Corp. ("Manchester") (See Note 4). Additionally, the expiration date of March 24, 2015 of warrants to purchase 390,720 shares of common stock issued to Manchester in connection with the Company's initial public offering ("IPO") was extended by one year to March 24, 2016. The Company recorded non-cash other expense of $1,583,252 for these warrants using the Black-Scholes option pricing model with the following assumptions:

Expected term (years)	1 - 5
Volatility	75.81% - 104.08%
Dividend yield	0.0%
Risk-free interest rate	0.01% - 1.61%

Stock-based Deferred Compensation Plan for Non-Employee Directors

During the third quarter of 2014, the Company established an unfunded stock-based deferred compensation plan, providing non-employee directors the opportunity to defer up to one hundred percent of fees and compensation, including restricted stock units. The amount of fees and compensation deferred by a non-employee director is converted into stock units, the number of which is determined based on the closing price of the Company's common stock on the date such compensation would have otherwise been payable. At all times, the plan participants are one hundred percent vested in their respective deferred compensation accounts. On the tenth business day of January in

the year following a director's termination of service, the director will receive a number of common shares equal to the number of stock units accumulated in the director's deferred compensation account. The Company accounts for this plan as stock based compensation under ASC 718. During the year ended December 31, 2016, 2015 and 2014, the amount of compensation that was deferred under this plan was $95,666, $79,200 and $21,826, respectively.

Note 9 — Concentrations:

During the years ended December 31, 2015 and 2014, the Company had revenues of $100,000 and $55,000 from one customer which represented 48% and 29% of the Company's total revenue, respectively. At December 31, 2015, approximately 93% of net accounts receivable was due from this same customer. During the year ended December 31, 2016, the Company did not have individual sales in excess of 10% of its total sales.

Note 10 — Quarterly Results of Operations (Unaudited):

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The following table sets forth certain of the Company's unaudited quarterly consolidated results of operations for the years ended December 31, 2016 and 2015 (amounts in thousands, except for per share amounts):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
December 31, 2016:				
Net sales	$41	$16	$44	$121
Cost of sales	(50)	(187)	(44)	(85)
Gross profit (loss)	(9)	(171)	-	36
Research and development	(2,089)	(2,773)	(6,840)	(4,032)
Selling, general and administrative	(2,163)	(1,968)	(2,318)	(2,433)
(Loss) from operations	(4,261)	(4,912)	(9,158)	(6,429)
Total other income (expenses)	30	25	32	30
Net loss	(4,231)	(4,887)	(9,126)	(6,399)
Other comprehensive income (loss)	31	(3)	(7)	(2)
Comprehensive net (loss)	$(4,200)	$(4,890)	$(9,133)	$(6,401)
Net loss attributable to common shareholders	$(4,231)	$(4,887)	$(9,126)	$(6,429)
Net loss per common shares - basic and diluted	$(0.12)	$(0.13)	$(0.23)	$(0.16)
Weighted Average common shares outstanding – basic and diluted	36,013	36,447	39,054	40,381
December 31, 2015:				
Net sales	$31	$120	$36	$23
Cost of sales	(17)	(102)	(35)	(164)
Gross (loss)	14	18	1	(141)
Research and development	(1,235)	(1,798)	(1,764)	(1,485)
Selling, general and administrative	(2,693)	(2,355)	(2,949)	(2,267)
(Loss) from operations	(3,914)	(4,135)	(4,712)	(3,893)
Total other income (expenses)	(1,584)	-	24	27
Net loss	(5,498)	(4,135)	(4,688)	(3,866)
Other comprehensive income (loss)	3	(9)	7	(38)
Comprehensive net (loss)	$(5,495)	$(4,144)	$(4,681)	$(3,904)
Net loss attributable to common shareholders	$(5,498)	$(4,135)	$(4,688)	$(3,866)
Net loss per common shares - basic and diluted	$(0.23)	$(0.13)	$(0.14)	$(0.11)
Weighted Average common shares outstanding – basic and diluted	23,922	31,623	34,586	35,378

Note 11 — Subsequent Event:

During January 2017, the Company issued an aggregate of 198,630 shares under its current at-the-market sales agreement with a weighted average sale price of $1.80 per share, resulting in net proceeds of approximately $347,000.

