SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CorMedix Inc.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended: **December 31, 2014**

OR

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

For the transition period from _____ to _____

Commission file number: 001-34673

CORMEDIX INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	20-5894890
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

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

745 Route 202-206, Suite 303, Bridgewater, NJ	**08807**
(Former address if changed since last report)	(Zip Code)

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 Par Value	NYSE MKT LLC
Units, each consisting of two shares of Common Stock and a Warrant	NYSE MKT LLC
Warrants, exercisable for Common Stock at an exercise price of $3.4375 per share	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 $37.4 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 24,122,522 as of March 9, 2015.

DOCUMENTS INCORPORATED BY REFERENCE

None

Forward-Looking Statements

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

Item 1. Business

Overview

We seek to in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious diseases in cardiac, renal and oncology patients. As of the date of this report, we have in-licensed all of the product candidates in our pipeline.

We have the worldwide rights to develop and commercialize our product candidates, CRMD003 (Neutrolin®) and CRMD004, which we believe address potentially large market opportunities in the instances in which a central venous catheter is used, such as hemodialysis, intensive care units, oncology and total parenteral nutrition patients.

Our primary product is Neutrolin, a catheter lock solution, is for the prevention of catheter-related infections and thrombosis in the central venous catheter markets such as dialysis, critical care, and oncology. There are seven million central venous catheters and 160 million peripheral catheters placed per year in patients in the United States. There are 1.7 million infections per year of which 25% are due to catheter related bloodstream infections (CRBSI), which are also referred to as central line associated bloodstream infections (CLABSI). The mortality rate ranges from 20 to 25%. Neutrolin is a novel formulation of taurolidine, citrate and heparin 1000 u/ml that provides a combination preventative solution to decrease the development of biofilm, which reduces infection and thrombosis thereby keeping catheters operating optimally in the clinical settings in hemodialysis, critical care/intensive care and oncology. There are approximately 780,000 hemodialysis patients in the United States and the European Union, or EU. Hemodialysis using a tunneled central vein catheter was our initial target market with Germany being the first market in which we launched Neutrolin as a medical device in December 2013. We project that 91,000 patients in the European Union and 104,000 patients in the United States have these catheters in place. These hemodialysis patients represent over 30 million catheter/dialysis treatment days per year in the U.S. and Europe, which we believe represents a conservative market potential of $300 to $400 million. The market in the critical care/intensive care units is 15 million catheter days per year in the United States alone. There were over 13 million patients living with cancer in the United States in 2010 with an estimated 4 million having a long-term central venous catheter. However, when stages of disease, chemotherapy regimens and catheter types are factored, the oncology market is of a similar order. 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 when they occur.

During the third quarter of 2011, we received a notice from the U.S. Food and Drug Administration, or FDA, that Neutrolin had been assigned to the Center for Drug Evaluation and Research, or CDER, for review as a drug rather than a device. As a result of this, and given our limited resources, we decided to change our business strategy and focus the majority of our resources on the research and development of Neutrolin, rather than CRMD004 and to seek regulatory and commercialization approval for Neutrolin in Europe through a CE Mark application rather than pursue FDA approval at that time. During the first half of 2011, we submitted our design dossier to TÜV SÜD, the European notified body managing our CE Mark application. In the fourth quarter of 2011, we successfully completed our stage 1 audit with TÜV SÜD and we successfully completed the stage 2 audit in the third quarter of 2012.

On October 10, 2012, we received ISO 13485:2003 certification from TÜV SÜD. This certification, which is a stand-alone standard developed by the International Organization for Standardization, is the globally recognized standard that outlines consistent international processes for the design and manufacturing of medical devices, including many supply chain functions such as assembly, packaging, warehousing and distribution. Compliance with ISO 13485 is often seen as a step towards achieving compliance with European regulatory requirements. The conformity of medical devices and in-vitro diagnostic medical devices according to applicable EU standards must be assessed before sale is permitted. The preferred method to prove conformity is the certification by a notified body of the quality management system according to ISO 9001 and/or ISO 13485 and ISO 14971. The result of a positive assessment is the issuance of a certificate of conformity allowing the CE Mark and the permission to sell the medical device in the European Union.

On July 5, 2013, we received CE Mark approval for Neutrolin. As a result, in 2013, we began the commercial launch of 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 Austria, Germany, Italy, Malta, Saudi Arabia and The Netherlands for such treatment.

We have entered into agreements with human4farma, a German contract sales company, and with Arabian Trade House, a Saudi Arabian company, to market and sell Neutrolin for hemodialysis, critical care/intensive care and oncolytic patients in Germany and Saudi Arabia, respectively, and with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis, critical care/intensive care and oncolytic patients in that country upon receipt of regulatory approval. We also have independent sales representatives in The Netherlands and Austria.

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, or IV, nutrition was also approved. In September 2014, the TUV-SUD and The Medicinal Evaluation Board of the Netherlands (MEB) granted a label expansion for Neutrolin for these same expanded indications for the E.U.

In late 2013, we met with the FDA to determine the pathway for U.S. approval of Neutrolin. Based on our discussions with the FDA, we expect to conduct at least one Phase 3 clinical trial in hemodialysis catheters and one Phase 3 clinical trial in oncology/total parenteral nutrition. We have worked with the FDA to design the protocol for a planned Phase 3 trial in hemodialysis patients with a central venous catheter; this protocol was accepted in August 2014 and we filed an investigational new drug application, or IND, in September 2014. In October 2014, the FDA informed us that it had determined that the IND is not subject to a clinical hold, and that the Phase 3 clinical trial in hemodialysis patients can be initiated in the U.S. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

Neutrolin has Class III CE mark approval for use in the European Union and was recently approved to enter a Phase 3 clinical trial program in the United States where it will be reviewed as a new drug. The U.S. Food and Drug Administration (FDA) designated Neutrolin as a Qualified Infectious Disease Product (QIDP) for oncology, hemodialysis, and critical care/intensive care patients, where catheter-related blood stream infections and clotting can be life-threatening. The QIDP designation will make Neutrolin eligible to benefit from certain incentives such as FDA priority review, fast-track status and it also provides an additional five years of market exclusivity in addition to the five years granted for a New Chemical Entity under Hatch-Waxman patent exclusivity

In January 2015, the FDA granted Fast Track designation to Neutrolin® Catheter Lock Solution, pursuant to the Food and Drug Administration Safety and Innovation Act (FDASIA). Fast Track designation is granted to drug products designed to treat a serious condition, for which clinical data has been generated and shown to potentially address an unmet medical need. The Fast Track designation of Neutrolin provides CorMedix with the opportunity to meet with the FDA on a more frequent basis during the review process, and also ensures an expedited review of any marketing application.

Our other product candidate is CRMD004, which is the gel formulation of Neutrolin that we may develop for a variety of indications that include but are not limited to the treatment of wounds, skin infections, soft tissue infections, the prevention of catheter exit site infections and, based on the gel's thixotropic properties which cause it to liquefy under pressure/kinetic energy, as a follow-on to our Neutrolin catheter lock solution. CRMD004 is currently in the pre-clinical stage of development.

Corporate History and 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 operations to date have been primarily limited to organizing and staffing, licensing product candidates, developing clinical trials for our product candidates, seeking regulatory approvals for Neutrolin, establishing manufacturing for our product candidates and maintaining and improving our patent portfolio and launching Neutrolin in the E.U and other foreign countries.

Our executive offices are located at 1430 US Highway 206, Suite 200, Bedminster, NJ 07921. Our telephone number is (908) 517-9500. Our website address is www.cormedix.com. Information contained in, or accessible through, our website does not constitute part of this report.

CRMD003 (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.

Patients undergoing hemodialysis require access to the vascular system in order to perform treatments on a multiple scheduled basis each week. According to the United States Renal Disease System, there were 636,905 patients on dialysis. It has been reported that patients requiring catheter represent over 127 million catheter days. In the United States, there were five million intensive care patients representing 15 million catheter days associated with ICU stays alone. In 2010, an estimated four million cancer patients had a catheter placed when stages of disease and types of chemotherapy regime are considered, then number of catheter days are in similar ranges. 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 is an estimated 250,000 CRBSIs each year. The U.S. Centers for Disease Control and Prevention stated in the Journal of American Medicine, the total annual cost in the United States of treating all CRBI episodes and their complications would amount to approximately $6 billion.

As of 2010, there were over 13 million patients in the United States living with cancer, with an estimated four million having had a long-term central venous catheter. Infections and thrombosis represent key complications among cancer patients with central venous catheters.

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, 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 a catheter lock 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.

Development Strategy

Our strategy is to obtain worldwide approval for Neutrolin. On July 5, 2013, the MEB, which is responsible for authorizing and monitoring safe and effective medicinal products on the Dutch market and shares responsibility for authorizing medicinal products throughout the European Union, issued final approval for the CE Mark certification for Neutrolin. 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, or IV, nutrition was also approved. In September 2014, the TUV-SUD and The Medicinal Evaluation Board of the Netherlands (MEB) granted a label expansion for Neutrolin for these same expanded indications for the EU.

In the U.S., after receipt of the CE Mark, we resumed dialogue with the FDA in November 2013 to determine the pathway for U.S. approval of Neutrolin. Based on our discussions with the FDA, we expect to conduct at least one Phase 3 clinical trial in hemodialysis catheters, one Phase 3 clinical trial in oncology/total parenteral nutrition and a Phase 2b clinical trial in ICU-critical care. We have worked with the FDA to design the protocol for a planned Phase 3 trial in hemodialysis patients with a central venous catheter; this protocol was accepted in August 2014 and we filed an investigational new drug application, or IND, in September 2014. In October 2014, the FDA informed us that it had determined that the IND is not subject to a clinical hold, and that the Phase 3 clinical trial in hemodialysis patients can be initiated in the U.S. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S. for hemodialysis, oncology/TPN and ICU-critical care.

Sales and Marketing Strategy

After CE Mark approval, we launched Neutrolinfor the prevention of CRBI and maintenance of catheter patency in hemodialysis patients in Europe in the fourth quarter of 2013. To lead the commercialization of Neutrolin in the European Union, we have formed a European subsidiary, CorMedix Europe GmbH. We have entered into agreements with human4farma, a German contract sales company, and with Arabian Trade House, a Saudi Arabian company, to market and sell Neutrolin for hemodialysis and oncolytic patients in Germany and Saudi Arabia, respectively, and with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis and oncolytic patients in that country upon receipt of regulatory approval. We also have independent sales representatives in The Netherlands and Austria.

We intend to pursue FDA approval for Neutrolin in the U.S. If we obtain FDA approval, we would intend to launch Neutrolin for the prevention of CRBIs and maintenance of catheter patency initially in hemodialysis patients in the U.S. within six months after FDA approval. The sales model will primarily be one of achieving formulary listing with hospitals and inclusion as policy and procedure with key customers (for example, Fresenius and Davita, as dialysis providers, cover 70% of dialysis patients). Key account managers will be required as well as medical liaison specialists. It is anticipated that the costs of Neutrolin will be added to the dialysis "bundle" of reimbursable medical costs. In the interim, for those centers not participating in the bundle, we expect that Neutrolin will be billable on the basis of a separate billing "J" code. Clear demonstration of cost-effectiveness will be important for the Centers for Medicare & Medicaid Services, or CMS, private payers and users of Neutrolin. We also anticipate that reimbursement would be available for Neutrolin in other catheter indications in intensive care, oncology and total parenteral nutrition through traditional channels, either diagnosis-related group, or DRG, or outpatient J-coding. We are completing in-depth health economic studies to support these efforts in dialysis, the ICU and oncology.

We are aiming to develop Neutrolin for indications for prevention of catheter-related blood stream infections associated with any chronic central venous catheter and peripherally inserted central catheter use, such as cancer chemotherapy, intensive care and total parenteral nutrition. 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, or IV, nutrition was also approved. In September 2014, the TUV-SUD and The Medicinal Evaluation Board of the Netherlands (MEB) granted a label expansion for Neutrolin for these same expanded indications for the E.U.

Competitive Landscape

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

- 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.

Antibiotic or antimicrobial coated catheters have been launched by some device companies as short term prevention of catheter infection. 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.

Currently, 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 CRMD003, pursuant to a supply agreement dated December 7, 2009 (the "Navinta Agreement"). The Navinta Agreement expires March 31, 2015, but we are negotiating for a new agreement with Navinta. If unsuccessful, 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. 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;
- preliminary 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
- 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.

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 if new circumstances arise. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

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. Studies must also be conducted in compliance with good clinical practice requirements, and informed consent must be obtained from all study subjects.

The clinical trial process for a new compound can take 10 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, who must review and approve all research involving human 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 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 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 Good Manufacturing Practices, or cGMP, requirements.

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.

Each NDA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will “file” the NDA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. The FDA has established performance goals for the review of New Drug Applications - six months for priority applications and 10 months for standard applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an “action letter” that describes additional work that must be done before the application can be approved. The FDA’s review of an application may involve review and recommendations by an independent FDA advisory committee. 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 risk management plan, or otherwise limit the scope of any approval.

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 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 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.

Overall research, development, and approval times depend on a number of factors, including the period of review at 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.

Drugs for Serious or Life-Threatening Illnesses

The Federal Food, Drug, and Cosmetic Act, as amended, and FDA regulations provide certain mechanisms for the accelerated "Fast Track" approval of products intended to treat serious or life-threatening illnesses which have been studied for safety and effectiveness and which demonstrate the potential to address unmet medical needs. The procedures permit early consultation and commitment from the FDA regarding the preclinical and clinical studies necessary to gain marketing approval. Provisions of this regulatory framework also permit, in certain cases, NDAs to be approved on the basis of valid surrogate markets of product effectiveness, thus accelerating the normal approval process. Where the FDA approves a product on the basis of a surrogate market, it requires the sponsor to perform post-approval, or phase 4, studies as a condition of approval, and may withdraw approval if post-approval studies do not confirm the intended clinical benefit or safety of the product. Special rules would also apply to the submission to the FDA of advertising and promotional materials prior to use.

Other United States Regulatory Requirements

In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Heath Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provision of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws.

Moreover, we are now, and may become subject to, additional federal, state, and local laws, regulations, and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation, and disposal of human tissue, waste, and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

Reimbursement and Pricing Controls

In many of the markets where we or our collaborative partners have targeted or will target Neutrolin for sale, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms. Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. 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 these 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 are increasing. We may not be able to obtain 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. During the year ended December 31, 2014, a certain milestone was achieved resulting in the release of 35,886 shares held in escrow. The number of shares held in escrow as of December 31, 2014 is 109,657 shares of common stock. The maximum aggregate amount of cash payments upon achievement of milestones is $3,000,000. 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 12 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.

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 serves 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 sets 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 will become payable to Dr. Polaschegg if he develops new intellectual property that is applied to the Polaschegg Technology. As of December 31, 2014, we recorded an aggregate of approximately $270,000 in licensing and minimum royalty payments under the Polaschegg License Agreement.

We may terminate the Polaschegg License Agreement with respect to the gel lock invention or taurolidine treatments (individually or together) upon 60 days notice. Dr. Polaschegg has a 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.

We believe that the patents and patent applications we have licensed pursuant to the NDP License Agreement and the Polaschegg 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.

Employees

As of March 6, 2015, we had five 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 limited operating history and a history of operating losses, and expect to incur additional operating losses in 2015.

We were established in July 2006 and have only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. 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 a net loss of approximately $20.5 million for the year ended December 31, 2014. As of December 31, 2014, we had an accumulated deficit of approximately $76.2 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. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Neutrolin was launched in December 2013 and is currently distributed in Germany and Saudi Arabia. We have not generated any significant commercial revenue and do not expect to generate substantial revenues from Neutrolin until late 2015 at the earliest, 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; successful completion of the development of our other product candidates; 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 are not currently profitable and may never become profitable.

We have a history of losses, and we may never achieve or maintain profitability. Until we successfully commercialize Neutrolin or other product candidates and generate substantial earnings from those products, we expect to incur losses and may never become profitable. We also expect to continue to incur significant operating and capital expenditures as we pursue the U.S. development of Neutrolin and anticipate that our expenses will increase substantially in the foreseeable future as we continue to undertake development and commercialization of Neutrolin and our other product candidates, undertake clinical trials of our product candidates, seek regulatory approvals for product candidates, implement additional internal systems and infrastructure, and hire additional personnel.

We also expect to experience negative cash flow as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability would negatively impact the value of our securities.

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 Germany, Austria, The Netherlands and the Kingdom of Saudi Arabia, 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. and for any other product candidates, we cannot sell those products 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, 2014, without giving effect to the receipt of approximately $2 million from the exercises of warrants and stock options in January through March 9, 2015, will be sufficient to enable us to fund our projected operating requirements into the second quarter of 2015. However, we may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our research and development efforts more rapidly than we presently anticipate. 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, increase our business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S.

On March 3, 2015, we entered into a backstop agreement with an existing institutional investor, Manchester Securities Corp., an affiliate of Elliott Associates, L.P., pursuant to which Manchester has agreed to lend us, at our request, up to $4,500,000 less the dollar amount of gross proceeds received by us upon the exercise of warrants to purchase common stock issued in connection with our initial public offering on or before April 30, 2015, provided that the loan may not exceed $3,000,000. We may access this financing until April 30, 2015. To access the loan, we must meet customary conditions.

We may seek to 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 independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern and may do so again in the future.

Based on our cash resources at December 31, 2014, we believe that existing cash will be sufficient to enable us to fund our projected operating requirements into the third quarter of 2015, after giving effect to the receipt of approximately $2 million from the exercises of warrants and stock options through March 9, 2015 and the $2.5 million of availability under the Backstop Agreement, dated March 3, 2015, with Manchester Securities Corp. As a result, our independent registered public accounting firm in their report to accompany our audited financial statements for the year ended December 31, 2014, expressed substantial doubt as to our ability to continue as a going concern. A “going concern” opinion could impair our ability to finance our operations through the sale of debt or equity securities or through bank financing. Our ability to continue as a going concern will depend, on our ability to obtain additional financing. Thereafter, our ability to generate positive cash flow from operations will depend on our ability to successfully commercialize Neutrolin, which is uncertain. Additional capital may not be available on reasonable terms, or at all. If adequate financing is not available, we would be required to terminate or significantly curtail our operations, or enter into arrangements with collaborative partners or others that may require us to relinquish rights to certain aspects of our technologies, or potential markets that we would not otherwise relinquish. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operation. These and other factors raise substantial doubt about our ability to continue as a going concern.

Our continued operations will depend on whether we are able to generate substantial revenue from the sale of Neutrolin and on our ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products, until it achieves profitability, if ever. However, we can provide no assurances that such financing or strategic relationships will be available 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 foreign markets, increase our business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S.

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 we be unable to continue as a going concern.

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.

As announced on March 4, 2015, the Board has commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. No timetable has been set for completion of this evaluation process, and there can be no assurance that any transaction will result. The Board has engaged investment bank Evercore Group L.L.C. to provide financial advice and assist the Board with its evaluation process. 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. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

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 lead product has only recently been approved in Europe and is still in development in the U. S.

We are a pharmaceutical and medical device company with one commercially available product and another product candidate in various stages of development. In late 2011, we changed our strategy to primarily focus on the commercialization of Neutrolin in Europe through the CE Marking process and had elected to delay our other product candidates' development until we had obtained CE Marking approval in Europe for Neutrolin. Our product candidates are currently at the following stages:

- CRMD003 (Neutrolin) - received CE Mark approval in Europe on July 5, 2013, with first launch in Germany late in the fourth quarter of 2013;
- CRMD003 (Neutrolin) – IND filed with the FDA for a planned Phase 3 trial was accepted in October 2014 and we are seeking one or more strategic partners or other sources of capital to undertake the planned Phase 3 trial and to complete the development of Neutrolin in the U.S.; and
- CRMD004 - currently in the pre-clinical phase.

Our product 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 an agreement with human4farma to market and sell Neutrolin in Germany, which launched in Germany in the fourth quarter of 2013. We also have entered into agreements with Arabian Trade House to market and sell Neutrolin in Saudi Arabia, and with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin in South Korea upon receipt of regulatory approval in that country. We also have independent sales representatives in Austria and The Netherlands. 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. As an example, in late 2011, we terminated development of CRMD001 due to disappointing data from our Phase II study. 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. Although we have received approval from the FDA to proceed with a planned Phase 3 trial for Neutrolin, we do not have immediate plans to initiate that trial and are seeking one or more strategic partners or other sources of capital to start that trial. However, we might not obtain any commercial partner or financing and may never start the Phase 3 trial.

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 our products will depend on obtaining coverage and reimbursement for use of these products 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. Without the financial support of these government or private third-party payors, the market for our products will be limited. These third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. Recent proposals to change the health care system in the United States have included measures that would limit or eliminate payments for medical products and services or subject the pricing of medical treatment products to government control. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors may not reimburse sales of our products or enable our collaborators to sell them at profitable prices. The failure to obtain or maintain reimbursement coverage for any of our products could materially harm our operations.

Physicians and patients may not accept and use our products.

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

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product;
- cost-effectiveness of our product relative to competing products;
- availability of reimbursement for our product from government or other healthcare payors; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

Risks Related to Our Business and Industry

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

We compete with established pharmaceutical and medical device companies that are pursuing other forms of 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, Randy Milby, a director and our Chief Executive Officer, Harry O'Grady, our Chief Financial Officer, and Dr. Antony Pfaffle, a director and Chief Scientific Officer. We have an employment agreement with Mr. Milby but this agreement cannot ensure our retention of him. Furthermore, our future success will also depend in part on our ability to identify, hire, and retain 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. Additionally, our license agreement with Dr. Hans-Dietrich Polaschegg (referred to herein as the Polaschegg License Agreement) provides for a right of termination for, among other things, our failure to make a product with respect to either of the licensed technologies available to the market within eight years after (i) the effective date of the Polaschegg License Agreement, which was January 20, 2008, or (ii) the priority date of any new patent, whichever is later. Our intellectual property licensed under the Polaschegg License Agreement serves as a basis for CRMD004, the gel formation of Neutrolin. 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);
- European Patent EP 1 442 753 (expiring February 2023) (the "Polaschegg Patent") - use of a thixotropic gel as a catheter locking composition, and method of locking a catheter (for CRMD004); 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 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 recently initiated court proceedings in Germany for patent infringement and unfair use of our proprietary information related to Neutrolin (as described below). We also recently 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, or Geistlich, brought an action against the European Sodemann Patent covering our Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to us pursuant to the License and Assignment Agreement between us and ND Partners LLC. The action that was brought against the counterpart of the Sodemann Patent in Germany at the Board of the European Patent Office opposition division was for 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 Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. We filed a response to the appeal of Geistlich on March 25, 2009 where we requested a dismissal of the appeal and to maintain the patent as granted. As of March 27, 2014, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, we became aware that the Board of Appeals of the European Patent Office issued, on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the counterpart of the Sodemann Patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the counterpart of the Sodemann Patent claims. We received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. In a letter dated September 30, 2013, we were notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils 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 provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division has granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. 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 becomes final if no further appeal is lodged by Geistlich by January 15, 2015. As of the date of this report, we have not received a communication from the European Patent Office that Geistlich has filed such an appeal.