EXHIBIT INDEX

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
3.1	Form of Amended and Restated Certificate of Incorporation.	S-1/A	3/01/2010	3.3	
3.2	Form of Amended and Restated Bylaws.	S-1/A	3/01/2010	3.4	
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated December 3, 2012.	10-K	2/27/2013	3.3	
3.4	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on February 18, 2013, as corrected on February 19, 2013.	8-K	2/19/2013	3.3	
3.5	Certificate of Designation of Series B Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on July 26, 2013.	8-K	7/26/2013	3.4	
3.6	Certificate of Designation of Series C-1 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.5	
3.7	Certificate of Amendment to Certificate of Designation of Series C-1 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.10	
3.8	Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.6	
3.9	Certificate of Amendment to Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.11	
3.10	Certificate of Designation of Series C-3 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.9	
3.11	Certificate of Designation of Series D Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.7	
3.12	Certificate of Amendment to Certificate of Designation of Series D Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.12	
3.13	Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.8	
3.14	Certificate of Amendment to Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.13	
4.1	Specimen of Common Stock Certificate.	S-1/A	3/19/2010	4.1	
4.2	Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC.	S-1	11/25/2009	4.7	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
4.3	Form of Registration Rights Agreement.	10-Q	11/13/2012	4.5	
4.4	Form of Sales Agent Warrant issued in September 2012.	10-Q	11/13/2012	4.3	
4.5	Warrant issued to ND Partners in April 2013.	10-Q	5/15/2013	4.18	
4.6	Form of Warrant issued on February 19, 2013.	8-K	2/19/2013	4.13	
4.7	Form of Warrant issued on July 30, 2013.	8-K	7/26/2013	4.21	
4.8	Form of Warrant issued on October 22, 2013.	8-K	10/18/2013	4.22	
4.9	Form of Warrant issued on January 8, 2014.	8-K	1/09/2014	4.23	
4.10	Form of Warrant issued on March 4, 2014.	8-K	3/05/2014	4.24	
4.11	Form of Warrant issued on March 3, 2015.	8-K	3/04/2015	4.1	
4.12	Amended and Restated Warrant originally issued May 30, 2013.	8-K	3/04/2015	4.3	
4.13	Amended and Restated Warrant originally issued March 24, 2010.	8-K	3/04/2015	4.2	
4.14	Registration Rights Agreement, dated March 3, 2015, by and between CorMedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	4.5	
10.1*	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC.	S-1/A	12/31/2009	10.5	
10.2	Escrow Agreement, dated as of January 30, 2008, among the Company, ND Partners LLC and the Secretary of the Company, as Escrow Agent.	S-1	11/25/2009	10.6	
10.3	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl.	S-1	11/25/2009	10.12	
10.4*	Manufacture and Development Agreement, dated as of March 5, 2007, by and between the Company and Emcure Pharmaceuticals USA, Inc.	S-1/A	12/31/2009	10.14	
10.5	Amended and Restated 2006 Stock Incentive Plan.	S-1/A	3/01/2010	10.8	
10.6	Form of Indemnification Agreement between the Company and each of its directors and executive officers.	S-1/A	3/01/2010	10.17	
10.7	Agreement for Work on Pharmaceutical Advertising dated January 10, 2013 by and between MKM Co-Pharma GmbH and CorMedix Inc.	8-K	1/16/2013	10.22	
10.8	2013 Stock Incentive Plan	10-K	3/27/2013	10.27	
10.9	Form of Securities Purchase Agreement, dated January 7, 2014, between CorMedix Inc. and the investors named therein.	8-K	1/09/2014	10.36	
10.10	Preliminary Services Agreement dated April 8, 2015, between CorMedix Inc. and [RC]2 Pharma Connect LLC.	10-Q	8/06/2015	10.1	
10.11	Release of Claims and Severance Modification, dated July 17, 2015, between Randy Milby and CorMedix Inc.				X
10.12	Employment Agreement, effective February 1, 2017, between CorMedix Inc. and Robert Cook.**				X
10.13	Employment Agreement, effective February 1, 2017, between CorMedix Inc. and Judith Abrams.**				X

10.14	Employment Agreement, effective March 1, 2017, between CorMedix Inc. and John Armstrong.				X
21.1	List of Subsidiaries	10-K	3/27/2013	21.1	
23.1	Consent of Independent Registered Public Accounting Firm.				X

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following materials from CorMedix Inc. Form 10-K for the year ended December 31, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2016 and 2015, (ii) Statements of Operations for the years ended December 31, 2016, 2015 and 2014, (iii) Statements of Changes in Stockholders' Equity (Deficiency) for the years ended December 31, 2016, 2015 and 2014, (iv) Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014 and (v) Notes to the Financial Statements.**				X

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

** Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

*** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.