On September 9, 2014, we filed in the Mannheim, Germany District Court a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of our European Patent EP 1 814 562 B1, which was granted by the European Patent Office on January 8, 2014 (the “Prosl European Patent”). The Prosl European Patent covers a low 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 we are seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. An oral hearing in this action was scheduled for and held on January 30, 2015. The date for rendering judgment is scheduled for March 27, 2015. This judgment is subject to appeal. Separately, TauroPharm has filed an opposition with the European Patent Office 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 ND Partners' utility model DE 20 2005 022 124 U1 which is basically identical to the Prosl European Patent in its main aspects and claims. The Mannheim court separated the two proceedings so that the patent and the utility model proceeding are now tried separately and independently from each other due to the slightly differing requirements for both IP rights. An oral hearing with regard to the utility model has been scheduled for March 27, 2015. TauroPharm has filed a cancellation action against the utility model before the German Patent and Trademark Office based on the same arguments as the opposition against the Prosl European Patent. We cannot predict what other defenses the Defendants may raise, or the ultimate outcome of this matter.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of our proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using our proprietary information relating to the composition and manufacture of our product Neutrolin®, which is approved for sale in Germany, in its manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100TM and TauroLock-HEP500TM. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine as well as 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. A hearing in this matter has been scheduled in the District Court of Cologne for June 18, 2015.

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 or our product candidates. Specifically, for Neutrolin, we have entered into an agreement with human4farma to market and sell Neutrolin in Germany and a distributor agreement with 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 independent sales representatives marketing and selling in Austria and The Netherlands. 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 have no experience as a company in marketing medical devices or drug products. If we are unable to establish our own marketing and sales capabilities, or enter into agreements with third parties, to market and sell our products after they are approved, we may not be able to generate product revenues.

We do not have an internal sales organization for the marketing, sales and distribution of any drug products. In order to commercialize any products, we must develop these capabilities on our own or make arrangements with third parties for the marketing, sales and distribution of our products. 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. As a result, we may seek one or more third party organizations to handle some or all of the sales and marketing of Neutrolin, which we have done with independent companies in Germany and in Saudi Arabia and South Korea (upon receipt of approval to market in South Korea) and with independent sales representatives in Austria and The Netherlands. However, we may not be able to enter into or maintain arrangements with third parties to sell Neutrolin on favorable terms or at all. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize Neutrolin or any other product candidates that we develop, which would negatively impact our ability to generate product revenues. Further, whether we commercialize products on our own or rely on a third party to do so, our ability to generate revenue will be dependent on the effectiveness of the sales force. In addition, to the extent we rely on third parties to commercialize our approved products, we will likely receive less revenues than if we commercialized these products ourselves.

We have entered into an agreement with independent companies to market Neutrolin in Germany and in Saudi Arabia and, upon regulatory approval, South Korea. We also have independent sales representatives in Austria and The Netherlands. Consequently, we will be dependent on these firms and individuals for the success of sales in these countries and any continued success of the marketing and sales of Neutrolin in these countries. 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 replacement organization for these or any other organizations or individuals with which we might contract 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

We have identified a material weakness in our internal control over financial reporting, and our internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur.

We have identified material weaknesses in our internal control over financial reporting related to our limited finance staff and the resulting ineffective management review over financial reporting, coupled with increasingly complex accounting associated with our financing activities as well as the European commercialization and start up related activities. We have taken initial measures to remediate these weaknesses by increasing internal review processes, in addition to the previously established accounting oversight committee, which is comprised of members of our senior management and our third party GAAP advisor. The hiring of our full-time Chief Financial Officer in July 2014 and our increased use of external advisors were key steps in bolstering our financial infrastructure. We continue to build on our infrastructure to address these weaknesses. However, we cannot be assured that these weaknesses will be fully remediated or that other material weaknesses will not be discovered.

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 March 11, 2015, the high and low sales prices for our common stock were $9.48 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 February 28, 2015, 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;
- Series B Preferred Stock convertible into 454,546 shares of common stock;
- 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 (decreased to 500,000 shares as of January 31, 2015);
- 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;
- warrants for 3,646,380 shares of our common stock issued in connection with our IPO with an exercise price of $3.4375 per share that expire on April 30, 2015;
- Warrants for 390,720 shares of our common stock held by Manchester Securities Corp. issued in connection with our IPO with an exercise price of $3.4375 that expire on March 24, 2016.
- a warrant to purchase 774 shares of our common stock issued to the underwriters of our IPO with an exercise price of $3.4375 per share that expire on April 30, 2015;
- warrants for 503,034 shares of our common stock issued in our 2010 initial public offering to holders of bridge warrants issued in our 2009 private placement, which warrants have an exercise price of $3.4375 per share and expire on March 31, 2015;
- options to purchase an aggregate of 1,035,000 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 $0.73 per share;
- options to purchase an aggregate of 2,599,500 shares of our common stock issued to our officers, directors and non-employee consultants under our 2013 Stock Plan, with a weighted average exercise price of $1.44 per share;
- warrants issued to investors in our 2012 private placement to purchase an aggregate of 1,712,500 shares of our common stock with an exercise price of $0.40 per share, of which 1,687,500 expire on September 20, 2017 and 25,000 expire on November 13, 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 (decreased to 750,000 shares as of January 31, 2015);
- warrants for 875,000 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 1,475,000 shares of common stock;
- Series D Preferred Stock convertible 1,479,240 shares of common stock;
- Series E Preferred Stock convertible 2,021,358 shares of common stock; and
- warrants for 1,036,000 shares of common stock issued in March 2014 with an exercise price of $2.50 per shares that expire on September 9, 2019.

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

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

We anticipate that we will incur operating losses for the foreseeable future. Additionally, we believe 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 2006 Stock Plan, our Board of Directors is authorized to award up to a total of 2,300,000 shares of common stock or options to purchase shares of common stock to our officers, directors, employees and non-employee consultants. As of February 28, 2015, options to purchase 1,035,000 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of $0.73 per share, and options to purchase 2,599,500 shares of common stock issued under our 2013 Stock Plan at a weighted average exercise price of $1.44 per share were outstanding. In addition, at February 28, 2015, there were outstanding warrants to purchase an aggregate of 10,167,446 shares of our common stock at prices ranging from $0.40 to $3.4375, and shares of our outstanding Series B, C-2, C-3, D and E preferred stock convertible into an aggregate of 6,930,144 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 3,500 square feet of office space in Bridgewater, New Jersey. We lease this office space pursuant to a lease agreement dated March 18, 2010 with UA Bridgewater Holdings, LLC. The lease agreement has an initial term of 60 months, commencing on April 1, 2010 and expiring on March 31, 2015, and lease payments began on July 1, 2010. We have been granted the option to extend the lease term for one additional period of three years, commencing the day following the then-current expiration date of the term, March 31, 2015, provided we deliver notice to the landlord no later than nine months prior to March 31, 2015. We did not elect to extend the lease term. The total 60 month lease obligation is approximately $389,000. Our total remaining lease obligation is approximately $21,000 as of December 31, 2014.

We have entered into 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. We occupied the space beginning on March 1, 2015 for which month we are not obligated to pay rent, but must pay occupancy costs. The total lease obligation is approximately $180,000.

Our subsidiary leases its offices in Fulda, Germany pursuant to a lease agreement with ITZ GmbH. 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 and the remaining lease obligation was approximately €10,000 as of December 31, 2014.

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, or Geistlich, brought an action against the European Sodemann Patent covering our Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to us pursuant to the License and Assignment Agreement between us and ND Partners LLC. The action that was brought against the counterpart of the Sodemann Patent in Germany at the Board of the European Patent Office opposition division was for 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 Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. We filed a response to the appeal of Geistlich on March 25, 2009 where we requested a dismissal of the appeal and to maintain the patent as granted. As of March 27, 2014, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, we became aware that the Board of Appeals of the European Patent Office issued, on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the counterpart of the Sodemann Patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the counterpart of the Sodemann Patent claims. We received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. In a letter dated September 30, 2013, we were notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils 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 provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division has granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. 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 becomes final if no further appeal is lodged by Geistlich by January 15, 2015. As of the date of this report, we have not received a communication from the European Patent Office that Geistlich has filed such an appeal.

On September 9, 2014, we filed in the Mannheim, Germany District Court a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of our European Patent EP 1 814 562 B1, which was granted by the European Patent Office on January 8, 2014 (the “Prosl European Patent”). The Prosl European Patent covers a low 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 we are seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. An oral hearing in this action was scheduled for and held on January 30, 2015. The date for rendering judgment is scheduled for March 27, 2015. This judgment is subject to appeal. Separately, TauroPharm has filed an opposition with the European Patent Office 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 ND Partners’ utility model DE 20 2005 022 124 U1 which is basically identical to the Prosl European Patent in its main aspects and claims. The Mannheim court separated the two proceedings so that the patent and the utility model proceeding are now tried separately and independently from each other due to the slightly differing requirements for both IP rights. An oral hearing with regard to the utility model has been scheduled for March 27, 2015. TauroPharm has filed a cancellation action against the utility model before the German Patent and Trademark Office based on the same arguments as the opposition against the Prosl Patent. We cannot predict what other defenses the Defendants may raise, or the ultimate outcome of this matter.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of our proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using our proprietary information relating to the composition and manufacture of our product Neutrolin®, which is approved for sale in Germany, in its manufacture and sale of TauroPharm’s products TauroLockTM, TauroLock-HEP100TM and TauroLock-HEP500TM. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine as well as 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. A hearing in this matter has been scheduled in the District Court of Cologne for June 18, 2015.

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:

Fiscal Year 2014	High	Low
First Quarter	$ 3.20	$ 1.24
Second Quarter	$ 2.56	$ 1.25
Third Quarter	$ 2.12	$ 1.69
Fourth Quarter	$ 1.97	$ 1.29

Fiscal Year 2013	High	Low
First Quarter	$ 1.10	$ 0.71
Second Quarter	$ 1.00	$ 0.48
Third Quarter	$ 1.29	$ 0.75
Fourth Quarter	$ 1.27	$ 0.66

Based upon information furnished by our transfer agent, at February 27, 2015, we had approximately 120 holders of record of our common stock.

Dividend Policy

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

Equity Compensation Plan Information

The following table provides information as of December 31, 2014 about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing equity compensation plans (including individual arrangements):

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by security holders[1]	3,664,500	$ 1.25	2,215,500
Equity compensation plans not approved by security holders[2]	130,607	1.58	--
Total	3,795,107	$ 1.26	2,215,500

(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 2,406 units consisting of two shares of common stock issuable pursuant to a warrant issued to the underwriters of our IPO in 2010 (with an exercise price of $7.80 per unit); 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 Financial Data

Not applicable.

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

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

Overview

We are a commercial pharmaceutical and medical device company. We seek to in-license, develop and commercialize therapeutic products for the treatment of cardiorenal and infectious diseases, including the dialysis and non-dialysis areas. As of the date of this report, we have in-licensed all of the product candidates in our pipeline.

We have the worldwide rights to develop and commercialize our product candidates, CRMD003 (Neutrolin) and CRMD004, which we believe address potentially large market opportunities in the instances in which a central venous catheter is used, such as hemodialysis, intensive care units, oncology and total parenteral nutrition patients.

Our primary product is Neutrolin, a novel formulation of taurolidine, citrate and heparin with1000 u/ml that provides a combination preventative solution, decreases the triple threat of infection, thrombosis, and biofilm to keep catheter's operating safely and efficiently by optimizing catheter blood flow while minimizing infections and biofilm formation.. Neutrolin has shown antimicrobial activity against many of the pathogens that are known to pose a serious threat to public health by causing blood-stream infections in ICU, oncology and hemodialysis patients. CorMedix intends to expand on the previously collected clinical data by conducting clinical trials with Neutrolin® Catheter Lock Solution in oncology, hemodialysis and intensive care unit patients, where catheter-related blood stream infections and clotting can be life-threatening.

On July 5, 2013, we received CE Mark approval for Neutrolin. As a result, in December 2013, we began the commercial launch of 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. . 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, or IV, nutrition was also approved. In September 2014, the TUV-SUD and The Medicinal Evaluation Board of the Netherlands (MEB) granted a label expansion for Neutrolin for these same expanded indications for the EU.

To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia and The Netherlands for such treatment.

We are seeking to develop Neutrolin in the U.S. Based on our discussions with the FDA, we expect to conduct at least one Phase 3 clinical trial in hemodialysis catheters and one Phase 3 clinical trial in oncology/total parenteral nutrition. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

Financial Operations Overview

Revenue

We have not generated substantial revenue since our inception. As of December 31, 2014, we have funded our operations primarily through debt and equity financings and the IPO, our receipt of approximately $490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program, approximately $775,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and approximately $35,000 from the State of New York's Research and Development Tax Credit 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.

The following table summarizes the percentages of our R&D payments related to our two most advanced product candidates and other projects. 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 Ended December 31,	
	2014	2013
CRMD003	98%	97%
CRMD004	2%	3%

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. During the third quarter of 2011, we received a notice from the U.S. Food and Drug Administration, or FDA, that our product candidate, Neutrolin, had been assigned to the Center for Drug Evaluation and Research, or CDER. As a result of this, and given our limited resources, we decided to change our business strategy and focus the majority of our resources on the research and development of Neutrolin rather than CRMD004 and to seek regulatory and commercialization approval for Neutrolin in Europe through a CE Mark application rather than pursue FDA approval at that time.

On July 5, 2013, we received CE Mark approval for Neutrolin. As a result, in 2013, we began the commercial launch of 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. 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, or IV, nutrition was also approved. In September 2014, the TUV-SUD and The Medicinal Evaluation Board of the Netherlands (MEB) granted a label expansion for Neutrolin for these same expanded indications for the EU.

To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia and The Netherlands for such treatment.

We are seeking to develop Neutrolin in the U.S. Based on our discussions with the FDA, we expect to conduct at least one Phase 3 clinical trial in hemodialysis catheters and one Phase 3 clinical trial in oncology/total parenteral nutrition. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

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. We expect that our SG&A expenses will increase due to marketing of our Neutrolin product in Europe.

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. In 2013, the loss on the issuance of convertible notes and warrants represents the difference on the issuance date between the combined fair value of the convertible notes 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

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 are recorded at fair value on a recurring basis under generally accepted accounting principles. 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, 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) consists of foreign exchange transaction gains and losses on intercompany loans that are in place between the parent company based in New Jersey and its German subsidiary. Effective October 1, 2014, we concluded 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. Foreign exchange gain (loss) is reported in the consolidated statement of operations as a separate line item within other income (expense).

Interest Income

Interest income consists of interest earned on our cash and cash equivalents.

Interest Expense

Interest expense for 2014 consists of interest incurred on financing of expenses.

Results of Operations

Comparison of the Years Ended December 31, 2014 and December 31, 2013

Revenue. Revenue was approximately $189,000 for the year ended December 31, 2014 compared to approximately $2,000 in the prior year. The majority of the revenue is from sales of Neutrolin following the Europe commercial launch in December 2013 followed by Middle East launches during 2014. The majority of the net sales in 2014 occurred in German and Saudi Arabian markets. In addition, we realized $4,000 associated with the amortization of deferred revenue from a non-refundable payment received from a distribution agreement.

Cost of Sales. Cost of sales was approximately $446,000 for the year ended December 31, 2014 compared to approximately $202,000 in the same period last year. Cost of sales for the year ended December 31, 2014 are primarily comprised of non-recurring costs of approximately $140,000 associated with commercial production start-up and enhancing the process as well as on-going stability studies of approximately $80,000 and direct cost of materials of approximately $50,000. The costs associated with on-going stability studies are expected to continue into 2015. During the year ended December 31, 2014, a substantial part of the costs of raw materials and the cost to manufacture the product sold were previously charged to research and development expense because it had been purchased and manufactured prior to the receipt of the CE Mark. In addition, we recorded a charge of $175,000 associated with pre-launch inventory build-up and start-up related manufacturing inefficiencies.

Research and Development Expense. R&D expense was approximately $1,319,000 for the year ended December 31, 2014, an increase of $92,000 from $1,227,000 for the same period last year. The increase was primarily attributable to the costs related to regulatory development of Neutrolin in the U.S. of approximately $680,000, partially offset by the ND Partners LLC license fee of $500,000 incurred in 2013 from the milestone for the Neutrolin European Union CE Mark approval for Neutrolin together with a $77,000 non-cash charge for warrants issued to ND Partners, LLC as a result of the April 2013 amendment to the License and Assignment Agreement.

Selling, General and Administrative Expense. SG&A expense was $7,327,000 for the year ended December 31, 2014, an increase of $3,838,000 from $3,489,000 for the same period last year. The increase was primarily attributable to costs related to commercialization of Neutrolin in the EU of approximately $1,245,000, non-cash stock-based compensation expense of approximately $796,000, increase in legal fees due to ongoing intellectual property litigation of approximately $737,000, increased personnel cost and consulting costs of approximately $484,000, and increase accounting fees of approximately $166,000 and an increase in costs related to business development activities of approximately $109,000.

Loss on Issuance of Preferred Stock, Convertible Notes and Warrants. The loss on the issuance of preferred stock, convertible notes and warrants of approximately $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 approximately $2,054,000, and the combined proceeds received and liabilities settled, net of all issuance-related fees and expenses of approximately $1,964,000. For the year ended December 31, 2013, the loss on the issuance of preferred stock, convertible notes and warrants of approximately $946,000 represents the difference on the issuance date between the combined fair value of the convertible notes and the warrants of $2,231,000, and the proceeds received, net of all issuance-related fees and expenses, of $1,285,000.

Change in Fair Value of Derivative Liabilities. The change in the value of derivative liabilities for the year ended December 31, 2014 of approximately $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 approximately $7,138,000 and approximately $1,711,000, respectively. The change in the fair value of the preferred stock conversion options includes the combined changes in (i) the fair value of the converted and redeemed amounts between December 31, 2013 and the relevant conversion and redemption dates and (ii) the change in fair value of the preferred stock conversion options between December 31, 2013 and September 15, 2014. The change in fair value of the warrants is the difference between the fair value at December 31, 2013 and September 15, 2014. On September 15, 2014, the downround protection of these derivative liabilities was eliminated through an agreement modification resulting in the reclassification of derivative liabilities to equity amounting to approximately $17,955,000 and mark to market adjustments on the derivatives through the modification dates.

For the year ended December 31, 2013, the change in fair value of derivative liabiities of approximately $364,000 consists of an increase in the fair value of warrants between the issuance date and December 31, 2013 of approximately $142,000, reduction in the fair value of convertible notes of approximately $45,000 and increase in the fair value of preferred stock of approximately $267,000. The change in the fair value of the convertible notes and preferred stock include the combined changes in (i) the fair value of the converted and redeemed amounts between the issuance date and the relevant conversion and redemption dates and (ii) the change in fair value of the outstanding convertible notes and preferred stock between the issuance date and December 31, 2013. The change in fair value of the warrants is the difference between the fair value at the issuance date and December 31, 2013.

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 approximately $2,463,000 represents the change in the fair value of the preferred stock hybrid instruments of approximately $2,119,000 and liability classified warrants of approximately $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.

Loss on Extinguishment of Convertible Notes. The loss on extinguishment of convertible notes for the year ended December 31, 2013 of approximately $1,460,000 represents the excess of the fair value of shares issued in connection with the conversions and redemptions over the fair value of the convertible notes that were converted or redeemed for shares.

Foreign Exchange Transaction Gain (Loss). Foreign exchange transaction gain (loss) increased by approximately $151,000 for the year ended December 31, 2014 due to additional funding to the foreign 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 was approximately $2,700 for the year ended December 31, 2014, an increase of approximately $2,000 from approximately $700 for the same period last year. The increase was attributable to having higher average interest-bearing cash balances during the year ended December 31, 2014 as compared to the same period last year.

Interest Expense. Interest expense was approximately $2,000 for the year ended December 31, 2014 as compared to approximately $1,444,000 for the same period last year a decrease of approximately $1,442,000. The interest expense for the year ended December 31, 2013 consisted primarily of a beneficial conversion feature charge of approximately $1,054,000 related to the senior convertible notes and warrants issued in 2012 and 2013, amortization of deferred financing fees of approximately $283,000 and accrued interest of approximately $107,000 related to the senior convertible notes. These convertible notes matured during the year ended December 31, 2013.

Other Comprehensive Loss. Unrealized foreign exchange movements related to long-term intercompany loans and the translation of the foreign affiliate financial statements to U.S. dollars are recorded in other comprehensive income totaling approximately $108,000 gain for the year ended December 31, 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 CE Mark approval for our Neutrolin product in July 2013 and launched our product in the EU in December 2013.

In February 2013, we sold 761,429 shares of our Series A non-voting convertible preferred stock and a warrant to purchase up to 400,000 shares of our common stock for gross proceeds of $533,000.

In May 2013, we sold $1,500,000 of convertible notes and warrants to purchase up to 750,000 shares of our common stock.

In July 2013, we sold 454,546 shares of Series B non-voting convertible preferred stock and a warrant to purchase up to 227,273 shares of our common stock for gross proceeds of $500,000.

In October 2013 we sold 150,000 shares of our Series C-1 and 150,000 shares of our Series C-2 non-voting convertible preferred stock and warrants to purchase up to 1,500,000 shares of our common stock for gross proceeds of $3,000,000. Additionally, we exchanged $400,000 in principal amount of convertible notes issued in September 2012 for 57,400 shares of our Series D non-voting convertible preferred stock and also exchanged $750,000 in principal amount of convertible notes issued in May 2013 for 53,537 shares of our Series E non-voting convertible preferred stock.

All of the Series A and Series C-1 non-voting convertible preferred stock have converted to common stock.

In January 2014, we sold 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.

In March 2014, we sold 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 was approximately $6,321,000 for the year ended December 31, 2014. The net loss of approximately $20,453,000 for the year ended December 31, 2014 was higher than cash used in operating activities by approximately $14,132,000. The difference is attributable primarily to revaluation of derivative liabilities of approximately $8,849,000, non-cash loss on extinguishment of derivative liabilities of approximately $ 2,463,000, non-cash stock-based compensation of approximately $2,168,000, and losses on foreign currency transactions and issuance of preferred stock of approximately $151,000 and $90,000, respectively.

Net Cash Used in Investing Activities

Net cash used in investing activities was approximately $25,000 for the year ended December 31, 2014 as compared to approximately $36,000 for the same period last year a decrease of approximately $11,000 primarily due to the database programming software of the Neutrolin usage monitoring program in Germany.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was approximately $8,358,000 for the year ended December 31, 2014 as compared to approximately $5,204,000 for the same period last year. The increase was attributable to the net proceeds from the sale of common stock of approximately $6,723,000 and Series C-3 preferred stock of approximately $1,319,000, and exercise of stock options of approximately $318,000. In comparison, for the same period last year, we received proceeds from the sale of Series C-1 and Series C-2 preferred stock of approximately $2,927,000; sale of 8% senior convertible notes of approximately $1,373,000; proceeds from the sale of Series A and Series B preferred stock of $1,033,000; proceeds from exercise of warrants of $60,000; offset by repurchase of outstanding warrants of $33,000 and payment of deferred financing costs of $158,000.

Funding Requirements and Ability to Continue as a Going Concern

Our total cash on hand as of December 31, 2014 was approximately $4,340,000, compared to approximately $2,374,000 at December 31, 2013. Because our business to date does not generate positive operating cash flow, we will need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development, as well as to fund operations generally. Our continued operations will depend on whether we are able to generate substantial revenue from the sale of Neutrolin or raise additional funds through various potential sources, such as equity, debt financing, strategic relationships, out-licensing or distribution arrangements of our products.

Through December 31, 2014, all of our financing has been through the issuance of convertible notes in 2012 and 2013, the issuances of preferred stock in 2013 and 2014, the issuance of common stock in 2014, our 2010 IPO, previous debt financings and our receipt of a total of approximately $490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program, a total of approximately $775,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and approximately $35,000 from the State of New York's Research and Development Tax Credit Program, net of application fees. We expect to continue to fund operations from cash on hand and through either capital raising sources as previously described, which may be dilutive to existing stockholders, or through generating revenues from the licensing of our products or strategic alliances. We plan to seek additional debt and/or equity financing, but can provide no assurances that such financing 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 also result in covenants that would restrict our operations. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors including the changes in the focus and direction of our research and development programs, the acquisition and pursuit of development of new product candidates, competitive and technical advances, 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 substantially, we do not anticipate that we will generate significant product sales revenue for 2015. In the absence of such revenue, we would experience continuing operating cash flow losses. We expect to incur increases in our cash used in operations over the next several quarters as we continue to commercialize Neutrolin and seek FDA approval of Neutrolin in the U.S.

Based on our cash resources at December 31, 2014, our expectations on product sales and our current plan of expenditure on continuing development of Neutrolin, we believe that we have sufficient capital to fund our operations into the third quarter of 2015, after giving effect to the receipt of approximately $2 million from the exercises of warrants and stock options through March 9, 2015, and the $2.5 million of availability under the Backstop Agreement with Manchester Securities that we executed in March 2015. However, we will need additional financing thereafter until we can achieve profitability, if ever. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our products, or we could 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 and raise substantial doubt about our ability to continue as a going concern.

Critical Accounting Policies

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"). Under ASC 718, share-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is 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 505. The non-cash charge to operations for non-employee options with vesting is based upon the change in the fair value of the options and amortized to expense over the related vesting period.

For the purpose of valuing options and warrants granted to our directors, officers, employees and consultants, we used the Black-Scholes option pricing model. For the purpose of valuing performance based options granted to non-employees, we use the guidelines in accordance with FASB ASC No. 505-50 ("ASC 505"), "Equity-Based Payments to Non-Employees." If the performance condition is outside of the control of the non-employee, the cost to be recognized is the lowest aggregate fair value prior to the achievement of the performance condition, even if we believe it is probable that the performance condition will be achieved.

Valuations incorporate several variables, including expected term, expected volatility, expected dividend yield and a risk-free interest rate. We estimate the expected term of the options granted based on anticipated exercises in future periods. The expected stock price volatility for our stock options is calculated by examining historical volatilities for publicly traded industry peers, since we have limited trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for our common stock becomes available. 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.

Stock compensation expense is recognized by applying the expected forfeiture rate during the vesting period to the fair value of the award. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, compensation expense may need to be revised. We consider many factors when estimating expected forfeitures for stock awards granted to employees, officers and directors, including types of awards, employee class, and an analysis of our historical forfeitures.

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.

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.

Inventory Valuation

We engage third parties to manufacture and package inventory held for sale, takes title to certain inventory once manufactured, and warehouses 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 the 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.

Embedded Derivative Liabilities and Warrant Liabilities:

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks; however, we had several series of preferred stock and warrants that contain 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). The warrants issued in March 2014, which do not have downround protection, were valued using a Black Scholes option pricing model.

Recently Adopted Accounting Standards

The Financial Accounting Standards Board ("FASB") establishes changes to accounting principles under GAAP in the form of accounting standards updates ("ASUs") to the FASB's Accounting Standards Codification. We consider the applicability and impact of all ASUs. Any ASUs not listed below were assessed and determined to be either not applicable or are expected to have an immaterial impact on our results of operations, financial position or cash flows.

In June 2014, the FASB issued Accounting Standards Update No. 2014-10, *Development Stage Entities (Topic 915) – Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation* (ASU 2014-10). ASU 2014-10 eliminates the concept of a development stage entity in its entirety from current accounting guidance. The new guidance eliminates the requirements for development stage entities to (i) present inception-to-date information in the statement of operations, stockholders’ equity and cash flows, (ii) label the financial statements as those of a development stage entity, (iii) disclose a description of the development stage activities in which the entity is engaged, and (iv) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU 2014-10 is effective prospectively for public entities for annual reporting periods beginning after December 15, 2015, and interim periods within those annual periods, however early adoption is permitted. We evaluated and elected to adopt ASU 2014-10 as permitted, beginning with the quarter ended June 30, 2014 and, accordingly, have not included the inception-to-date disclosures and other previously required disclosures for development stage entities.

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 condition, results of operations and cash flows.

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. Earlier adoption is permitted. The standard may be applied prospectively to all awards granted or modified after the effective date; or retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. We are currently evaluating the impact of adopting this guidance on our consolidated financial condition, results of operations and cash flows.

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

On May 15, 2014, we changed our independent registered public accounting firm from CohnReznick LLP to Friedman LLP for the year ending December 31, 2014. The change was approved by the Audit Committee of the Board of Directors.

CohnReznick's reports on our consolidated financial statements as of December 31, 2012 and 2013, and for the two years then ended and for the period from July 28, 2006 (inception) to December 31, 2013 did not contain an adverse opinion or a disclaimer of opinion , and were not qualified or modified as to uncertainty, audit scope or accounting principles, although the report for the year ended December 31, 2012 contained an explanatory paragraph relating to our ability to continue as a going concern.

During the two years ended December 31, 2013 and through the date of their dismissal, there were no: (a) disagreements with CohnReznick on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to CohnReznick's satisfaction, would have caused CohnReznick to make reference to the subject matter thereof in connection with its reports on our financial statements as of December 31, 2012 and 2013, and for the two years then ended and for the period from July 28, 2006 (inception) to December 31, 2013; or (b) "reportable events", as defined under Item 304(a)(1)(v) of Regulation S-K. However, CohnReznick identified material weaknesses in our financial reporting process 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.

CohnReznick has indicated to us that it agrees with the foregoing statements contained in the paragraphs above as they relate to CohnReznick and has furnished a letter dated May 16, 2014 to the United States Securities and Exchange Commission to this effect. A copy of the letter from CohnReznick was Exhibit 16.1 to our Current Report on Form 8-K filed on May 16, 2014.

During the two years ended December 31, 2013 and through May 16, 2014, neither we nor anyone acting on our behalf consulted with Friedman LLP regarding any of the matters or events set forth in Item 304(a)(2)(i) or (ii) of Regulation S-K.

Item 9A. Controls and Procedures

Under the supervision of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of December 31, 2014. Although the actions outlined below have allowed us to make significant progress towards our goal of remediating our material weakness in internal control over financial reporting discussed above, we believe that the material weakness was not fully remediated as of December 31, 2014. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of December 31, 2014 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 SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosures.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. As of the end of the period covered by this report, our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. Based on their evaluation of our disclosure controls and procedures, and as a result of the material weakness described above, our management, including our principal executive officer and principal financial officer, have concluded that our disclosure controls and procedures were not effective as of December 31, 2014 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (b) accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow for timely decisions regarding required disclosure.

Management's Annual Report on Internal Controls Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended). Our system of internal control over financial reporting is 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.

Because of the inherent limitations, a system of 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.

Our management, including our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (COSO 2013). Based on its assessment, our management concluded that our internal control over financial reporting was not effective as of December 31, 2014.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this annual report.

Changes in Internal Control Over Financial Reporting

Our management previously determined that as of December 31, 2013, we had a material weakness in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) 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. We have concluded that this material weakness in our internal control over financial reporting was due to the fact that we did not yet have the appropriate resources with the appropriate level of experience and technical expertise to oversee our closing and financial reporting processes.

In order to remediate this material weakness, we have taken the following actions since December 31, 2013:

- We have hired Harry O'Grady as our full-time Chief Financial Officer. Mr. O'Grady is a certified public accountant who has held various senior financial positions in several pharmaceutical companies including Dey/Mylan Specialty, L.P. Catalent Pharma Solutions and Bayer Healthcare Pharmaceuticals, Inc.

- We are continuing to formalize and implement accounting policies and internal controls and the related documentation and we have strengthened our financial statements review procedures and the supervisory reviews by our management that are performed during the financial close process and which support the accurate and timely preparation of consolidated financial statements that are fairly presented in accordance with U.S. generally acceptable accounting principles.

- We have strengthened our relationship with our external accounting advisors knowledgeable in technical accounting matters to assist us in the ongoing preparation of financial reports and the appropriate accounting for complex transactions.

In addition, we continue to utilize the services of an accounting firm in Germany to assist us with the accounting for our German subsidiary and the services of an external tax advisor to assist us with the preparation of the tax provision and the evaluation of the tax implications of our foreign operations and various complex accounting transactions.

Although the actions outlined above have allowed us to make significant progress towards our goal of remediating our material weakness in internal control over financial reporting discussed above, we believe that the material weakness was not fully remediated as of December 31, 2014.

Other than as described above, there were no changes in our internal control over financial reporting during the quarter ended December 31, 2014, 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.

Item 9B. Other Information

We intend to hold our 2015 Annual Meeting of Stockholders on June 4, 2015.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock to file with the Securities and Exchange Commission ("SEC") initial reports of ownership and reports of changes in the ownership of our common stock and other equity securities. Such persons are required to furnish us copies of all Section 16(a) filings. Based solely upon a review of the copies of the forms furnished to us, we believe that our officers, directors and holders of more than 10% of our common stock complied with all applicable filing requirements during the fiscal year ended December 31, 2014, with the exception of a Form 4 for Cora Tellez to report the purchase of 2,100 shares of common stock on October 17, 2014, which report was due on October 21, 2014 and was filed on October 31, 2014, and a Form 4 for Steven Lefkowitz to report the purchase of warrants to purchase up to 7,900 shares of common stock on December 10, 2014, which report was due on December 12, 2014 and was filed on December 18, 2014.

Directors and Executive Officers

The following table sets forth the name, age and position of each of our directors and executive officers as of February 28, 2015.

Name	Age	Position
Randy Milby	61	Chief Executive Officer and Director
Harry O'Grady	53	Chief Financial Officer
Cora Tellez	65	Chairman of the Board
Matthew Duffy	52	Director
Michael George	66	Director
Steven W. Lefkowitz	59	Director
Taunia Markvicka	47	Director
Antony E. Pfaffle, M.D.	51	Chief Scientific Officer and Director

The business experience for the past five years (and, in some instances, for prior years) of each of our executive officers and directors, and the experiences and skills that led to the conclusion that our directors should serve as directors, are set forth below.

Randy Milby joined CorMedix in May 2012 to serve as our Chief Operating Officer pursuant to a consulting agreement with MW Bridges LLC, a Life Science consulting firm, of which Mr. Milby is Managing Partner. On January 1, 2013, Mr. Milby was appointed as our Chief Executive Officer. Mr. Milby had previously served as Global Business Director, Applied Biosciences, and other management positions at DuPont Company from 1999 through 2010. Since September 2010, Mr. Milby was co-founder and a managing director of WaterStone Bridge, LLC, a healthcare consulting services firm. From 1998 through 1999, Mr. Milby was also a healthcare analyst at Goldman, Sachs & Company. Mr. Milby received his Pharmacy degree at the University of Kansas and received his Masters of Business Administration from Washington University in St. Louis. Among other experience, qualifications, attributes and skills, Mr. Milby's pharmacy training and healthcare and life science industry expertise led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Harry O'Grady joined CorMedix in July 2014 as our Chief Financial Officer. Prior to that, Mr. O'Grady had been the Vice President, Finance, CFO, for Dey/Mylan Specialty, L.P. since 2010. Mr. O'Grady was a Vice President, Finance – Sterile Business Unit, at Catalent Pharma Solutions, Inc. from 2008 through 2010. From 2006 through 2008, he was the Vice President, Business Planning and Administration, at Bayer Healthcare Pharmaceuticals, Inc. He was also the Vice President, Finance and Controlling at Bayer from 2004 through 2006, and the Controller at Bayer from 2001 to 2003. From 1995 through 2003, Mr. O'Grady held several other positions with Bayer. Mr. O'Grady, a certified public accountant, received his Bachelor of Business Administration in Accounting from Pace University, and his Masters of Business Administration from Lehigh University.

Cora M. Tellez joined the Board of CorMedix in April 2014. She is currently President and CEO of Sterling HSA, a company she founded in 2004. Mr. Tellez has 25 years of management experience in health care finance and delivery. Prior to founding Sterling HSA, Ms. Tellez was President of the Health Plans division of Health Net, Inc., an insurance provider that operated in seven states and achieved revenue of $8 billion from health plans. She has also served as President of Prudential's western health operations, CEO of Blue Shield of California, Bay Region and Regional Manager for Kaiser Permanente of Hawaii. She serves on the boards of HMS Holdings, Inc. (NASDAQ:HMSY) and Practice Fusion, a venture backed company. She previously served as a former board director of Crescent Healthcare, Bank of Hawaii, Glendale Federal Bank, Cal Fed Bank, Catellus Development Company and First Consulting Group. Among other experience, qualifications, attributes and skills, Ms. Tellez's business experience in the healthcare industry, and her service on as a directors of a public company, led to the conclusion of our Board that she should serve as a director of our company in light of our business and structure.

Matthew P. Duffy has been a director of CorMedix since November 2011. Mr. Duffy is currently Managing Director at LifeSci Advisors and Capital, LLC, a boutique Investor Relations and Investment Bank in New York. He has also been Managing Partner and founder of Black Diamond Research, LLC, since July 2001. Further, he is a founder of Algorithm Sciences, LLC and Identic Pharmaceuticals, LLC. In addition, he is a managing member of NSIP LLC, and a member of the Executive Committee of Ellington Asset Management, LLC. He led commercial operations at Lev Pharmaceuticals, from November 2007 to October 2008. From 1995 to 2001, Mr. Duffy led the marketing group at MedImmune, Inc., and prior to that a series of positions in sales and Marketing at Pfizer Inc. Mr. Duffy holds the series 7, 63 and 65 securities licenses and received his undergraduate degree from Duke University. Among other experience, qualifications, attributes and skills, Mr. Duffy's commercial and marketing expertise with development stage biotechnology companies led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Michael George joined our Board in February 2014. Mr. George is currently the Chief Executive Officer of Michael George & Associates, a health care consulting firm. Prior to forming Michael George & Associates, Mr. George served as a restructuring and turnaround executive for aaiPharma Inc., Derm Tech International and Urocor, Inc. Prior to that, he served as President/North America of Elan Pharmaceuticals. He has over 25 years of sales and marketing experience, including senior management positions, with three large pharmaceutical companies, DuPont Merck Pharmaceutical Company, Bristol Myers Pharmaceutical Company and Sandoz Pharmaceuticals, Inc. (now Novartis). Mr. George serves on the board of ClearPath Diagnostics, Inc., a private company, and Coastal Horizons, Inc., a non-profit corporation. He holds a B.S. in Business Administration from Central Missouri State University (now the University of Central Missouri) and a Masters of Business Administration from New Hampshire College (now the University of Southern New Hampshire). Among other experience, qualifications, attributes and skills, Mr. George's executive, commercial and marketing expertise with pharmaceutical companies led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Steven W. Lefkowitz has been a director of CorMedix since August 2011. He also served as our acting Chief Financial Officer from August 2013 to July 2014. Mr. Lefkowitz has been the President and Founder of Wade Capital Corporation Money Purchase Plan a financial advisory services company, since June 1990. Mr. Lefkowitz also serves as a director in both publicly traded and privately held companies. Mr. Lefkowitz has been a director of Franklin Credit Management Corporation, formerly known as Franklin Credit Holding Corporation, a public specialty consumer finance company since 1996, a director of AIS, RE., a privately held reinsurance company since 2001 and a director and chairman of the board of MedConx, Inc., a privately held medical devices connector company since 2007. Mr. Lefkowitz received his A.B. from Dartmouth College in 1977 and his M.B.A. from Columbia University in 1985. Among other experience, qualifications, attributes and skills, Mr. Lefkowitz's financial expertise with development stage biotechnology companies led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Taunia Markvicka, PharmD, MBA became a director of CorMedix in April 2014. She is currently Senior Vice President, Chief Commercial Officer at Pacira Pharmaceuticals (Nasdaq: PCRX). Ms. Markvicka has a strong commercial and clinical background, and has extensive experience in managing a product strategy from development to commercialization. She has been responsible for all facets of commercialization, market analysis, pre-launch planning, forecasts, budgets and launches. She has held leadership roles at Stack Pharma, The Medicines Company, Watson Pharmaceuticals, and Sandoz Pharmaceuticals (now Novartis). Among other experience, qualifications, attributes and skills, Ms. Markvicka's commercial and marketing expertise with pharmaceutical companies led to the conclusion of our Board that she should serve as a director of our company in light of our business and structure.

Antony E. Pfaffle, M.D. has been a director of CorMedix since February 2007, was appointed as our interim Chief Scientific Officer effective January 1, 2013, and became our Chief Scientific Officer in July 2014. Dr. Pfaffle has been Director of Healthcare Research at Bearing Circle Capital, L.P., an investment fund, since May 2007. Dr. Pfaffle is an Advisory Medical Director for ParagonRx, an Inventiv Company specializing in drug and device risk evaluation and mitigation. He was a Managing Director at Paramount BioCapital, Inc. and Senior Vice-President of Business Development at Paramount BioSciences, LLC from December 2005 to May 2007. Dr. Pfaffle was a Principal and Founder of Black Diamond Research, an investment research company, from July 2001 to December 2005. Dr. Pfaffle is an internist who practiced nephrology at New York Hospital-Weill Cornell Medical Center, Lenox Hill Hospital and Memorial Sloan-Kettering Cancer Center. Dr. Pfaffle received his M.D. from New York Medical College in 1989. Among other experience, qualifications, attributes and skills, Dr. Pfaffle's financial expertise, knowledge of the investment community, medical science background and experience with development stage biopharmaceutical companies led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Board Committees

The composition and responsibilities of each of the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee are described below. Members will serve on these committees until their resignation or until otherwise determined by the Board.

Audit Committee

The Audit Committee consists of Ms. Tellez (Chair), Mr. Duffy and Ms. Markvicka, each of whom satisfies the independence requirements under NYSE MKT and SEC rules and regulations applicable to audit committee members and is able to read and understand fundamental financial statements.

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

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

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

Compensation Committee

The Compensation Committee consists of Ms. Markvicka (Chair), Mr. George and Mr. Duffy each of whom satisfies the independence requirements of NYSE MKT rules and regulations. Each member of this committee is a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code").

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

We did not use the services of any compensation consultant in matters affecting the compensation of named executive officers or directors during 2014. In the future, we, or the Compensation Committee, may engage or seek the advice of a compensation consultant.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee consists of Mr. George (Chair), Ms. Markvicka, and Ms. Tellez each of whom satisfies the independence requirements of NYSE MKT rules and regulations.

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

Code of Ethics

We have adopted a Code of Conduct and Ethics (the "Code of Ethics") applying to all of our directors, officers and other employees. The Code of Ethics is designed to provide guidance regarding our standards of integrity and business conduct and to promote (i) honest and ethical conduct, including fair dealing and the ethical handling of actual or apparent interest between personal and professional relationships; (ii) conducting business with professional competence and integrity; (iii) full, fair, accurate, timely and understandable disclosure; (iv) compliance with applicable laws, rules and regulations; (v) prompt reporting of violations of the Code of Ethics; and (vi) accountability for adherence to the Code of Ethics.

A copy of the Code of Ethics is available in the Investor Relations; Corporate Governance, portion of our website, www.cormedix.com. Additional copies of the Code of Ethics may be obtained without charge, from us by writing or calling: 1430 US Highway 206, Suite 200, Bedminster, NJ 07921, Attn: Chief Executive Officer; Telephone: (908) 517-9500.

Item 11. Executive Compensation

EXECUTIVE COMPENSATION

Compensation Objectives and Philosophy

The Compensation Committee is responsible for reviewing and approving the compensation payable to our named executive officers and other key employees. As part of such process, the Compensation Committee seeks to accomplish the following objectives with respect to our executive compensation programs:

- motivate, recruit and retain executives capable of meeting our strategic objectives;
- provide incentives to ensure superior executive performance and successful financial results for our company; and
- align the interests of the named executive officers with the long-term interests of our stockholders.

The Compensation Committee seeks to achieve these objectives by:

- establishing a compensation structure that is both market competitive and internally fair;
- linking a substantial portion of compensation to our achievement of financial objectives and the individual's contribution to the attainment of those objectives;
- providing upward leverage for overachievement of goals; and
- providing long-term equity-based incentives.

In order to achieve the above goals, our total compensation package includes base salary and annual bonus, all paid in cash, as well as long-term compensation in the form of stock options and/or restricted stock. We believe that appropriately balancing the total compensation package is necessary in order to provide market-competitive compensation.

Setting Executive Compensation

The Compensation Committee oversees the design, development and implementation of the compensation program for the Chief Executive Officer and the other named executive officers. The Compensation Committee evaluates the performance of the Chief Executive Officer and determines the Chief Executive Officer's compensation in light of the goals and objectives of the compensation program. The Chief Executive Officer and the Compensation Committee together assess the performance of the other named executive officers and determine their compensation, based on initial recommendations from the Chief Executive Officer. Our Chief Executive Officer provided the Compensation Committee with a detailed review of the performance of the other named executive officers and made recommendations to the Compensation Committee with respect to the compensation packages for those officers for 2014.

The other named executive officers do not play a role in their own compensation determination, other than discussing individual performance objectives and results with the Chief Executive Officer.

We did not use the services of any compensation consultant in matters affecting the compensation of named executive officers or directors during 2013 or 2014. In the future, we, or the Compensation Committee, may engage or seek the advice of a compensation consultant.

The Compensation Committee has structured our annual and long-term incentive-based cash and non-cash executive compensation to motivate executives to achieve the business goals set by the Board and reward the executives for achieving such goals. At the end of the year, the Compensation Committee reviews the performance of each named executive officer in achieving the established objectives. These results are included with the overall performance review provided by the Chief Executive Officer, after which the Compensation Committee votes upon any recommendations for salary adjustments, stock option grants and cash incentives. The Chief Executive Officer then executes the actions approved by the Compensation Committee with respect to such matters.

Components of Compensation

The key components of our executive compensation package are cash compensation (salary and annual bonuses), long-term equity incentive awards and change in control and other severance agreements. These components are administered with the goal of providing total compensation that recognizes meaningful differences in individual performance, is competitive, varies the opportunity based on individual and corporate performance, and is valued by our named executive officers.

Base Salary

It is the Compensation Committee's objective to set a competitive rate of annual base salary for each named executive officer. The Compensation Committee believes competitive base salaries are necessary to attract and retain top quality executives, since it is common practice for public companies to provide their named executive officers with a guaranteed annual component of compensation that is not subject to performance risk. The Compensation Committee, on its own or with outside consultants, may establish salary ranges for the named executive officers, with minimum to maximum opportunities that cover the normal range of market variability. The actual base salary for each named executive officer is then derived from those salary ranges based on his responsibility, tenure and past performance and market comparability. Annual base salaries for the named executive officers are reviewed and approved by the Compensation Committee in the first quarter following the end of the previous performance year. Changes in base salary are based on the scope of an individual's current job responsibilities, individual performance in the previous performance year, target pay position relative to the peer group, and our salary budget guidelines. The Compensation Committee reviews established goals and objectives, and determines an individual's achievement of those goals and objectives and considers the recommendations provided by the Chief Executive Officer to assist it in determining appropriate salaries for the named executive officers other than the Chief Executive Officer. For any given performance year, actual salary increases may range from 0% to 10% of the salary guidelines based on individual performance. This broad range allows for meaningful differentiation on a pay for performance basis.

The base salary information for our named executive officers for 2014 is set forth in the Summary Compensation Table below. In May 2014, we entered into an employment agreement with our Chief Executive Officer, Randy Milby, and in July 2014, we entered into a letter agreement with each of Dr. Anthony Pfaffle, our Chief Scientific Officer, and Harry O'Grady, our Chief Financial Officer, that provides the terms of their employment, which is at will. These agreements provide for a salary for each officer and are described under the caption "Employment Agreements and Arrangements."

Annual Bonuses

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

At the beginning of the performance year, each named executive officer, in conjunction with the Chief Executive Officer, establishes annual goals and objectives. Actual bonus awards are based on an assessment against the pre-established goals for each named executive officer's individual performance, the performance of the business function for which he is responsible, and/or our overall performance for the year. For any given performance year, proposed annual bonuses may range from 0% to 100% of target, or higher under certain circumstances, based on corporate and individual performance. Corporate and individual performance has a significant impact on the annual bonus amounts because the Compensation Committee believes it is a precise measure of how the named executive officer contributed to business results.

Long-Term Incentive Equity Awards

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

Stock Options

Our 2013 Stock Plan (and formerly our 2006 Stock Plan) authorizes us to grant options to purchase shares of common stock to our employees, directors and consultants.

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

Stock options granted to employees have an exercise price equal to the fair market value of our common stock on the day of grant, typically vest over a time or upon the achievement of certain performance-based milestones and are based upon continued employment, and generally expire 10 years after the date of grant. The fair value of the options granted to the named executive officers in the Summary Compensation Table is determined in accordance with the Black-Scholes method of valuation for share-based compensation. Incentive stock options also include certain other terms necessary to ensure compliance with the Internal Revenue Code of 1986.

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

- Stock options align the interests of our named executive officers with those of our stockholders, supporting a pay-for performance culture, foster employee stock ownership, and focus the management team on increasing value for our stockholders.

- Stock options are performance-based. All of the value received by the recipient of a stock option is based on the growth of the stock price. In addition, stock options can be issued with vesting based on the achievement of specified milestones.

- Stock options help to provide balance to the overall executive compensation program as base salary and annual bonuses focus on short-term compensation, while the vesting of stock options increases stockholder value over the longer term.

- The vesting period of stock options encourages executive retention and the preservation of stockholder value. In determining the number of stock options to be granted to our named executive officers, we take into account the individual's position, scope of responsibility, ability to affect profits and stockholder value and the individual's historic and recent performance and the value of stock options in relation to other elements of the individual named executive officer's total compensation.

- Restricted Stock. Our 2013 Stock Plan (and formerly our 2006 Stock Plan) authorizes us to grant restricted stock. No restricted stock grants were awarded during 2013 or 2014. In order to implement our long-term incentive goals, we may grant shares of restricted stock in the future.

Restricted Stock

Our 2013 Stock Plan (and formerly our 2006 Stock Plan) authorizes us to grant restricted stock. No restricted stock grants were awarded during 2013 or 2014. In order to implement our long-term incentive goals, we may grant shares of restricted stock in the future.

Executive Benefits and Perquisites

Our named executive officers, some of whom may be parties to employment or consulting agreements, will continue to be parties to such agreements in their current form until the expiration or termination of the employment or consulting agreement or until such time as the Compensation Committee determines in its discretion that revisions to such agreements are advisable. In addition, consistent with our compensation philosophy, we intend to continue to maintain our current benefits for our named executive officers, including medical, dental and life insurance and the ability to contribute to a 401(k) plan; however, the Compensation Committee in its discretion may revise, amend or add to the officer's executive benefits if it deems it advisable. We believe these benefits are currently comparable to benefit levels for comparable companies.

Employment Agreements and Arrangements

On May 9, 2014, we entered into an employment agreement, effective March 31, 2014, with our Chief Executive Officer, Randy Milby. Unless renewed pursuant to the terms thereof, the agreement will expire on March 31, 2016. Pursuant to the agreement, we must use best efforts to cause Mr. Milby to be elected as a member of our Board of Directors and we must include him in the management slate for election as a director at every stockholders meeting during the term of the agreement at which his term as a director would otherwise expire. Mr. Milby will not receive additional compensation for his services as a member of our Board of Directors.

In exchange for his service as our Chief Executive Officer, Mr. Milby will receive an annual base salary of $300,000.00, up to 50% of which may be paid in the form of unregistered common stock at the discretion of Mr. Milby and subject to specified limitations. Mr. Milby will be eligible for an annual target bonus, the cash portion of which may equal up to 100% of his base salary then in effect, as determined by our Board or compensation committee. In determining such bonus, our Board or compensation committee will take into consideration the achievement of specified company objectives, predetermined by the Board, and specified personal objectives, predetermined by the Board and Mr. Milby. Mr. Milby's annual bonus, if any, will be paid in cash or a combination of cash and equity, provided that the equity portion will make up no more than 50% of the value of such annual bonus. Mr. Milby is eligible to participate in all employee benefits available to our senior executives from time-to-time, and we must designate Mr. Milby as a named insured on our directors' and officers' liability insurance policy. Pursuant to the agreement, Mr. Milby is eligible for up to four weeks of paid vacation per year and may be reimbursed for specified business-related expenses.

If we terminate Mr. Milby's employment for Cause (as defined below), Mr. Milby will be entitled to receive only the accrued compensation due to him as of the date of such termination, all shares of restricted stock then held by him will be forfeited to us as of such date, and all unexercised options to purchase shares of our capital stock, whether or not vested, will immediately terminate. If Mr. Milby resigns for other than Good Reason, he will be entitled only to payment of his accrued compensation as of such date. If we terminate Mr. Milby's employment other than for Cause, death or disability, or if Mr. Milby resigns for Good Reason (as each such term is defined below), Mr. Milby will continue to receive his base salary and benefits for a period of 12 months following the effective date of the termination of his employment, or, in the case of benefits, until such time as he receives equivalent coverage and benefits under plans and programs of a subsequent employer. All shares of restricted stock and all unvested options to purchase shares of our capital stock then held by Mr. Milby will be accelerated and deemed to have vested as of the effective date of the termination of his employment. To the extent any of the aforementioned benefits cannot be provided to former employees, we will pay Mr. Milby a lump-sum payment in the amount necessary to allow Mr. Milby to purchase the equivalent benefits. Upon a Change of Control of our company (as defined in the agreement), all shares of our company's restricted stock and all unvested options to purchase shares of our capital stock then held by Mr. Milby will be accelerated and deemed to have vested as of the date of such Change of Control.

For purposes of the agreement, "Cause" is defined as: (a) the willful failure, disregard or refusal by Mr. Milby to perform his material duties or obligations under the agreement; (b) any willful, intentional, or grossly negligent act by Mr. Milby having the effect of materially injuring (whether financial or otherwise and as determined reasonably and in good-faith by a majority of the members of our Board of Directors) the business or reputation of our company or any of our affiliates (provided, however, that this provision will not apply to any company affiliate that is engaged in a business competitive with our company's business); (c) Mr. Milby's conviction of any felony involving moral turpitude (including entry of a guilty or nolo contendere plea); (d) a good faith determination by the Board and/or any government representative or agency that Mr. Milby is a 'bad actor" as defined by 17 CFR 230.506(a); (e) the good faith determination by our Board of Directors, after a reasonable and good-faith investigation by our company following any allegation by another employee of our company, that Mr. Milby engaged in some form of harassment prohibited by law (including, without limitation, harassment on the basis of age, sex, or race) unless Mr. Milby's actions were specifically directed by the Board; (f) any material misappropriation or embezzlement by Mr. Milby of the property of our company or our affiliates (whether or not a misdemeanor or felony); or (g) any breach by Mr. Milby of any material provision of the agreement that is not cured by him to our reasonable satisfaction within 30 days after written notice thereof.

For purposes of the agreement, “Good Reason” is defined as: (a) any material breach of the agreement by our company if Mr. Milby has provided us with written notice of the breach within 90 days of the breach and we have not cured such breach within 30 days from such notice; (b) without Mr. Milby’s express written consent, we materially reduce his duties, responsibilities, or authority as Chief Executive Officer including, without limitation, a change in the line of reporting between him and our Board of Directors, that causes his position with us to become of less responsibility or authority than his position as of the effective date of the agreement; (c) a relocation of our principal place of business outside the New York metropolitan area or to a location more than 50 miles from the immediately preceding location without Mr. Milby’s written consent; (d) a material reduction in his annual base salary unless all officers and/or members of our executive management team experience an equal or greater percentage reduction in annual base salary and/or total compensation; or (e) our failure to include Mr. Milby in our management’s slate for election to the Board.

On July 21, 2014, we entered into a letter agreement with each of our Chief Scientific Officer, Dr. Antony Pfaffle, and our Chief Financial Officer, Harry O’Grady. Pursuant to their respective agreements, we agreed to pay a base salary of $230,000 to Mr. O’Grady and $200,000 to Dr. Pfaffle. Additionally, we agreed to review each of Mr. O’Grady and Dr. Pfaffle’s (each, an “Executive”) salary in early 2015 with the goal of achieving market value for a CFO or CSO, respectively, with such Executive’s experience operating in a company of similar size and with revenue similar to ours, but in any event not less than $230,000 and $200,000, respectively. Mr. O’Grady was eligible to participate in the Short Term Incentive Plan (STIP) beginning January 1, 2015, with a target award opportunity equal to 40% of his base salary. Dr. Pfaffle was eligible to participate in the STIP beginning on his employment date. His 2015 target award opportunity is equal to 30% of his base salary.

Upon a change of control of our company, as defined in each Executive’s employment agreement, all shares of our capital stock held by such Executive that are subject to vesting (“Restricted Stock”) and all options to purchase shares of our capital stock (“Options”) will be accelerated and deemed to have vested as of the date of the change of control.

If the Executive’s employment is terminated, we will pay him his base salary and benefits otherwise payable to him through the last day of his actual employment, including any earned but unpaid bonuses. In addition, if the Executive’s employment is terminated as a result of his death or disability, we will pay him or his estate, as applicable (i) his base salary for 180 days after the termination of his employment, and (ii) additional benefits, if any, as may be provided under our applicable employee benefit plans, programs and arrangements. All shares of Restricted Stock and Options that are scheduled to vest on or before the next succeeding anniversary of the date of his employment agreement will be accelerated and deemed to have vested as of the termination date. All other shares of Restricted Stock and Options that have not vested or been deemed to have vested will be forfeited.

If we terminate the Executive’s employment without “cause” (as defined in the Executive’s agreement) or the Executive terminates his employment for “good reason” (as defined in the agreement), then we will (i) pay the Executive his then-current salary for 12 months, and (ii) provide the Executive such other benefits, if any, as may be provided under our applicable employee benefit plans, programs and arrangements. In addition, any all Restricted Shares and unvested Options will be accelerated and deemed to have vested as of the termination date.

Summary Compensation Table

The following table sets forth information with respect to compensation earned by our named executive officers in the years ended December 31, 2014 and 2013:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards [1] ($)	All Other Compensation ($)	Total ($)
Randy Milby [2]	2014	287,500	-	147,500	-	435,000
Chief Executive Officer	2013	223,500	-	368,500	-	592,000
Steven W. Lefkowitz [3]	2014	60,000	-	339,250	26,483(4)	425,733
Interim Chief Financial Officer	2013	30,000	-	88,440	39,650(4)	158,090
Antony E. Pfaffle [5]	2014	219,800	30,000	356,550	16,928(4)	623,278
Chief Scientific Officer	2013	120,000	-	154,770	37,500(5)	312,270
Harry O'Grady [6]	2014	103,795	-	111,000	-	214,295
Chief Financial Officer	2013	-	-	-	-	-

[1] The amounts included in this column are the dollar amounts representing the full grant date fair value of each stock option award calculated in accordance with FASB ASC Topic 718 and do not represent the actual value that may be recognized by the named executive officers upon option exercise.

[2] Mr. Milby became our Chief Executive Officer on January 1, 2013, but was a consultant until becoming an employee on April 1, 2013. The amount of salary reported for 2013 includes $36,000 paid in consulting fees to MW Bridges LLC, of which Mr. Milby is Managing Partner.

[3] Mr. Lefkowitz served as our Interim Chief Financial Officer from August 15, 2013 until July 20, 2014.

[4] Consists of director fees.

[5] Dr. Pfaffle became our Acting Chief Scientific Officer on January 1, 2013 and our Chief Scientific Officer effective July 1, 2014.

[6] Mr. O'Grady became our Chief Financial Officer on July 21, 2014.

Outstanding Equity Awards at Fiscal Year-End

The following table contains certain information concerning unexercised options for the Named Executive Officers as of December 31, 2014.

	Number of Shares Underlying Unexercised Options (#) – Exercisable	Number of Shares Underlying Unexercised Options (#) - Unexercisable	Option Exercise Price ($)	Option Expiration Date
Randy Milby	50,000	-	0.29	5/14/2022
	100,000	-	0.68	12/05/2022
	437,500	-	0.90	3/20/2023
	100,000		2.02	1/09/2024
Steven W. Lefkowitz	30,000	-	1.10	8/11/2021
	30,000	-	0.29	1/06/2022
	150,000	-	0.68	12/5/2022
	105,000	15,000	0.90	3/20/2023
	200,000		2.02	1/09/2024
	-	30,000	2.02	1/09/2024
Antony E. Pfaffle	20,000	-	3.125	3/30/2020
	30,000	-	2.10	1/14/2022
	30,000	-	0.29	1/06/2022
	250,000	-	0.68	12/05/2022
	175,000		0.90	3/20/2023
	100,000	-	2.02	1/09/2024
	-	30,000	2.02	1/09/2024
	100,000	-	2.27	4/01/2024
Harry O'Grady	25,000	75,000	1.80	7/21/2024

Director Compensation in Fiscal Year 2014

The following table shows the compensation earned by each non-employee director of our company for the year ended December 31, 2014.

Name	Fees Earned ($)	Option Awards [1] [2] ($)	Total ($)
Cora Tellez [3]	32,637[3]	44,640	77,277
Michael W. George	30,075[3]	83,745	113,820
Taunia Markvicka	28,073	44,640	72,713
Gary A. Gelbfish, M.D.[4]	20,100	339,250	359,350
Antony E. Pfaffle, M.D[5]	-	-	-
Steven W. Lefkowitz [6]	-	-	-
Matthew P. Duffy	37,818	265,500	303,318

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(1) The amounts included in this column are the dollar amounts representing the full grant date fair value of each stock option award calculated in accordance with FASB ASC Topic 718 and do not represent the actual value that may be recognized by the directors upon option exercise. For information on the valuation assumptions used in calculating this amount, see Note 2 to our audited financial statements included in this Annual Report on Form 10-K.

(2) As of December 31, 2014, the number of shares underlying options held by each non-employee director was as follows: 30,000 shares for Ms. Tellez, 45,000 shares for Mr. George, 30,000 shares for Ms. Markvicka, no shares for Dr. Gelbfish; and 465,000 shares for Mr. Duffy. For information on options held by Dr. Pfaffle and Mr. Lefkowitz, see the "Outstanding Equity Awards at Fiscal Year End" table above.

(3) Includes fees of $15,786 for Ms. Tellez and $6,040 for Mr. George that were deferred. See "Directors Compensation Plan" below for a description of the deferral plan pursuant to which the deferrals were made.

(4) Dr. Gelbfish resigned on June 13, 2014.

(5) On July 21, 2014, Antony Pfaffle was appointed our Chief Scientific Officer. All compensation paid to Dr. Pfaffle as an officer and a director is set forth in the "Summary Compensation Table" below.

(6) On August 15, 2013, Steven Lefkowitz was appointed our Interim Chief Financial Officer, which position he resigned on July 20, 2014. All compensation paid to Mr. Lefkowitz as an officer and a director is set forth in the "Summary Compensation Table" below.

Directors Compensation Plan

The following director cash and equity compensation policies were in effect prior to October 20, 2014. Non-employee directors are entitled to receive the following cash compensation: (i) a $20,000 annual retainer, except that the Chairman of the Board receives $30,000, (ii) $5,000 annually for service on the Audit Committee, except that the Chairman of the Audit Committee receives $12,000, (iii) $4,000 annually for service on the Nominating and Corporate Governance Committee, except that the Chairman of the Nominating and Corporate Governance Committee receives $5,000, (iv) $4,000 annually for service on the Compensation Committee, except that the Chairman of the Compensation Committee receives $5,000, (v) $1,000 for each in-person meeting of the Board attended, and (vi) $500 for each telephonic meeting of the Board attended. Employee directors do not receive any compensation for their services on the Board. Non-employee directors are entitled to receive: (i) an annual grant to each non-employee director at the first Board meeting of the calendar year of an option to purchase 30,000 shares of our common stock at an exercise price equal to the closing price of the common stock on the grant date, which option vests on the first anniversary of the grant date; and (ii) a one-time grant to each new non-employee director in connection with his or her initial election to the Board of an option to purchase 30,000 shares of our common stock at an exercise price equal to the closing price of the common stock on the grant date, which option vests in equal installments on each of the grant date, the first anniversary of the grant date and the second anniversary of the grant date.

Effective October 20, 2014, we adopted the following cash and equity compensation policies for non-employee directors. Each director receives an annual cash fee of $25,000, the Board Chair receives an additional $5,000 and committee Chairs receive an additional $5,000. Upon a director's first election to the Board, he or she will be granted an option to purchase 50,000 shares of our common stock. After election to the Board, in the next calendar year after his or her election and annually thereafter, each director will be granted an option to purchase 50,000 shares of our common stock for his or her service on the Board. Vesting for all option grants will be 25% on the second anniversary of grant and an additional 25% on the third, fourth and fifth anniversaries of grant, provided the director remains a member of the Board on the respective anniversary date.

In July 2014, we adopted a Deferred Compensation Plan for Directors, pursuant to which our non-employee directors may defer all of their cash director fees. Any cash fees due a participating director will be converted into a number of shares of our common stock by dividing the dollar amount of fees payable by the closing price of our common stock on the date such fees would be payable, and the director's unfunded account would be credited with the shares. The shares that accumulate in a director's account will be paid to the director on the tenth business day in January following the year in which the director's service terminates for whatever reason, other than death, in which case the account will be paid within 30 days of the date of death to the designated beneficiaries, if any. If there are no designated beneficiaries, the account will be paid out the same as with any other termination of service. In the event of a change in control of our company, the director would receive cash in an amount equal to the number of shares in the account multiplied by the fair market value of our common stock on the change in control date, and the payment would be accelerated to five business days after the effective date of the change in control.

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

The following table shows the number of shares of our common stock beneficially owned as of January 31, 2015 by:

- each person known by us to own beneficially more than 5% of the outstanding shares of our common stock;
- each director and nominee for director;
- each of our executive officers named in the Summary Compensation Table above (the "Named Executive Officers"); and
- all of our current directors and executive officers as a group.

This table is based upon the information supplied by our Named Executive Officers, directors and principal stockholders and from Schedules 13D and 13G filed with the SEC. Except as indicated in footnotes to this table, the persons named in this table have sole voting and investment power with respect to all shares of common stock shown, and their address is c/o CorMedix Inc., 1430 US Highway 206, Suite 200, Bedminster, New Jersey 07921. As of January 31, 2015, we had 23,461,008 shares of common stock outstanding. Beneficial ownership in each case also includes shares issuable upon exercise of outstanding options that can be exercised within 60 days after January 31, 2015 for purposes of computing the percentage of common stock owned by the person named. Options owned by a person are not included for purposes of computing the percentage owned by any other person.

Name and Address of Beneficial Owner	Common Stock Beneficially Owned [1]	
	Shares	%
5% or Greater Stockholders:		
Elliott Associates, L.P. [2]	3,004,085	9.9
Directors and Named Executive Officers:		
Randy Milby [3]	1,367,541	5.8
Matthew P. Duffy [4]	520,723	2.2
Steven W. Lefkowitz [5]	998,712	4.1
Antony E. Pfaffle, M.D. [6]	751,725	3.2
Michael W. George [7]	45,000	*
Cora Tellez [8]	98,386	*
Taunia Markvicka [9]	10,000	*
Harry O'Grady [10]	25,000	*
All executive officers and directors as a group (8 persons) [11]	2,484,097	10.0

**Less than 1%*

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[1] Based upon 23,461,008 shares of our common stock outstanding on January 31, 2015 and, with respect to each individual holder, rights to acquire our common stock exercisable within 60 days of January 31, 2015.

[2] Due to the Ownership Limitation (as defined below), Elliott Associates, L.P. ("Elliott Associates") may be deemed the beneficial owner of 3,004,085 shares of our common stock through securities held by it and by Manchester Securities Corp., a wholly-owned subsidiary of Elliott Associates ("Manchester"), and Elliott International, L.P., a wholly-owned subsidiary of Elliott Associates ("Elliott International"). Notwithstanding the above, Elliott Associates beneficially holds: (i) 781,440 shares of our common stock held by Manchester, (ii) 2010 warrants held by Manchester exercisable for 390,720 shares of our common stock, (iii) 2012 warrants exercisable for 1,000,000 shares of our common stock, (iv) May 2013 warrants exercisable for 500,000 shares of our common stock, (v) 52,500 shares of our Series C-2 non-voting convertible preferred stock convertible into 525,000 shares of our common stock, (vi) October 2013 warrants exercisable for 262,500 shares of our common stock, (vii) 97,500 shares of our Series C-2 non-voting convertible preferred stock held by Elliott International convertible into 975,000 shares of our common stock, (viii) October 2013 warrants held by Elliott International exercisable for 487,500 shares of our common stock, (ix) 73,962 shares of our Series D non-voting convertible preferred stock held by Manchester convertible into 1,479,240 shares of our common stock, and (x) 89,623 shares of our Series E non-voting convertible preferred stock held by Manchester convertible into 1,959,759 shares of our common stock (the 2012 warrants, the May 2013 warrants and the October 2013 warrants shall collectively be referred to herein as the "Convertible Securities"). However, in accordance with Rule 13d-4 under the Exchange Act, the number of shares of our common stock into which the Convertible Securities are convertible or exercisable, as applicable, are limited pursuant to the terms of the Convertible Securities to that number of shares of our common stock which would result in Elliott Associates having aggregate beneficial ownership of (a) with respect to the 2012 warrants, 4.999% of the total issued and outstanding shares of our common stock, and (b) with respect to the May 2013 warrants, the October 2013 warrants, the Series C-2 preferred stock, the Series D preferred stock and the Series E preferred stock, 9.99% of the total issued and outstanding shares of our common stock (the "Ownership Limitation"). Elliott Associates disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Convertible Securities if such conversion or exercise would cause Elliott Associates' aggregate beneficial ownership to exceed or remain above the applicable Ownership Limitation (as is currently the case). Therefore, Elliott Associates disclaims beneficial ownership of any of our common stock issuable upon any conversion or exercise of the 2012 warrants, and any shares of our common stock, issuable upon any conversion or exercise of the May 2013 warrants, the October 2013 warrants, the Series C-2 preferred stock, the Series D preferred stock and the Series E preferred stock, which conversion of exercise would be prohibited by the ownership limitation. The business address of Elliott Associates is 40 West 57th Street, 30th Floor, New York, New York 10019. Based solely on information contained in a Schedule 13D filed with the SEC on February 17, 2015 by Elliott Associates and other information known to us.

(3) Consists of (i) 46,298 shares of common stock held by Mr. Milby, (ii) 196,243 shares of our common stock held by MW Bridges LLC, of which Mr. Milby is Managing Partner, (iii) 687,500 shares of our common stock issuable upon exercise of stock options, (iii) 62,500 shares of our common stock issuable upon exercise of 2012 warrants held by MW Bridges LLC, (iv) 237,000 shares of our common stock issuable upon conversion of 23,700 shares of our Series C-3 non-voting convertible preferred stock, (v) 13,000 shares of our common stock issuable upon conversion of 1,300 shares of our Series C-3 non-voting convertible preferred stock held by MW Bridges LLC, (vi) 118,500 shares of our common stock issuable upon exercise of 2014 warrants, and (vii) 6,500 shares of our common stock issuable upon exercise of 2014 warrants held by MW Bridges LLC. The 2012 warrants identified in clause (iii) above prohibit conversion or exercise if after such conversion or exercise Mr. Milby and his affiliates would beneficially own more than 4.9% of our outstanding common stock, and the Series C-3 preferred stock and 2014 warrants identified in clauses (iv) through (vii) above prohibit conversion or exercise if after such conversion or exercise Mr. Milby and his affiliates would beneficially own more than 9.9% of our outstanding common stock (together with the limitation imposed upon the conversion of the 2012 warrants, the "Milby Ownership Limitation"). In accordance with Rule 13d-4 under the Exchange Act, Mr. Milby disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Milby Convertible Securities if such conversion or exercise would cause Mr. Milby's aggregate beneficial ownership to exceed or remain above the Milby Ownership Limitation.

(4) Consists of (i) 38,339 shares of our common stock, (ii) 452,500 shares of our common stock issuable upon exercise of stock options, (iii) 25,000 shares of our common stock issuable upon exercise of 2012 warrants, and (iv) 4,884 shares of our common stock issuable upon conversion of 2010 warrants. The warrants identified in clause (iii) above prohibit conversion or exercise if after such conversion or exercise Mr. Duffy and his affiliates would beneficially own more than 4.9% of our outstanding common stock.

(5) Consists of (i) 124,035 shares of our common stock held by Mr. Lefkowitz individually, (ii) 10,000 shares of our common stock held by Mr. Lefkowitz's spouse, (iii) 174,741 shares of our common stock held by Wade Capital Corporation Money Purchase Plan, an entity for which Mr. Lefkowitz has voting and investment control, (iv) 545,000 shares of our common stock issuable upon exercise of stock options, (v) 45,000 shares of our common stock issuable upon conversion of 4,500 shares of our Series C-3 convertible preferred stock held by Mr. Lefkowitz individually, (vi) 30,000 shares of our common stock issuable upon conversion of 3,000 shares of our Series C-3 convertible preferred stock held by Wade Capital Corporation Money Purchase Plan, (vii) 22,500 shares of our common stock issuable upon exercise of 2014 warrants held by Mr. Lefkowitz individually, (viii) 15,000 shares of our common stock issuable upon exercise of 2014 warrants held by Wade Capital Corporation Money Purchase Plan, and (ix) 32,436 shares of our common stock issuable upon exercise of 2010 warrants held by Mr. Lefkowitz individually. The number of shares of our common stock into which the Series C-3 preferred stock and 2014 warrants are convertible or exercisable, as applicable, are limited pursuant to their terms to that number of shares of our common stock which would result in Mr. Lefkowitz having aggregate beneficial ownership of 9.99% of the total issued and outstanding shares of our common stock (the "Lefkowitz Ownership Limitation"). In accordance with Rule 13d-4 under the Exchange Act, Mr. Lefkowitz disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Lefkowitz Convertible Securities if such conversion or exercise would cause Mr. Lefkowitz's aggregate beneficial ownership to exceed or remain above the Lefkowitz Ownership Limitation.

(6) Consists of (i) 16,725 shares of our common stock, and (ii) 735,000 shares of our common stock issuable upon exercise of stock options.

(7) Consists of 45,000 shares of our common stock issuable upon exercise of stock options.

(8) Consists of (i) 63,386 shares of our common stock, (ii) 10,000 shares of our common stock issuable upon exercise of stock options, and (iii) 25,000 shares of our common stock issuable upon exercise of 2014 warrants.

(9) Consists of 10,000 shares of our common stock issuable upon the exercise of stock options.

(10) Consists of 25,000 shares of our common stock issuable upon the exercise of stock options.

(11) Consists of (i) 1,368,808 shares of our common stock, (ii) 2,210,000 shares of our common stock issuable upon exercise of stock options, (iii) 825,000 shares of our common stock issuable upon conversion of Series C-3 convertible preferred stock, and (iv) 625,420 shares of our common stock issuable upon exercise of warrants, as referenced in footnotes 4 through 8. However, pursuant to the various ownership limitations discussed in footnotes 4, 6 and 7, in accordance with Rule 13d-4 under the Exchange Act, an aggregate of 571,207 shares of our common stock issuable upon conversion or exercise of certain shares of Series C-3 preferred stock and warrants to purchase common stock are excluded from the table.

Item 13. Certain Relationships and Related Transactions and Director Independence

Director Independence

The Board has determined that all directors, except Randy Milby, Steven W. Lefkowitz and Antony Pfaffle, are independent as defined in Rule 803A(2) of the NYSE MKT Rules. In addition to the specific bars to independence set forth in that rule, we also consider whether a director or his or her affiliates have provided any services to, worked for or received any compensation from us or any of our subsidiaries in the past three years in particular.

Related Party Transactions

On January 8, 2014, the following individuals purchased shares of our Series C-3 convertible preferred stock and warrants to purchase shares of our common stock in a private placement, all on the same terms as other investors in the private placement, as follows:

- Cora Tellez, director, 5,000 shares and a warrant to purchase 25,000 shares of our common stock;
- Steven W. Lefkowitz, director, purchased (indirectly through Wade Capital Corporation Money Purchase Plan, an entity for which Mr. Lefkowitz has voting and investment control) and individually 4,500 and 3,000 shares, respectively, and warrants to purchase 22,500 and 15,000 shares, respectively; and
- Randy Milby, our Chief Executive Officer and a director, indirectly through MW Bridges LLC (an entity for which he is Managing Partner, and has voting and investment control) and individually 23,700 and 1,300 shares, respectively, and warrants to purchase 118,500 and 6,500 shares, respectively.

On September 15, 2014, we entered into a consent and exchange agreement with the holders of our Series C-3 preferred stock and related warrants, including Ms. Tellez, Mr. Lefkowitz and Mr. Milby, pursuant to which, we amended and restated the Series C-3 preferred stock and the related warrants to remove anti-dilution, price reset and certain change of control provisions that caused those securities to be classified as derivative liabilities under U.S. generally accepted accounting principles. The exchange was on the same terms as those provided to all other investors in the January 2014 Series C-3 financing.

On March 4, 2014, we sold to Integrated Core Strategies (US) LLC 400,000 units in a registered direct offering. Each unit consisted of one share of our common stock and 0.35 of a warrant, each to purchase one share of our common stock, which resulted in an aggregate of 400,000 shares of common stock and a warrant to purchase 140,000 shares of common stock. The purchase price was $2.50 per unit. The warrants have 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. Integrated Core Strategies (US) LLC, along with affiliated entities, beneficially owns in excess of 5% of the outstanding shares of our common stock. September 15, 2014, we entered into consent and exchange agreement with Integrated Core Strategies (US) LLC to remove anti-dilution, price reset and certain change of control provisions that caused those securities to be classified as derivative liabilities under U.S. generally accepted accounting principles. In exchange, we agreed to decrease the exercise price of the warrants from $3.10 to $2.50. The sale and the subsequent exchange were on the same terms as those provided to all other investors in the March 2014 financing.

On September 15, 2014, we entered into consent and exchange agreements with Kingsbrook Opportunities Master Fund LP ("Kingsbrook") and Elliot International, L.P. and Manchester Securities Corp. (collectively, "Elliott"). Each of Elliot and Kingsbrook beneficially owns in excess of 5% of the outstanding shares of our common stock. Elliot beneficially owns all of our outstanding Series C-2 preferred stock (and related warrants) and Series D preferred stock. Elliott and Kingsbrook beneficially own all of our outstanding Series E preferred stock and related warrants. Pursuant to the exchange agreements, we amended and restated the Series C-2 preferred stock, Series D preferred stock and Series E preferred stock and the related warrants to remove anti-dilution, price reset and certain change of control provisions that caused those securities to be classified as derivative liabilities under U.S. generally accepted accounting principles. We also removed the preferred dividend payable on the Series D preferred stock and Series E preferred stock. In exchange for the removal of the anti-dilution, price reset, change of control and dividend provisions from the Series C-2 preferred stock, Series D preferred stock and Series E preferred stock and the related warrants, we decreased the exercise price of the warrants issued in May 2013 from $1.00 to $0.65 and the exercise price of the warrants issued in October 2013 from $1.25 to $0.90. We also increased 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. In addition, we issued 16,562 shares of our Series D preferred stock to Elliott in satisfaction of the 9.0% payment-in-kind dividend on the Series D preferred stock, and issued 36,086 shares of Series E preferred stock to Elliott and 1,140 shares of Series E preferred stock to Kingsbrook in satisfaction of the 8.0% payment-in-kind dividend on the Series E preferred stock.

Procedures for Review and Approval of Transactions with Related Persons

Pursuant to the Audit Committee Charter, the Audit Committee is responsible for reviewing and approving all related party transactions as defined under Item 404 of Regulation S-K, after reviewing each such transaction for potential conflicts of interests and other improprieties.

Item 14. Principal Accountant Fees and Services

The following table sets forth fees billed to us by Friedman LLP, our independent registered public accounting firm for the year ended December 31, 2014 and CohnReznick LLP, our independent registered public accounting firm for the year ended December 31, 2013 for services relating to: auditing our annual financial statements; reviewing our financial statements included in our quarterly reports on Form 10-Q; reviewing registration statements in connection with a Forms S-3 and S-8 filed during 2013 ; financing activities in 2013 and 2014; and services rendered in connection with tax compliance, tax advice and tax planning, and all other fees for services rendered.

	2014	2013
Audit Fees:		
Friedman LLP	$ 29,935	$ -
CohnReznick LLP	67,500	190,445
Audit Related Fees:		
Friedman LLP	33,607	
CohnReznick LLP	80,102	
Tax Fees:		
Friedman LLP	-	-
CohnReznick LLP	16,000	7,850
All Other Fees:	-	-
Friedman LLP	-	-
CohnReznick LLP	-	-
Totals	$ 227,144	$ 198,295

Audit Committee Pre-Approval Policies and Procedures

Pursuant to its charter, the Audit Committee is responsible for reviewing and approving in advance any audit and any permissible non-audit engagement or relationship between us and our independent registered public accounting firm. The Audit Committee may delegate to one or more designated members of the Audit Committee the authority to grant pre-approvals, provided such approvals are presented to the Audit Committee at a subsequent meeting. If the Audit Committee elects to establish pre-approval policies and procedures regarding non-audit services, the Audit Committee must be informed of each non-audit service provided by our independent registered public accounting firm. Audit Committee pre-approval of audit and non-audit services will not be required if the engagement for the services is entered into pursuant to pre-approval policies and procedures, provided the policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service provided and such policies and procedures do not include delegation of the Audit Committee's responsibilities under the Exchange Act to our management. Audit Committee pre-approval of non-audit services (other than review and attestation services) also will not be required if such services fall within available exceptions established by the SEC. All services performed by our independent registered public accounting firm during 2014 were pre-approved by the Audit Committee.

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	3/02/2010	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 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 4, 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 21, 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	Specimen Unit certificate.	S-1/A	3/19/2010	4.2
4.3	Specimen warrant certificate.	S-1/A	3/19/2010	4.3
4.4	Form of warrant agreement.	S-1/A	3/19/2010	4.4
4.5	Common Stock Exchange and Stockholder Agreement, dated as of October 6, 2009, by and between CorMedix Inc. and Shiva Biomedical, LLC.	S-1	11/25/2009	4.6
4.6	Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC.	S-1	11/25/2009	4.7
4.7	Form of Third Bridge Warrant.	S-1/A	1/20/2010	4.18
4.8	Form of 9% Senior Convertible Note due 2013.	10-Q	11/13/2012	4.1
4.9	Form of Purchaser Warrant.	10-Q	11/13/2012	4.2
4.10	Form of Placement Agent Warrant.	10-Q	11/13/2012	4.3
4.11	Form of Subscription Agreement.	10-Q	11/13/2012	4.4
4.12	Form of Registration Rights Agreement.	10-Q	11/13/2012	4.5
4.13	Form of Senior Secured Convertible Note.	8-K	5/24/2013	4.19
4.14	Form of Warrant issued on February 19, 2013.	8-K	2/19/2013	4.13
4.15	Form of Warrant issued on May 30, 2013.	8-K	5/24/2013	4.20
4.16	Form of Warrant issued on July 30, 2013.	8-K	7/26/2013	4.21
4.17	Form of Warrant issued on October 22, 2013.	8-K	10/18/2013	4.22
4.18	Form of Warrant issued on January 8, 2014.	8-K	1/09/2014	4.23
4.19	Form of Warrant issued on March 10, 2014.	8-K	3/05/2014	4.24
4.20	Form of Warrant issued on March 3, 2015.	8-K	3/04/2015	4.1
4.21	Amended and Restated Warrant originally issued May 30, 2013.	8-K	3/04/2015	4.2
4.22	Amended and Restated Warrant originally issued March 24, 2010.	8-K	3/04/2015	4.3
4.23	Form of Convertible Note	8-K	3/04/2015	4.4
4.24	Registration Rights Agreement dated March 3, 2015, by and between Cormedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	4.5
10.4*	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC.	8-K	2/06/2015	10.1
10.5	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
10.6*	Exclusive License and Consulting Agreement, dated as of January 30, 2008, between the Company and Hans-Dietrich Polaschegg.	S-1/A	3/01/2010	10.7
10.7	Amended and Restated Consulting Agreement, dated as of January 10, 2008, between the Company and Sudhir V. Shah, M.D.	S-1	11/25/2009	10.11
10.8	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl.	S-1	11/25/2009	10.12
10.9*	Supply Agreement, dated as of December 7, 2009, between the Company and Navinta, LLC.	8-K	2/06/2015	10.1
10.10*	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
10.11	Amended and Restated 2006 Stock Incentive Plan.	S-1/A	3/01/2010	10.8

10.12	Form of Indemnification Agreement between the Company and each of its directors and executive officers.	S-1/A	3/01/2010	10.17	
10.14	Subscription Agreement by and between the Company and certain accredited investors (with attached schedule of parties thereto).	8-K	11/15/2012	10.1	
10.15	Amended and Restated Investment Banking Agreement, dated August 20, 2012, between the Company and John Carris Investments, LLC.	8-K	11/15/2012	10.2	
10.16	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	
10.17	Form of Securities Purchase Agreement, dated February 18, 2013, between CorMedix Inc. and the investor named therein.	8-K	2/19/2013	10.23	
10.18	Consulting Agreement, as amended December 24, 2012, between the Company and MW Bridges LLC.	10-K	3/27/2013	10.26	
10.19	2013 Stock Incentive Plan	10-K	3/27/2013	10.27	
10.20	Form of Securities Purchase Agreement, dated May 23, 2013, between CorMedix Inc. and the investor named therein.	8-K	5/24/2013	10.29	
10.21	Form of Securities Purchase Agreement, dated July 25, 2013, between CorMedix Inc. and the investor named therein.	8-K	7/26/2013	10.30	
10.22	Form of Securities Purchase Agreement, dated October 17, 2013, between CorMedix Inc. and the investor named therein.	8-K	10/18/2013	10.32	
10.23	Form of Securities Purchase Agreement, dated October 17, 2013, between CorMedix Inc. and the investor named therein.	8-K	10/18/2013	10.33	
10.24	Form of Securities Purchase Agreement, dated January 7, 2014, between CorMedix Inc. and the investors named therein.	8-K	1/09/2014	10.36	
10.25	Backstop Agreement, dated March 3, 2015, by and between Cormedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	10.1	
21.1	List of Subsidiaries	10-K	3/27/2013	21.1	
23.1	Consent of Independent Registered Public Accounting Firm.				X
23.2	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, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2014 and 2013, (ii) Statements of Operations for the years ended December 31, 2014 and 2013, (iii) Statements of Changes in Stockholders' Equity (Deficiency) for the years ended December 31, 2014 and 2013, (iv) Statements of Cash Flows for the years ended December 31, 2014 and 2013 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.

** 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 12, 2015 By: /s/ Randy Milby
Randy Milby
Chief Executive Officer
(Principal Executive Officer)

March 12, 2015 By: /s/ Harry O'Grady
Harry O'Grady
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/ Randy Milby Randy Milby	Chief Executive Officer and Director (Principal Executive Officer)	March 12, 2015
/s/ Harry O'Grady Harry O'Grady	Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2015
/s/ Cora Tellez Cora Tellez	Chairman of the Board and Director	March 12, 2015
/s/ Matthew Duffy Matthew Duffy	Director	March 12, 2015
/s/ Michael George Michael George	Director	March 12, 2015
/s/ Steven Lefkowtiz Steven Lefkowitz	Director	March 12, 2015
/s/ Taunia Markvicka Taunia Markvicka	Director	March 12, 2015
/s/ Antony E. Pfaffle Antony E. Pfaffle	Chief Scientific Officer and Director	March 12, 2015

CORMEDIX INC. AND SUBSIDIARY

FINANCIAL STATEMENTS

Financial Statements Index

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

CorMedix, Inc.

We have audited the accompanying consolidated balance sheet of CorMedix, Inc. and Subsidiary (the "Company") as of December 31, 2014 and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficiency), and cash flows for the year ended December 31, 2014. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements 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 the financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2014 and the results of their operations and their cash flows for year ended December 31, 2014, 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 more fully described in Note 2, the Company has an accumulated deficit of $76.2 million as of December 31, 2014 and has incurred a loss from operations of $8.9 million for the year then ended. If the Company is unable to raise additional capital, their liquidity will only be sufficient to meet operating needs into the third quarter of 2015. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that may result from the outcome of these uncertainties. If the Company is unable to successfully raise additional capital to satisfy the obligations, there could be a material adverse effect on the Company.

/s/ Friedman LLP

East Hanover, NJ
March 12, 2015

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
CorMedix Inc.

We have audited the accompanying consolidated balance sheet of CorMedix Inc. and Subsidiary as of December 31, 2013, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficiency) and cash flows for the year then ended. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements 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 the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of CorMedix Inc. and Subsidiary as of December 31, 2013, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ CohnReznick LLP

Roseland, New Jersey
March 31, 2014

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
December 31, 2014 and 2013

	December 31, 2014	December 31, 2013
ASSETS		
Current assets		
Cash and cash equivalents	$ 4,339,540	$ 2,373,893
Restricted cash	-	220,586
Trade receivables	80,183	2,339
Inventories, net	463,029	80,021
Prepaid research and development expenses	-	6,205
Other prepaid expenses and current assets	155,210	232,987
Total current assets	5,037,962	2,916,031
Property and equipment, net	41,458	36,061
Deferred financing costs	-	2,366
Security deposit	18,342	13,342
TOTAL ASSETS	$ 5,097,762	$ 2,967,800
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities		
Accounts payable	$ 893,385	$ 939,785
Accrued expenses	521,525	713,179
Deferred rent	1,654	-
Deferred revenue	8,823	-
Dividend payable	-	21,117
Total current liabilities	1,425,387	1,674,081
Derivative liability	-	5,308,804
Deferred rent, long term	403	7,258
Deferred revenue, long term	37,500	-
TOTAL LIABILITIES	1,463,290	6,990,143
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIENCY)		
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 949,948 and 857,160 shares issued and outstanding at December 31, 2014 and 2013, respectively (See Note 8)	950	857
Common stock - $0.001 par value: 80,000,000 shares authorized; 22,461,668 and 16,606,695 shares issued and outstanding at December 31, 2014 and 2013, respectively	22,461	16,606
Deferred stock issuances	(110)	(146)
Accumulated other comprehensive gain (loss)	98,972	(9,323)
Additional paid-in capital	79,716,265	51,720,302
Accumulated deficit	(76,204,066)	(55,750,639)
TOTAL STOCKHOLDERS' EQUITY (DEFICIENCY)	3,634,472	(4,022,343)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)	$ 5,097,762	$ 2,967,800

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE GAIN (LOSS)
Years Ended December 31, 2014 and 2013

	December 31,	
	2014	2013
Revenue		
Net sales	$ 189,274	$ 2,001
Cost of sales	(445,799)	(201,605)
Gross loss	(256,525)	(199,604)
Operating Expenses		
Research and development	(1,318,734)	(1,226,874)
Selling, general and administrative	(7,326,861)	(3,488,917)
Total operating expenses	(8,645,595)	(4,715,791)
Loss From Operations	(8,902,120)	(4,915,395)
Other Income (Expense)		
Other income (expense)	-	(4,513)
Interest income	2,714	668
Foreign exchange transaction gain (loss)	(150,803)	-
Loss on issuance of preferred stock, convertible notes and warrants	(89,590)	(945,892)
Change in fair value of derivative liabilities	(8,848,953)	(363,919)
Loss on modification of equity instruments and extinguishment of derivative liabilities	(2,462,588)	-
Loss on extinguishment of convertible notes	-	(1,459,661)
Interest expense, including amortization and write-off of deferred financing costs and debt discounts	(2,087)	(1,444,386)
Net Loss	(20,453,427)	(9,133,098)
Other Comprehensive Loss		
Foreign currency translation gain (loss)	108,295	(9,323)
Comprehensive Loss	$ (20,345,132)	$ (9,142,421)
Net Loss	$ (20,453,427)	$ (9,133,098)
Dividends, including beneficial conversion feature	(82,899)	(384,307)
Net Loss Attributable To Common Shareholders	$ (20,536,326)	$ (9,517,405)
Net Loss Per Common Share – Basic and Diluted	$ (0.96)	$ (0.69)
Weighted Average Common Shares Outstanding – Basic and Diluted	21,441,906	13,823,130

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Years Ended December 31, 2014 and 2013

	Common Stock		Non-Voting Preferred Stock – Series A, Series B, Series C-1, Series C-2, Series C-3, Series D and Series E		Deferred Stock	Accumulated Other Comprehen-sive Gain	Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Issuances	(Loss)	Capital	Deficit	(Deficiency)
Balance at December 31, 2012	11,408,274	$ $11,408	-	$ -	$ (146)	$ -	$ 45,886,596	$ (46,233,234)	$ (335,376)
Series A non-voting preferred stock issued in February 2013 private placement at $0.70 per share, net			761,429	761			506,372		507,133
Conversion of Series A non-voting preferred stock to common stock and reclassification of derivative liability to equity	761,429	761	(761,429)	(761)			-	-	-
Deemed dividend related to beneficial conversion feature of Series A non-voting preferred stock							309,944	(309,944)	-
Series B non-voting preferred stock issued in July 2013 private placement at $1.10 per share, net			454,546	455			480,007		480,462
Deemed dividend related to beneficial conversion feature of Series B non-voting preferred stock							53,246	(53,246)	-
Repurchase of outstanding warrants							(33,000)		(33,000)
Stock-based compensation							1,345,136		1,345,136
Dividends related to Series D and Series E preferred stock								(21,117)	(21,117)
Warrants issued in connection with license agreement							76,574		76,574
Stock issued in connection with 9% senior convertible note at $0.35 per share	2,640,000	2,640					921,360		924,000
Stock issued in connection with 8% senior convertible note and interest conversion, fair value	1,009,238	1,009					866,557		867,566
Stock issued in connection with warrants exercised	677,754	678					59,322		60,000
Stock issued in connection with stock options exercised	10,000	10					2,390		2,400
Series C-1 and Series C-2 non-voting preferred stock issued in October 2013 financing at $10 per share, net, fair value			300,000	300			57,555		57,855
Conversion of Series C-1 non-voting preferred stock to common stock, fair value	100,000	100	(10,000)	(10)			69,015		69,105
Stock issued in connection with the exchange of 8% senior convertible notes and interest into Series D non-voting preferred stock, net, fair value			57,400	57			500,169		500,226
Stock issued in connection with the exchange of 8% senior convertible notes and interest into Series E non-voting preferred stock, net, fair value			55,214	55			619,059		619,114
Other comprehensive loss						(9,323)			(9,323)
Net loss								(9,133,098)	(9,133,098)
Balance at December 31, 2013	16,606,695	16,606	857,160	857	(146)	(9,323)	51,720,302	(55,750,639)	(4,022,343)

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Years Ended December 31, 2014 and 2013

	Common Stock		Non-Voting Preferred Stock – Series A, Series B, Series C-1, Series C-2, C-3, Series D and Series E		Deferred Stock	Accumulated Other Comprehen-sive Gain	Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares		Shares	Amount	Issuances	(Loss)	Capital	Deficit	(Deficiency)
Balance at December 31, 2013 (carried forward)	16,606,695	$ 16,606	857,160	$ 857	$ (146)	$ (9,323)	$ 51,720,302	$ (55,750,639)	$ (4,022,343)
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		2,447,384
Stock issued in connection with March 2014 public offering at $2.50 per unit, net	2,960,000	2,960					4,991,838		4,994,798
Reclassification of Series C-2 and Series C-3 preferred stock conversion option derivative liability to equity							6,235,398		6,235,398
Reclassification of derivative liabilities to equity from modification of various equity instruments including payment-in-kind dividends			53,788	54			11,740,809		11,740,863
Shares held in escrow upon achievement of certain milestone					36		(36)		-
Stock-based compensation							2,168,303		2,168,303
Stock issued in connection with warrants exercised	772,589	773					(773)		-
Stock issued in connection with stock options exercised	455,000	455					317,695		318,150
Conversion of wages and fees to common stock	57,384	57					96,794		96,851
Conversion of Series C-3 non-voting preferred stock to common stock	210,000	210	(21,000)	(21)			(189)		-
Other comprehensive gain						108,295			108,295
Net loss							-	(20,453,427)	(20,453,427)
Balance at December 31, 2014	22,461,668	$ 22,461	949,948	$ 950	$ (110)	98,972	$ 79,716,265	$ (76,204,066)	$ 3,634,472

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2014 and 2013

	December 31, 2014	December 31, 2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (20,453,427)	$ (9,133,098)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,168,303	1,345,136
Warrants issued in connection with license agreements	-	76,574
Amortization of deferred financing costs	-	282,886
Amortization of debt discount	-	1,054,255
Loss on foreign exchange transactions	150,803	-
Loss on issuance of preferred stock, convertible notes and warrants	89,590	945,892
Loss on modification of equity instruments and extinguishment of derivative liabilities	2,462,588	1,459,661
Non-cash interest expense	-	41,113
Inventory reserve	175,000	-
Revaluation of derivative liabilities	8,848,953	363,919
Depreciation	15,074	5,161
Changes in operating assets and liabilities:		
Restricted cash	220,586	(220,586)
Trade receivables	(85,412)	(2,279)
Inventory	(558,008)	(80,021)
Prepaid expenses and other current assets	72,958	(195,350)
Accounts payable	8,055	10,560
Accrued expenses and accrued interest	522,995	448,747
Accrued interest, related party	-	(16,175)
Deferred revenue	46,324	-
Deferred rent	(5,201)	(4,927)
Net cash used in operating activities	(6,320,819)	(3,618,532)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of equipment	(25,402)	(35,683)
Net cash used in investing activities	(25,402)	(35,683)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from senior convertible notes, net	-	686,250
Proceeds from senior convertible notes, related party, net	-	686,250
Proceeds from Series C-1 preferred stock, net	-	1,463,439
Proceeds from Series C-2 preferred stock, related party, net	-	1,463,439
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	-	60,000
Proceeds from exercise of stock options	318,150	2,400
Payment of deferred financing costs	(2,366)	(157,696)
Proceeds from sale of equity securities	6,723,248	1,033,000
Repurchase of outstanding warrants	-	(33,000)
Net cash provided by financing activities	8,357,916	5,204,082
Foreign exchange effect on cash	(46,048)	(11,445)
NET INCREASE IN CASH AND CASH EQUIVALENTS	1,965,647	1,538,422
CASH AND CASH EQUIVALENTS – BEGINNING OF YEAR	2,373,893	835,471
CASH AND CASH EQUIVALENTS – END OF YEAR	$ 4,339,540	$ 2,373,893

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

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2014 and 2013

	December 31,	
	2014	2013
Cash paid for interest	$ 2,074	$ 118,064
Supplemental Disclosure of Non Cash Financing Activities:		
Conversion of notes payable and accrued interest to common stock, fair value	$ -	$ 1,768,722
Exchange of convertible notes to preferred stock	$ -	$ 1,119,340
Conversion of preferred stock to common stock	$ 2,447,384	$ 602,105
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	$ 96,851	$ -
Dividend, including beneficial conversion feature	$ 82,899	$ 384,307
Accrued deferred financing costs	$ -	$ 2,366

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

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business:

CorMedix Inc. ("CorMedix" or the "Company") was incorporated in the State of Delaware on July 28, 2006. The Company seeks to in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious diseases in cardiac, renal and oncology patients. In 2013, the Company formed a wholly-owned subsidiary, CorMedix Europe GmbH. The Company has in-licensed all of the product candidates in its pipeline.

The Company's primary activities since incorporation have been organizational activities, including recruiting personnel, establishing office facilities, acquiring licenses for its pharmaceutical product candidates, performing business and financial planning, performing research and development, seeking regulatory approval for its products, and raising funds through the issuance of debt and equity securities.

The Company received CE Mark approval for Neutrolin in 2013 and began the commercial launch of 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 Austria, Germany, Italy, Malta, Saudi Arabia and The Netherlands for such treatment.

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

Note 2 — Liquidity and Going Concern:

The financial statements have been prepared in conformity with generally accepted accounting principles which contemplate continuation of the Company as a going concern. As of December 31, 2014, the Company has an accumulated deficit of $76.2 million, has incurred an operating loss of $8.9 million and a net loss of $20.5 million for the year then ended.

Management believes that the Company's existing cash at December 31, 2014 will be sufficient to meet the Company's operating needs and fund limited research and development into the third quarter of 2015, after giving effect to the receipt of approximately $2 million from the exercises of warrants and stock options subsequent to year end and the $2.5 million of availability under the "Backstop Agreement" (See Note 12). The Company's continued operations will depend on whether it is able to generate substantial revenue from the sale of Neutrolin and 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, until it achieves profitability, if ever. However, the Company can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. The Company expects to incur increases in its cash used in operations as it continues to commercialize Neutrolin in Europe and other foreign markets, increases its business development activities, incurs additional legal costs to defend its intellectual property and seeks FDA approval of Neutrolin in the U.S. These and other factors raise substantial doubt about the Company's ability to continue as a going concern.

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.

Note 3 — Summary of Significant Accounting Policies:

Significant Risks and Uncertainties

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 products, the Company's ability to obtain regulatory approval to market its products, 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.

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.

Cash and Cash Equivalents:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. 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.

Foreign Currency:

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.

Geographic Information:

The Company reported revenues of $189,274 and $2,001 for the years ended December 31, 2014 and 2013, respectively. Of the Company's 2014 revenue, $185,598 was attributable to its European and Mideast operations which are based in Germany. All of the Company's 2013 revenue was attributable to its European operations. Total assets at December 31, 2014 and 2013 were $5,097,762 and $2,967,801, respectively, of which $4,416,074 and $2,826,274 were located in the United States at December 31, 2014 and 2013, respectively, with the remainders in Germany. Net property and equipment at December 31, 2014 and 2013 were $41,458 and $36,061, respectively, of which $1,089 and $2,497 was located in the United States at December 31, 2014 and 2013, respectively, with the remainders located in Germany.

Restricted Cash:

As of December 31, 2014, the Company has no restricted cash. During the year ended December 31, 2013, the Company invested in a twelve-month 0.14% certificate of deposit held by the bank as collateral for a letter of credit in connection with the Company's purchase of raw materials due to be delivered in the next twelve months. The certificate of deposit terminated without penalties once the transaction covered by the letter of credit was completed. The certificate of deposit is recorded on the consolidated balance sheet as restricted cash.

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.

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, 2014	December 31, 2013
Raw materials	$ 293,976	$ 77,103
Work in process	166,807	-
Finished goods	2,246	2,918
Total	$ 463,029	$ 80,021

The Company has an inventory reserve of $175,000 and $0 at December 31, 2014 and 2013, respectively.

Property and Equipment:

Property and equipment consist primarily of furnishings, fixtures, leasehold improvements, office equipment and computer equipment which are recorded at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation of property and equipment 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, 2014 and 2013 were $41,458 and $36,061, respectively, net of accumulated depreciation of $77,277 and $62,283, 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:

	2014	2013
Licensing fee	$ -	$ 500,000
Royalty fee	10,000	-
Accrued payroll and payroll taxes	13,393	197,969
Professional and consulting fees	225,726	12,000
Market research	137,345	-
Monitoring program fees	82,861	-
Other	52,200	3,210
Total	$ 521,525	$ 713,179

Deferred Revenue:

In August 2014, the Company entered into an exclusive distribution agreement (the “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 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 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.

Revenue Recognition:

CorMedix recognizes revenue in accordance with SEC Staff Accounting Bulletin (“SAB”) No. 101, *Revenue Recognition in Financial Statements* (“SAB 101”), as amended by SAB No. 104, *Revenue Recognition* (“SAB 104”) and FASB Accounting Standards Codification (“ASC”) 605, *Revenue Recognition* (“ASC 605”). This guidance requires that 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.

CorMedix’s product 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.

Stock-Based Compensation:

The Company accounts for stock options according to the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") No. 718, "Compensation — Stock Compensation" ("ASC 718"). Under ASC 718, share-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense net of expected forfeitures, over the employee's requisite service period on a straight-line basis.

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 505. The non-cash charge to operations for non-employee options with time based vesting provisions is based upon the change in the fair value of the options and amortized to expense over the related vesting period.

For the purpose of valuing options and warrants granted to directors, officers, employees and consultants, the Company used the Black-Scholes option pricing model. For the purpose of valuing performance based options granted to non-employees, the Company uses the guidelines in accordance with FASB ASC No. 505-50 ("ASC 505"), "Equity-Based Payments to Non-Employees." 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 to be achieved which is typically when the performance condition is satisfied.

Valuations incorporate several variables, including expected term, expected volatility, expected dividend yield and a risk-free interest rate. The Company estimates the expected term of the options granted based on anticipated exercises in future periods. The expected stock price volatility for our stock options is calculated by examining historical volatilities for publicly traded industry peers, since the Company has limited trading history for its common stock. The Company will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for its common stock becomes available. The expected dividend yield reflects our current and expected future policy for dividends on its common stock. To determine the risk-free interest rate, the Company utilizes the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of its awards.

Stock compensation expense is recognized by applying the expected forfeiture rate during the vesting period to the fair value of the award. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, compensation expense may need to be revised. The Company considers many factors when estimating expected forfeitures for stock awards granted to employees, officers and directors, including types of awards, employee class, and an analysis of its historical forfeitures.

The Company records compensation expense associated with stock options and other forms of equity compensation using the Black-Scholes option-pricing model and the following assumptions:

	Year Ended December 31,	
	2014	2013
Risk-free interest rate	1.5% - 2.9%	0.34% - 2.88%
Expected volatility	74% - 113%	86% - 131%
Expected life of options in years	5 - 10 years	2 - 10 years
Expected dividend yield	0.0%	0.0%

Embedded Derivative Liabilities and Warrant Liabilities:

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks; however, the Company has several series of preferred stock and warrants that contained embedded derivatives. The Company 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.

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.

As discussed in Note 8, the warrants issued in March 2014, which do not have downround protection, were valued using a Black Scholes option pricing model.

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:

Under ASC 740, "Income Taxes" ("ASC 740"), 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. Under ASC 740, 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.

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 reflect 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. The following potentially dilutive shares have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive.

	December 31,	
	2014	2013
Series B non-voting preferred stock	454,546	454,546
Series C non-voting preferred stock	3,290,000	2,900,000
Series D non-voting preferred stock	1,479,240	1,148,000
Series E non-voting preferred stock	2,021,358	1,104,280
Shares underlying outstanding warrants	11,520,762	10,422,525
Shares underlying outstanding stock options	3,664,500	3,453,630
Total	22,430,406	19,482,981

Foreign Currency Exchange Transaction Gain (Loss):

The Company has intercompany loans that are in place between the parent company based in New Jersey and its German subsidiary. Effective October 1, 2014, the Company concluded 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 recognized in other comprehensive income totaling approximately $108,000 gain for the year ended December 31, 2014.

Fair Value Option:

As permitted under FASB ASC 825, *Financial Instruments*, ("ASC 825"), the Company elected the fair value option to account for its convertible notes that were issued during the year ended December 31, 2012 and matured during the year ended December 31, 2013. ASC 825 requires that the Company record the financial asset or financial liability at fair value rather than at historical cost with changes in fair value recorded in the statement of operations. In addition, it requires that upfront costs and fees related to items for which the fair value option is elected be recognized in earnings as incurred and not deferred.

Accounting Standards Updates:

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. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial condition, results of operations and cash flows.

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. Earlier adoption is permitted. The standard may be applied prospectively to all awards granted or modified after the effective date; or retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial condition, results of operations and cash flows.

Note 4 — Related Party Transactions:

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	CEO and Director	$ 237,000	23,700	118,500
MW Bridges LLC, an entity for which Randy Milby is Managing Partner		$ 13,000	1,300	6,500
Steven W. Lefkowitz	Director and Former Interim CFO	$ 45,000	4,500	22,500
Wade Capital Corporation Money Purchase Plan, an entity for which Steven W. Lefkowitz has voting and investment control		$ 30,000	3,000	15,000

[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.

Note 5 — Income Taxes:

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

	December 31, 2014	December 31, 2013
United States	$ (18,653,576)	$ (8,745,624)
Foreign	(1,799,851)	(387,474)
Total	$ (20,453,427)	$ (9,133,098)

There was no current or deferred income tax provision for the year ended December 31, 2014 or 2013.

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

	December 31, 2014	December 31, 2013
Net operating loss carryforwards – Federal	$ 12,928,000	$ 10,957,000
Net operating loss carryforwards – state	1,531,000	1,331,000
Net operating loss carryforwards –foreign	655,000	116,000
Capitalized licensing fees	2,135,000	2,361,000
Convertible debt and warrants	-	1,106,000
Stock-based compensation	1,457,000	690,000
Other	38,000	3,000
Totals	18,744,000	16,564,000
Less valuation allowance	(18,744,000)	(16,564,000)
Deferred tax assets	$ -	$ -

At December 31, 2014, the Company had potentially utilizable Federal, state and foreign net operating loss tax carryforwards of approximately $38,023,000, $25,772,000 and $2,183,000, respectively. The net operating loss tax carryforwards will start to expire in 2026 for Federal purposes and 2015 for state purposes. The foreign net operating loss tax carryforwards do not expire.

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

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

	December 31,	
	2014	2013
Statutory Federal tax rate	(34.0)%	(34.0)%
State income tax rate (net of Federal)	(0.6)%	(4.6)%
Effect of foreign operations	0.4%	0.2%
Non-deductible expenses associated with derivative liabilities	23.5%	-
Other permanent differences	(0.1)%	(0.6)%
Effect of valuation allowance	10.8%	39.0%
Effective tax rate	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, 2014 and 2013, 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 net change in the total valuation allowance for the years ended December 31, 2014 and 2013 was $2,180,000 and $3,031,000, respectively.

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, 2014	$ 16,564,000	$ 2,212,000	$ (32,000)	$ 18,744,000
December 31, 2013	13,533,000	3,031,000	-	16,564,000

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, 2014 and 2013. The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense.

The Company files income tax returns in the U.S. federal, state and foreign jurisdictions. Tax years 2011 to 2014 remain open to examination for both the U.S. federal and state jurisdictions. Tax years 2013 and 2014 remain open for Germany.

Note 6 — Commitments and Contingencies:

Operating Leases:

On March 18, 2010, the Company entered into a lease agreement with UA Bridgewater Holdings, LLC for office space located in Bridgewater, New Jersey, for an initial term of 60 months, with a commencement date of April 1, 2010, an expiration date of March 31, 2015, and lease payments beginning on July 1, 2010. In accordance with the lease agreement, the Company has deposited $13,342 with the landlord, the equivalent of two months' rent. The Company has been granted the option to extend the lease term for one additional period of three years, commencing the day following the then-current expiration date of the term, March 31, 2015, provided the Company delivers notice to the landlord no later than nine months prior to March 31, 2015. The Company did not elect to extend the lease term.

The Company entered into 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 has occupied the space beginning on March 1, 2015 for which month it is not obligated to pay rent, but must pay occupancy costs. Rent expense for the years ended December 31, 2014 and 2013, was $70,337 and $85,203, respectively.

The Company's subsidiary entered into a lease agreement for its offices in Fulda, Germany with ITZ GmbH. 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. Additionally, its subsidiary leases its copier pursuant to a lease agreement dated October 10, 2013 with Frima Buromaschinen Schafer GmbH & Co. KG. The lease has a term of 48 months which commenced on November 1, 2013 for a monthly payment of €59. The total 48 month lease obligation is approximately €2,800.

The Company's total remaining lease obligation as of December 31, 2014 is set forth below:

Years Ending December 31,		
2015	$	74,883
2016		66,236
2017		60,784
2018		15,000
Total	$	216,903

The Company believes that its existing facilities are adequate to meet its current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Other:

The Company has entered into various contracts with third parties in connection with the development of the licensed technology described in Note 10.

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland, or Geistlich, brought an action against the European Sodemann Patent covering our Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to the Company pursuant to the License and Assignment Agreement between the Company and ND Partners LLC. The action that was brought against the counterpart of the Sodemann Patent in Germany at the Board of the European Patent Office opposition division was for 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 Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. The Company filed a response to the appeal of Geistlich on March 25, 2009 where it requested a dismissal of the appeal and to maintain the patent as granted. As of March 27, 2014, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, the Company became aware that the Board of Appeals of the European Patent Office issued, on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the counterpart of the Sodemann Patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the counterpart of the Sodemann Patent claims. The Company received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. In a letter dated September 30, 2013, the Company was notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils 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 provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division has granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. 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 becomes final if no further appeal is lodged by Geistlich by January 15, 2015. As of the date of this report, the Company has not received a communication from the European Patent Office that Geistlich has filed such an appeal. The Company intends to continue to vigorously defend the patent in a restricted form. However, the Company can provide no assurances regarding the outcome of this matter.

On September 9, 2014, the Company filed in the Mannheim, Germany District Court 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 on January 8, 2014 (the "Prosl European Patent"). The Prosl European Patent covers a low heparin catheter lock solution for maintaining patency and preventing infection in a hemodialysis catheter. In this action, the Company 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. 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. An oral hearing in this action was scheduled for and held on January 30, 2015. The date for rendering judgment is scheduled for March 27, 2015. The judgment is subject to appeal. Separately, TauroPharm has filed an opposition with the European Patent Office 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 ND Partners' utility model DE 20 2005 022 124 U1 which is basically identical to the Prosl European Patent in its main aspects and claims. The Mannheim court separated the two proceedings so that the patent and the utility model proceeding are now tried separately and independently from each other due to the slightly differing requirements for both IP rights. An oral hearing with regard to the utility model has been scheduled for March 27, 2015. TauroPharm has filed a cancellation action against the utility model before the German Patent and Trademark Office based on the same arguments as the opposition against the Prosl Patent. The Company cannot predict what other defenses the Defendants may raise, or the ultimate outcome of this matter.

On January 16, 2015, the Company also filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, the Company allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of our proprietary information obtained in confidence by TauroPharm. The Company allege that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of its product Neutrolin®, which is approved for sale in Germany, in its manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100TM and TauroLock-HEP500TM. The Company seeks a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine as well as 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. A hearing in this matter has been scheduled in the District Court of Cologne for June 18, 2015.

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company does not anticipate recognizing any significant losses relating to these arrangements.

Note 7 — Equity Instruments Modification and Fair Value Measurements:

The fair value of the Company's cash, accounts receivable and accounts payable at December 31, 2014 approximate their carrying values due to the relative liquidity and/or short-term nature of these instruments. As defined by ASC Topic 820, *"Fair Value Measurements and Disclosures"* ("ASC 820"), fair value measurements and disclosures establish a fair value hierarchy that prioritizes fair value measurements based on the type of inputs used for the various valuation techniques (market approach, income approach and cost approach). The three levels of the fair value hierarchy under ASC 820 are described below:

- Level 1 - observable inputs such as quoted prices in active markets for identical assets or liabilities;
- Level 2 - inputs other than quoted market prices that are observable for the asset or liability, either directly or indirectly; these include quoted prices for similar assets or liabilities in active markets, such as interest rates and yield curves that are observable at commonly-quoted intervals; and
- Level 3 - unobservable inputs that reflect the Company's own assumptions, as there is little, if any, related market activity.

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.

	Fair Value Hierarchy Level	Fair Value December 31, 2013	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	$ 2,027,330	$ 599,814
Series D non-voting preferred stock conversion option issued in October 2013	3	901,625	2,017,960
Series E non-voting preferred stock conversion option issued in October 2013	3	735,619	1,786,902
Warrants issued in connection with convertible debt issued in May 2013	3	660,869	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	983,361	3,732,962
Warrants issued in March 2014 in connection with the private placement of common stock and warrants	3	-	(855,129)
Total		$ 5,308,804	$ 8,848,953

The Company's derivative liabilities are classified as Level 3. Changes in the unobservable input values would likely cause material changes in the fair value of the Company's Level 3 derivative liabilities. Significant unobservable inputs are implied volatilities. Significant increases (decreases) in implied volatilities in isolation would result in a significantly higher (lower) fair value measurement. The Company reviews these valuations and the changes in the fair value measurements for reasonableness.

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 issued in May 2013, October 2013 and March 2014, 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 from the Series C-2 preferred stock, Series C-3 preferred stock, Series D preferred stock and Series E preferred stock and the related warrants, as applicable, 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 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

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. The Company applied the accounting treatment prescribed for the modification of stock options under ASC 718 to the modification of the preferred stock and warrant instruments by analogy. The outstanding warrants and the preferred stock Series E and Series D hybrid instruments were 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 end of year	$ -

Note 8 — Stockholders' Equity (Deficiency):

Common Stock and Warrants:

During the year ended December 31, 2013, 9% senior convertible notes in the aggregate principal amount of $924,000 were converted at a conversion price of $0.35 per share resulting in the issuance of an aggregate 2,640,000 shares of the Company's common stock.

During the year ended December 31, 2013, the Series A non-voting convertible preferred stock was converted into 761,429 shares of the Company's common stock.

During the year ended December 31, 2013, warrants to purchase 150,000 shares of the Company's common stock were exercised resulting in gross proceeds of $60,000 to the Company.

During the year ended December 31, 2013, warrants to purchase 890,413 shares of the Company's common stock were exercised on a cashless basis resulting in the issuance of 527,754 shares of common stock.

During the year ended December 31, 2013, a portion of 8% senior convertible note in the principal amount of $750,000 was converted into common shares and interest in the aggregate amount of $36,313 which was paid in common shares resulting in the issuance of an aggregate 1,009,238 shares of the Company's common stock.

In December 2013, 10,000 shares of the Series C-1 preferred stock were converted into 100,000 shares of the Company's common stock.

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. 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. A holder is prohibited from exercising a warrant if, as a result of such exercise, the holder, together with its affiliates, would own more than 3.99% or 4.99%, at the holder's election, of the total number of shares of the Company's common stock then issued and outstanding. The Company received net proceeds of $6,723,248. 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. The Company revalued the warrants on September 15, 2014 immediately prior to the modification which resulted in a change in fair value recorded in other income (expense) in the statement of operations, and immediately subsequent to the modification which resulted in a loss on modification of equity instruments and extinguishment of derivative liabilities recorded in other income (expense) in the statement of operations. 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%

During the year ended December 31, 2014, stock options to purchase 455,000 shares of the Company's common stock were exercised resulting in gross proceeds of $318,150 to the Company.

During the year ended December 31, 2014, an aggregate of 140,000 shares of the Series C-1 non-voting preferred stock were converted into 1,400,000 shares of the Company's common stock.

During the year ended December 31, 2014, 21,000 shares of the Series C-3 non-voting preferred stock were converted into 210,000 shares of the Company's common stock.

During the year ended December 31, 2014, warrants to purchase 919,513 shares of the Company's common stock were exercised on a cashless basis resulting in the issuance of 772,589 shares of the Company's common stock.

During the year ended December 31, 2014, wages and board fees in an aggregate amount of $96,851 were converted into 57,384 shares of common stock by an officer and board member at prices of $1.32 - $2.00 per share.

During the year ended December 31, 2014, 35,886 shares of common stock held in escrow was released upon achievement of certain milestones.

Preferred Stock and Warrants

Under the terms of our Amended and Restated Certificate of Incorporation, as amended, our board of directors is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. 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, 2014			As of December 31, 2013		
	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference
Series B	454,546	$ 0.001	455	454,546	$ 0.001	455
Series C-1	-	10.000	-	140,000	10.000	1,400,000
Series C-2	150,000	10.000	1,500,000	150,000	10.000	1,500,000
Series C-3	179,000	10.000	1,790,000	-	-	-
Series D	73,962	21.000	1,533,202	57,400	7.000	401,800
Series E	92,440	49.200	4,548,048	55,214	16.400	905,510
Total	949,948		9,391,705	857,160		4,207,765

On September 15, 2014 the Company entered into consent and exchange agreements with investors holding its outstanding Series C-2, Series C-3, Series D, and Series E non-voting convertible preferred stock. The Company modified certain terms within the preferred stock, as described in Note 7, which resulted in the reclassification of the remaining derivative liability to equity.

The Company used a Monte Carlo simulation model to separately value the conversion options associated with the preferred stock instruments and the warrants issued in connection with the preferred stock. 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%

The following terms and conditions apply to all of the non-voting convertible preferred stock outstanding at December 31, 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 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, or mandatory sinking fund or analogous fund provisions.

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 do 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 A Non-Voting Convertible Preferred Stock and Warrants

On February 19, 2013, the Company sold 761,429 shares of its Series A non-voting convertible preferred stock and a warrant to purchase up to 400,000 shares of the Company's common stock for gross proceeds of $533,000. The Series A shares and the warrant were sold together at a price of $0.70 per share for each share of Series A stock. Each share of Series A stock was convertible into one share of the Company's common stock at any time at the holder's option. However, the holder would be prohibited from converting Series A stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 3.99% of the total number of shares of the Company's common stock then issued and outstanding.

The warrant was exercisable immediately upon issuance and had an exercise price of $1.50 per share and a term of five years. However, the holder would be prohibited from exercising the warrant if, as a result of such exercise, the holder, together with its affiliates, would own more than 3.99% of the total number of shares of the Company's common stock then issued and outstanding.

Because the Series A non-voting preferred stock was immediately convertible at the option of the holder, the Company recorded a deemed dividend of $309,944 from the beneficial conversion feature associated with the issuance of the Series A non-voting convertible preferred stock and the warrant for the year ended December 31, 2013.

During the year ended December 31, 2013, all of the Series A non-voting convertible preferred stock was converted into 761,429 shares of common stock.

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. The Series B shares and the warrant were sold together at a price of $1.10 per share for each share of Series B stock. Each share of Series B stock is convertible into one share of the Company's common stock at any time at the holder's option. However, the holder will be prohibited from converting Series B stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 3.99% of the total number of shares of the Company's common stock then issued and outstanding.

The Series B non-voting preferred stock ranks senior to the Company's common stock, senior to any class or series of the Company's capital stock hereafter created specifically ranking by its terms junior to the Series B preferred stock, on parity with the Series C-2 non-voting convertible preferred stock and the Series C-3 non-voting convertible preferred stock and any class or series of the Company's capital stock hereafter created specifically ranking by its terms on parity with the Series B non-voting convertible preferred stock; and junior to any class or series of the Company's capital stock hereafter created specifically ranking by its terms senior to the Series B non-voting convertible preferred stock. Shares of Series B non-voting convertible preferred stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B preferred stock will be required to amend the terms of the Series B non-voting convertible preferred stock or the certificate of designation for the Series B non-voting convertible preferred stock.

The warrant was exercisable immediately upon issuance and has an exercise price of $1.50 per share and a term of five years. However, the holder would be prohibited from exercising the warrant if, as a result of such exercise, the holder, together with its affiliates, would own more than 3.99% of the total number of shares of the Company's common stock then issued and outstanding.

Because the Series B non-voting preferred stock was immediately convertible at the option of the holder, the Company recorded a deemed dividend of $53,246 from the beneficial conversion feature associated with the issuance of the Series B non-voting convertible preferred stock and the warrant during the year ended December 31, 2013.

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

On October 22, 2013, the Company sold to existing institutional investors 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, for aggregate gross proceeds of $3,000,000. 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.

The Series C-1 non-voting preferred stock and Series C-2 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. However, the holder will be prohibited from converting Series C Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would 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 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.

Due to the existence of downround provisions, both the conversion features of the Series C Stock and the associated warrants are liability classified and are valued using a Monte Carlo model. On the issuance date, the estimated value of the conversion features and warrants was $1,953,965 and $915,058, respectively, and the fair value of the preferred stock, including additional paid-in capital, net of issuance cost was $57,855 during the year ended December 31, 2013.

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.

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 for each share of Series C-3 preferred stock. The Series C-3 non-voting convertible preferred stock has rights, privileges and terms that are identical to the Company's Series C Stock. Each share of Series C-3 preferred stock is convertible into 10 shares of common stock at any time at the holder's option. However, the holder is prohibited from converting Series C-3 non-voting convertible preferred stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding. 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. However, a holder is prohibited from exercising a warrant if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% or 9.99%, at the holder's election, of the total number of shares of the Company's common stock then issued and outstanding. Included in this financing was the settlement of an aggregate amount of $645,458 in accruals and payables owed to ND Partners, the Company's CEO for his 2013 salary, and a consultant. The Company received net proceeds of $1,318,884.

The Series C-1 non-voting convertible preferred stock that was previously designated has all been converted to shares of common stock during the years ended December 31, 2013 and 2014. The Series C-2 and Series C-3 non-voting preferred stock, referred to collectively as the Series C Preferred Stock, have identical rights, privileges and terms. The Series C Preferred Stock rank 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; on parity with the Series B non-voting convertible preferred stock; and junior to the Series D non-voting convertible preferred stock and Series E non-voting convertible preferred stock. Shares of Series C Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of two thirds of the outstanding Series C-2 and Series C-3 Preferred Stock, respectively, will be required to amend the terms of the Series C-2 and C-3 non-voting convertible preferred stock or the certificate of designation for the Series C-2 and C-3 preferred stock, respectively. As long as any of the Series C-2 Preferred Stock is outstanding, we 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.

As a result of the Series C-3 non-voting convertible preferred financing in January 2014, the anti-dilution provisions of the 8% senior convertible notes and the warrants issued with them caused the conversion price of the 8% senior convertible notes and the exercise price of the warrants to decrease from $1.10 to $1.00.

In February 2014, the downround protection of Series C-2 and Series C-3 non-voting convertible preferred stock was eliminated as, pursuant to its 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, resulting in the reclassification of the related derivative liability to equity in the amount of $6,235,398 (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 contain 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 receives 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

As described above, the Series D non-voting convertible preferred stock was issued in exchange for the extinguishment of $400,000 of convertible debt and $1,800 of interest which resulted in a loss on extinguishment of $930,708 during the year ended December 31, 2013.

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 was 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, Series B non-voting convertible preferred 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) and are entitled to receive dividends on shares of the Series D non-voting convertible preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

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 B non-voting convertible preferred stock, 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. Shares of Series D non-voting convertible preferred stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series D non-voting convertible preferred stock will be required to amend the terms of the Series D non-voting convertible preferred stock or the certificate of designation for the Series D 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

As described above, the issuance of the Series E non-voting convertible preferred stock in exchange for the extinguishment of convertible debt with a carrying value of $801,231 and $3,000 of accrued interest resulted in a loss on extinguishment of $495,326 during the year ended December 31, 2013.

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, Series B non-voting convertible preferred stock, the Series C-1 non-voting convertible preferred stock and 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) and are entitled to receive dividends on shares of the Series E non-voting convertible preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

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 B non-voting convertible preferred stock, 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 D non-voting convertible preferred stock. Shares of Series E non-voting convertible preferred stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series E non-voting convertible preferred stock will be required to amend the terms of the Series E non-voting convertible preferred stock or the certificate of designation for the Series E 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 of 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, which includes the dividends on the Series D non-voting convertible preferred stock and the Series E non-voting convertible preferred stock); 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 the 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.

The Company used a Monte Carlo model to separately value the Series C-1, C-2, 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 US 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.

Common Stock Options:

In March 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.

In 2006, the Company established a stock incentive plan (the 2006 "Plan") under which restricted stock, stock options and other awards based on the Company's common stock could be granted to the Company's employees, directors, consultants, advisors and other independent contractors. On January 28, 2010, the Company amended and restated the Plan to, among other things, increase the shares of common stock issuable under the 2006 Plan from 925,000 to 2,300,000. No stock options are available for issuance under the 2006 Plan when the 2013 Plan was approved.

During the year ended December 31, 2013, the Company granted to its officers and directors, ten-year non-qualified stock options under the 2013 Plan, covering an aggregate of 1,020,000 shares of the Company's common stock with an exercise price of $0.90 per share. The 310,000 options granted to four directors vest quarterly over two years. The remaining 710,000 options vest upon specified milestones. The Company recorded the pro rata expense for these options during the year ended December 31, 2013.

During the year ended December 31, 2013, the Company granted to various non-officer consultants ten-year non-statutory stock options under the 2013 Plan, covering an aggregate of 380,000 shares of the Company's common stock with an exercise price of $0.90 per share. Of these options, 260,000 vest upon specified performance milestones, and 120,000 options vest in three years. At December 31, 2013, 40,000 of these performance options were forfeited due to non-achievement of performance and 220,000 performance options were achieved. The Company recorded the value of the options on the date the performance was achieved. Additionally, the Company recorded the pro rata expense for the 120,000 options during the nine months ended September 30, 2013. No expense was recognized for the options subject to performance milestones that were not achieved or forfeited at December 31, 2013.

In March 2013, the Company's board of directors amended the vesting schedule of the options granted in December 2012 to various officers and directors of the Company for an aggregate of 765,000 ten-year stock options with an exercise price of $0.68 per share based on the closing price of the Company's common stock on the date of grant. Given the anticipated final approval for the CE Mark certification for Neutrolin® during the second quarter of 2013, 50% of such options were amended to vest on the date of issuance of the CE Mark certification for Neutrolin® in Europe, if the CE Mark approval was obtained on or before June 30, 2013 (as opposed to March 31, 2013 as previously provided by the board of directors). In June 2013, these options were further modified such that vesting would occur if the CE Mark was issued on or before July 14, 2013 (as opposed to June 30, 2013). During the quarter ended June 30, 2013, the Company reversed the expense recorded related to the previous value of the options and recorded the pro rata expense related to the modified value of these options. The expense was fully amortized through July 5, 2013, the date the CE Mark certification was received.

In August 2013, the Company's board of directors accelerated the vesting of an aggregate of 70,000 unvested options granted to the Company's former Chief Financial Officer at the time of his departure from the Company. Additionally, the exercise period of his total outstanding options was extended to two years from three months. These modifications resulted in an aggregate expense of $51,079 to the Company.

During the year ended December 31, 2013, an aggregate of 237,333 unvested stock options granted to its former Chief Medical Officer under the 2006 Plan were forfeited as a result of his departure from the Company. The Company reversed the recorded expense related to the forfeited stock options during year ended December 31, 2013.

During the year ended December 31, 2013, the Company granted to its various consultants, ten-year non-qualified stock options under the 2013 Plan, covering an aggregate of 414,000 shares of the Company's common stock with an exercise price of $0.90 per share. Of these options, 294,000 vest upon specified performance milestones, and 120,000 options vest in one year. At December 31, 2013, 30,000 of these performance options were forfeited due to non-achievement of performance and 90,000 performance options were achieved. The Company recorded the value of the options on the date the performance was achieved. Additionally, the Company recorded the pro rata expense for the 120,000 options during the year ended December 31, 2013. No expense was recognized for the options subject to performance milestones that were not achieved or forfeited at December 31, 2013.

During the year ended December 31, 2014, the Company granted to its officers, directors and employees, ten-year non-qualified stock options under the 2013 Plan, covering an aggregate of 1,185,000 shares, respectively, of the Company's common stock with exercise prices ranging from $1.80 to $2.79 per share. Of these options, 896,000 vested on the date of grant, 204,000 options vest one year after the grant date, 45,000 options vest two years after the grant date and 25,000 options vest three years after the grant date. The remaining 15,000 options are subject to certain performance milestones which were achieved during the year ended December 31, 2014, resulting in the vesting of 15,000 options in addition to the 896,000 options that vested on the date of grant.

During the year ended December 31, 2014, the Company granted to its consultants ten-year non-qualified stock options under the 2013 Plan, covering an aggregate of 396,000 shares, respectively, of the Company's common stock with exercise prices ranging from $1.40 to $2.24 per share. Of these options, 44,250 vested on the grant date, 18,750 options vest quarterly for a year, 40,000 options vest quarterly for two years from grant date and the remaining 293,000 options are subject to performance milestones. Some of these milestones were achieved at December 31, 2014 which resulted in the vesting of 50,000 options in addition to the 44,250 options that vested on the date of grant.

During the years ended December 31, 2014 and 2013, total compensation expense for stock options issued to employees, directors, officers and consultants was $2,168,303 and $1,345,136, respectively, in accordance with ASC 718 and ASC 505 for stock options issued to employees and non-employees.

A summary of the Company's stock options activity under the Plan and related information is as follows:

	Year Ended December 31, 2014		Year Ended December 31, 2013	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	3,453,630	$ 1.06	2,135,630	$ 1.26
Granted	1,581,000	$ 1.98	1,814,000	$ 0.90
Exercised	(455,000)	$ 0.70	(10,000)	$ 0.24
Cancelled	(574,630)	$ 2.65	(118,667)	$ 1.61
Forfeited	(340,500)	$ 1.13	(367,333)	$ 1.28
Outstanding at end of year	3,664,500	$ 1.25	3,453,630	$ 1.06
Outstanding at end of year expected to vest	481,835	$ 1.25	587,278	$ 0.90
Options exercisable	3,092,250	$ 1.15	2,490,880	$ 1.12
Weighted-average fair value of options granted during the year		$ 1.50		$ 0.76

The Company estimated the expected term of the stock options granted based on anticipated exercises in future periods. The expected term of the stock options granted to consultants is based upon the full term of the respective option agreements. Given the Company's short period of publicly-traded stock history, management's estimate of expected volatility is based on the average historical volatilities of a sampling of five companies with similar attributes to the Company, including: industry, stage of life cycle, size and financial leverage. The Company will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. 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. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, compensation expense may need to be revised. The Company considers many factors when estimating expected forfeitures for stock awards granted to employees, officers and directors, including types of awards, employee class, and an analysis of the Company's historical forfeitures.

The weighted average remaining contractual life of stock options outstanding at December 31, 2014 and 2013 is 8.2 years and 7.5 years, respectively. The weighted average remaining contractual life of stock options exercisable at December 31, 2014 is 8.0 years. 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. The aggregate intrinsic value of all stock options exercised during the year ended December 31, 2014 and 2013 was $636,250 and $6,100, respectively. The aggregate intrinsic value of outstanding stock options at December 31, 2014 and 2013 was $2,659,665 and $1,404,110, respectively.

As of December 31, 2014 and 2013 the total compensation expense related to non-vested options not yet recognized totaled $308,005 and $479,182, respectively. The weighted-average vesting period over which the total compensation expense related to non-vested options not yet recognized at December 31, 2014 and 2013 was approximately 0.5 years and 0.9 years, respectively.

Warrants:

The following table is the summary of warrant activity for the year ended December 31, 2014:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at beginning of period	10,422,525	$ 2.00	3.12
Granted	2,036,000	$ 2.19	5.11
Expired	(18,250)	-	-
Exercised	(919,513)	$ 0.41	-
Outstanding at end of period	11,520,762	$ 1.99*	2.57**

* Reflects reduced exercise prices of warrants as per September 15, 2014 amendment, see Note 7.

**Reflects extension of the expiration date of 503,034 warrants issued in connection with 2009 private placement from October 29, 2014 to December 31, 2014 then to March 31, 2015. The extension of the expiration dates resulted in deemed dividend attributable to common shareholders of $1,172.

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, 2014, the amount of compensation that was deferred under this plan was $21,826.

Note 9 — Convertible Notes:

On July 5, 2013, the Company received from existing institutional investors net proceeds of $1,372,500 upon approval of a CE Mark certification. The Company had entered into an agreement with existing stockholders in May 2013 for an aggregate principal amount of $1,500,000 of senior secured convertible notes and warrants to purchase up to an aggregate of 1,000,000 shares of its common stock. The receipt of net proceeds of $1,372,500 was dependent upon receipt of a CE Mark certification, which occurred on July 5, 2013. The notes bore interest at the rate of 8.0% per annum and were subject to a "make-whole" upon any conversion of the notes into common stock, as if the notes being converted were outstanding to April 1, 2014. Interest was first payable on September 3, 2013 and was payable on the first trading day of each month thereafter. The notes were to mature on April 1, 2016 unless redeemed prior to that date, subject to amortization, discussed below. A noteholder could elect to have any interest due prior to April 1, 2014 added to the principal amount of a note; thereafter, interest will be paid in cash only. The warrants are exercisable one year after issuance, have an exercise price of $1.10 per share, subject to anti-dilution adjustment, and a term of five years from the date they are first exercisable. The holders of the notes and warrants will be prohibited from converting the notes into or exercising the warrants for shares of common stock if, as a result of such conversion or exercise, the holder, together with its affiliates, would own more than 4.99% or 9.99%, respectively, at the initial holder's election, of the total number of shares of the Company's common stock then issued and outstanding.

The Company could redeem the notes in cash at par value or in shares of stock which are priced in accordance with a pricing formula set forth in the notes, in eight equal monthly installment payments beginning on September 1, 2013, and continuing thereafter on the first business day of each month, ending on April 1, 2014. At the Company's option, and if certain equity conditions are waived or satisfied, the Company could elect to pay these installment payments in shares of common stock, in cash, or in any combination of shares and cash. To the extent the Company paid all or any portion of an installment payment in common stock, the Company would deliver to each noteholder the amount of shares equal to the applicable installment payment being paid in shares of common stock, divided by the lower of (i) the conversion price then in effect, and (ii) 90% of the average of the 10 lowest-volume weighted-average prices of our common stock during the 20 trading day period ending two trading days prior to the applicable payment date (the "Company Conversion Price").

All installment payments were subject to the right of each noteholder to defer payment of some or all of any installment payment to a subsequent installment date or the maturity date, and, with respect to any installment date, convert, at the then-prevailing Company Conversion Price, any amount of principal and capitalized interest up to an amount equal to four installment payments. Each noteholder could also convert, at any time, all or a portion of any deferred installment payment. The Company Conversion Price for any such deferred installment payment would be the lower of the Company Conversion Price in effect on the date of the original installment date and the Company Conversion Price then in effect.

Due to the complexity and number of embedded features within the convertible note and as permitted under under ASC 825, the Company elected to account for the convertible notes and all the embedded features (collectively, the "hybrid instrument") under the fair value option. ASC 825 requires the entity to record the financial asset or financial liability at fair value rather than at historical cost with changes in fair value recorded in the statement of operations. In addition, it requires that upfront costs and fees related to items for which the fair value option is elected be recognized in earnings as incurred and not deferred. On the initial measurement date of July 5, 2013, the fair value of the hybrid instrument was estimated at $1,643,500, which was $143,500 higher than the principal amount of $1,500,000.

During the year ended December 31, 2013, the Company redeemed the 8% convertible notes in the principal amount of $750,000 and interest in the amount of $3,000 for an aggregate of 53,537 shares of its Series E non-voting preferred stock. Prior to the redemption, the convertible notes were revalued to fair value, resulting in a loss on revaluation of $4,640. The issuance of the 53,537 shares of the Series E non-voting preferred stock in exchange for the convertible notes resulted in a loss on extinguishment of $495,326. Also, during the fourth quarter of 2013, the balance of the convertible note in the principal amount of $298,750 was converted to common stock, resulting in an $8,148 gain from the revaluation of the portion of the note that was converted. The Company recorded $1,459,661 loss on extinguishment of convertible notes related to the conversions and redemptions during the year ended December 31, 2013 and a gain of $44,642 in the change in fair value of the converted amounts between the issuance date and the relevant conversion dates.

The Company used a Monte Carlo model to separately value the warrants issued in connection with the convertible notes in order to take into account the possibility of an adjustment to the exercise price associated with new rounds of financing in the future. The most likely exercise price of the warrants was estimated under various stock price scenarios and the noteholders' payoffs were computed under each scenario. The present value of the mean of such payoffs represents the value of the warrant on any given valuation date. When the stock price was simulated in the model, the possible scenarios were always between the valuation date stock price and the initial exercise price of $1.10. As a result, the Company estimated the fair value of the warrant liability on the issuance date to be $587,600.

A summary of the key assumptions used by the Company in the Monte Carlo simulation model to value the hybrid instrument at each of the relevant measurement dates during the year is 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 – Given that the Company recently received CE Mark approval for Neutrolin, the volatility used in the analysis was a weighted average of 1) the Company's historical volatility, 2) the Company's volatility after the receipt of CE approval and 3) the volatilities of comparable companies following the receipt of product approval. The resulting volatility used in the analysis was 75%.

Term – Based on an evaluation of the terms of the agreement, management has assumed that it would be advantageous for the holders of the Convertible Notes to redeem all installments by April 2014 rather than defer them to a later date.

Probability of Event of Default or Change in Control– Management has concluded that the probability of a change in control or event of default during the term of the hybrid instrument is only 5%.

Risk-free Rate – The US 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.

The following table is a rollforward for the year ended December 31, 2013 of the carrying amount of the convertible notes for which the fair value option was elected:

Balance at January 1, 2013	$ -
Issuance of convertible notes	1,643,500
Conversions and redemptions of convertible notes	(1,598,858)
Realized gain resulting from change in fair value on converted/redeemed note	(44,642)
Balance at December 31, 2013	$ -

All of the remaining convertible notes were converted into shares of common stock or the Company's Series E non-voting convertible preferred stock in the fourth quarter of 2013.

The following table is a rollforward for the year ended December 31, 2013 of the carrying amount of the warrant liability that was issued during the year ended December 31, 2013 in connection with the issuance of convertible notes and Series C-1 and Series C-2 non-voting preferred stock. The warrants are accounted for as a derivative liability and are valued using a Monte Carlo simulation model in order to take into account the possibility of adjustments to the exercise price resulting from additional rounds of financing. During the year ended December 31, 2013, there were no exercises of these warrants.

Balance at January 1, 2013	$ -
Issuance of warrants	1,502,658
Unrealized loss resulting from change in fair value	141,573
Balance at December 31, 2013	$ 1,644,231

Note 10 — License and Other Agreements:

On January 30, 2008, the Company entered into a License and Assignment Agreement (the "NDP License Agreement") with ND Partners LLC, a Delaware limited liability company ("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 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 the Company 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, 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 connection with this stock issuance, the Company recorded $328,948 of research and development expense in 2008. 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 Company was also obligated to issue additional shares of common stock to NDP sufficient to maintain its ownership percentage at 5.0% of the outstanding common stock (7.0%, including the escrow shares) on a fully diluted basis, until such time that the Company has raised $25 million through the sale of its equity securities or until an initial public offering, reverse merger or a sale of the Company. As a result of this obligation, in October 2009, the Company issued an additional 28,156 shares to NDP and an additional 11,263 shares into the escrow, at a price of $32.05 per share, in connection with the issuance of shares to Shiva under the Exchange Agreement, and in March 2010 the Company issued an additional 297,398 shares to NDP and an additional 118,288 shares into the escrow, at a price of $3.125 per share, in connection with the Company's IPO; however, such anti-dilution obligation terminated upon the completion of the IPO. The maximum aggregate number of shares issuable upon achievement of milestones is 145,543 shares. During the year ended December 31, 2014, certain milestone was achieved resulting in the release of 35,886 shares held in escrow. The number of shares held in escrow as of December 31, 2014 is 109,657 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, 2014. 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. Through December 31, 2014, no milestone payments have been earned by or paid to NDP.

On April 11, 2013, the Company entered into an amendment to the NDP License Agreement. Under Article 6 of the NDP License Agreement, the Company was obligated to make a milestone payment of $500,000 to ND Partners upon the first issuance of a CE Marking for a licensed product, which payment was payable to ND Partners within 30 days after such issuance. Pursuant to the terms of the amendment, the Company and ND Partners agreed to delay such milestone payment to a time, to be chosen by the Company, anytime within 12 months after the achievement of such issuance. As consideration for the amendment, the Company issued ND Partners a warrant to purchase 125,000 shares of the Company's 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. In January 2014, the Company settled this milestone payment which resulted in the issuance of 50,000 shares of the Company's Series C-3 non-voting convertible preferred and 250,000 shares issuable upon exercise of warrants at an exercise price of $1.25 per share which was decreased to $0.90 per share in January 2014, as described in Note 7.

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"). The Polaschegg License Agreement replaced the original license agreement between NDP and Dr. Polaschegg that the Company was assigned and the Company assumed under the NDP 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 sets 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. As compensation for Dr. Polaschegg's consulting services to be provided under the Polaschegg License Agreement, Dr. Polaschegg is being paid €200 per hour for services consisting of scientific work and €250 per hour for services consisting of legal work.

The Company may 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 will revert to Dr. Polaschegg.

During the years ended December 31, 2014 and 2013, the Company expensed $40,000 and $45,000, respectively, in connection with the Polaschegg License Agreement.

Navinta LLC, a U.S.-based Active Pharmaceutical Ingredient ("API") developer, provides API manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for CRMD003, pursuant to a supply agreement dated December 7, 2009 (the "Navinta Agreement"). The Navinta Agreement provides that Navinta 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 purchased a minimum of $350,000 of product from Navinta by December 30, 2010, which the Company achieved, and following the Company's first commercial sale of a product incorporating taurolidine, purchases a minimum of $2,250,000 of product on an annual basis for five years. The Company did not purchase the required amount in 2014 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. The maximum aggregate amount of such payments, assuming achievement of all milestones, is $1,975,000 over five years. The Navinta Agreement expires on March 31, 2015, but may be terminated by either party upon 30 days written notice.

On May 9, 2014, the Company entered into an employment agreement, effective March 31, 2014, with its Chief Executive Officer, Randy Milby. Unless renewed pursuant to the terms thereof, the agreement will expire on March 31, 2016. Pursuant to the agreement, the Company must use best efforts to cause Mr. Milby to be elected as a member of its Board of Directors and must include him in the management slate for election as a director at every stockholders meeting during the term of the agreement at which his term as a director would otherwise expire. Mr. Milby will not receive additional compensation for his services as a member of the Companys's Board of Directors.

In exchange for his service as the Company's Chief Executive Officer, Mr. Milby will receive an annual base salary of $300,000.00, up to 50% of which may be paid in the form of unregistered common stock at the discretion of Mr. Milby and subject to specified limitations. Mr. Milby will be eligible for an annual target bonus, the cash portion of which may equal up to 100% of his base salary then in effect, as determined by our Board or compensation committee. In determining such bonus, our Board or compensation committee will take into consideration the achievement of specified company objectives, predetermined by the Board, and specified personal objectives, predetermined by the Board and Mr. Milby. Mr. Milby's annual bonus, if any, will be paid in cash or a combination of cash and equity, provided that the equity portion will make up no more than 50% of the value of such annual bonus.

If the Company terminates Mr. Milby's employment for Cause as defined in the agreement, Mr. Milby will be entitled to receive only the accrued compensation due to him as of the date of such termination, all shares of restricted stock then held by him will be forfeited as of such date, and all unexercised options to purchase shares of the Company's capital stock, whether or not vested, will immediately terminate. If Mr. Milby resigns for other than Good Reason, he will be entitled only to payment of his accrued compensation as of such date. If the Company terminates Mr. Milby's employment other than for Cause, death or disability, or if Mr. Milby resigns for Good Reason (as each such term is defined below), Mr. Milby will continue to receive his base salary and benefits for a period of 12 months following the effective date of the termination of his employment, or, in the case of benefits, until such time as he receives equivalent coverage and benefits under plans and programs of a subsequent employer. All shares of restricted stock and all unvested options to purchase shares of our capital stock then held by Mr. Milby will be accelerated and deemed to have vested as of the effective date of the termination of his employment. To the extent any of the aforementioned benefits cannot be provided to former employees, the Company will pay Mr. Milby a lump-sum payment in the amount necessary to allow Mr. Milby to purchase the equivalent benefits. Upon a Change of Control of the company (as defined in the agreement), all shares of the company's restricted stock and all unvested options to purchase shares of the Company's capital stock then held by Mr. Milby will be accelerated and deemed to have vested as of the date of such Change of Control.

On July 21, 2014, the Company appointed Harry O'Grady as its Chief Financial Officer and Dr. Antony Pfaffle as its Chief Scientific Officer and entered into an agreement with each officer that provide the terms of their at will employment. Pursuant to their respective agreements, the Company will pay a base salary of $230,000 to Mr. O'Grady and $200,000 to Dr. Pfaffle. Mr. O'Grady will be eligible to participate in the Company's Short Term Incentive Plan ("STIP") beginning January 1, 2015, with a target award opportunity equal to 40% of his base salary. Dr. Pfaffle is eligible to participate in the STIP beginning on his employment date. His 2015 target award opportunity is equal to 30% of his base salary. Pursuant to his employment agreement, the Company also granted Mr. O'Grady an option to purchase 100,000 shares of the Company's common stock. If either officer's employment is terminated as a result of his death or disability, the Company will pay him or his estate, as applicable (i) his base salary for 180 days after the termination of his employment, and (ii) additional benefits, if any, as may be provided under applicable employee benefit plans, programs and arrangements of the Company. If the Company terminates either officer's employment without "cause" (as defined in the employment agreement) or the officer terminates his employment for "good reason" (as defined in the employment agreement), then the Company will (i) pay the officer his then-current salary for 12 months, and (ii) provide the officer such other benefits, if any, as may be provided under applicable employee benefit plans, programs and arrangements of the Company.

Note 11 — Concentrations:

During the year ended December 31, 2014, the Company recorded individual sales of $55,000 (29%) in excess of 10% of the Company's total sales. At December 31, 2014, approximately 68% of net accounts receivable was due from one customer.

Note 12 — Subsequent Events:

In January 2015, warrants to purchase 1,217,779 shares of the Company's common stock were exercised on a cashless basis resulting in the issuance of 857,324 shares of common stock.

In January and February 2015, 31,500 shares of Series C-3 preferred stock were converted into 315,000 shares of the Company's common stock.

In February 2015, stock options to purchase 30,000 shares of the Company's common stock were exercised resulting in gross proceeds of $63,000 to the Company.

In January through March 9, 2015, the following warrants were exercised, resulting in aggregate gross proceeds of approximately $2 million to the Company:

- 125,000 shares of the Company's common stock with exercise price of $0.90 per share;
- 305,000 shares of the Company's common stock with exercise price of $2.50 per share; and
- 321,844 shares of the Company's common stock with exercise prices of $3.4375 per share.

On March 3, 2015, the Company entered into a Backstop Agreement with an existing institutional investor, Manchester Securities Corp., an affiliate of Elliott Associates, L.P., pursuant to which Manchester has agreed to lend the Company, at its request, up to $4,500,000 less the dollar amount of gross proceeds received by the Company upon the exercise of warrants to purchase common stock issued in connection with its initial public offering on or before April 30, 2015, provided that the loan may not exceed $3,000,000, due to preferred stock agreement restrictions (See Note 8). The Company may access this financing until April 30, 2015. To access the loan, the Company must meet customary conditions. The loan would bear interest at 6% per annum and would be payable quarterly. The loan would be convertible into common stock of the Company at the lower of a) 80% of the closing price on the day preceding the issuance date of the Note or b) 80% of the average of the seven volume weighted average prices immediately prior to the issuance date of the Note. The loan would mature on April 30, 2020. In consideration for the backstop financing, the Company issued to Manchester a warrant, exercisable for five years, to purchase 200,000 shares of common stock at a per share exercise price of $7.00, and the Company extended by one year to March 24, 2016, the expiration date of a warrant that Manchester holds to purchase 390,720 shares of common stock at a per share exercise price of $3.4375.

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	3/02/2010	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 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 4, 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 21, 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	Specimen Unit certificate.	S-1/A	3/19/2010	4.2
4.3	Specimen warrant certificate.	S-1/A	3/19/2010	4.3
4.4	Form of warrant agreement.	S-1/A	3/19/2010	4.4
4.5	Common Stock Exchange and Stockholder Agreement, dated as of October 6, 2009, by and between CorMedix Inc. and Shiva Biomedical, LLC.	S-1	11/25/2009	4.6
4.6	Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC.	S-1	11/25/2009	4.7
4.7	Form of Third Bridge Warrant.	S-1/A	1/20/2010	4.18
4.8	Form of 9% Senior Convertible Note due 2013.	10-Q	11/13/2012	4.1
4.9	Form of Purchaser Warrant.	10-Q	11/13/2012	4.2
4.10	Form of Placement Agent Warrant.	10-Q	11/13/2012	4.3
4.11	Form of Subscription Agreement.	10-Q	11/13/2012	4.4
4.12	Form of Registration Rights Agreement.	10-Q	11/13/2012	4.5
4.13	Form of Senior Secured Convertible Note.	8-K	5/24/2013	4.19
4.14	Form of Warrant issued on February 19, 2013.	8-K	2/19/2013	4.13
4.15	Form of Warrant issued on May 30, 2013.	8-K	5/24/2013	4.20
4.16	Form of Warrant issued on July 30, 2013.	8-K	7/26/2013	4.21
4.17	Form of Warrant issued on October 22, 2013.	8-K	10/18/2013	4.22
4.18	Form of Warrant issued on January 8, 2014.	8-K	1/09/2014	4.23
4.19	Form of Warrant issued on March 10, 2014.	8-K	3/05/2014	4.24
4.20	Form of Warrant issued on March 3, 2015.	8-K	3/04/2015	4.1
4.21	Amended and Restated Warrant originally issued May 30, 2013.	8-K	3/04/2015	4.2
4.22	Amended and Restated Warrant originally issued March 24, 2010.	8-K	3/04/2015	4.3
4.23	Form of Convertible Note	8-K	3/04/2015	4.4
4.24	Registration Rights Agreement dated March 3, 2015, by and between Cormedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	4.5
10.4*	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC.	8-K	2/06/2015	10.1
10.5	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
10.6*	Exclusive License and Consulting Agreement, dated as of January 30, 2008, between the Company and Hans-Dietrich Polaschegg.	S-1/A	3/01/2010	10.7
10.7	Amended and Restated Consulting Agreement, dated as of January 10, 2008, between the Company and Sudhir V. Shah, M.D.	S-1	11/25/2009	10.11
10.8	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl.	S-1	11/25/2009	10.12
10.9*	Supply Agreement, dated as of December 7, 2009, between the Company and Navinta, LLC.	8-K	2/06/2015	10.1
10.10*	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
10.11	Amended and Restated 2006 Stock Incentive Plan.	S-1/A	3/01/2010	10.8

10.12	Form of Indemnification Agreement between the Company and each of its directors and executive officers.	S-1/A	3/01/2010	10.17	
10.14	Subscription Agreement by and between the Company and certain accredited investors (with attached schedule of parties thereto).	8-K	11/15/2012	10.1	
10.15	Amended and Restated Investment Banking Agreement, dated August 20, 2012, between the Company and John Carris Investments, LLC.	8-K	11/15/2012	10.2	
10.16	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	
10.17	Form of Securities Purchase Agreement, dated February 18, 2013, between CorMedix Inc. and the investor named therein.	8-K	2/19/2013	10.23	
10.18	Consulting Agreement, as amended December 24, 2012, between the Company and MW Bridges LLC.	10-K	3/27/2013	10.26	
10.19	2013 Stock Incentive Plan	10-K	3/27/2013	10.27	
10.20	Form of Securities Purchase Agreement, dated May 23, 2013, between CorMedix Inc. and the investor named therein.	8-K	5/24/2013	10.29	
10.21	Form of Securities Purchase Agreement, dated July 25, 2013, between CorMedix Inc. and the investor named therein.	8-K	7/26/2013	10.30	
10.22	Form of Securities Purchase Agreement, dated October 17, 2013, between CorMedix Inc. and the investor named therein.	8-K	10/18/2013	10.32	
10.23	Form of Securities Purchase Agreement, dated October 17, 2013, between CorMedix Inc. and the investor named therein.	8-K	10/18/2013	10.33	
10.24	Form of Securities Purchase Agreement, dated January 7, 2014, between CorMedix Inc. and the investors named therein.	8-K	1/09/2014	10.36	
10.25	Backstop Agreement, dated March 3, 2015, by and between Cormedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	10.1	
21.1	List of Subsidiaries	10-K	3/27/2013	21.1	
23.1	Consent of Independent Registered Public Accounting Firm.				X
23.2	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, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2014 and 2013, (ii) Statements of Operations for the years ended December 31, 2014 and 2013, (iii) Statements of Changes in Stockholders' Equity (Deficiency) for the years ended December 31, 2014 and 2013, (iv) Statements of Cash Flows for the years ended December 31, 2014 and 2013 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.

** 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.

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-170498 and 333-192840) and on Form S-3 (File Nos. 333-185737 and 333-185970) of CorMedix, Inc. and Subsidiary of our report dated March 12, 2015, relating to the consolidated financial statements which appear in this Form 10-K.

/s/ Friedman LLP

March 12, 2015
East Hanover, New Jersey

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements of CorMedix Inc. on Forms S-8 (File Nos. 333-170498 and 333-192840) and Forms S-3 (File Nos. 333-185737 and 333-185970) of our report, dated March 31, 2014 on our audit of the consolidated financial statements of CorMedix Inc. and Subsidiary as of December 31, 2013, and for the year then ended, which report is included in this Annual Report on Form 10-K of CorMedix Inc. for the year ended December 31, 2014.

/s/ CohnReznick LLP

Roseland, New Jersey
March 12, 2015

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Randy Milby, certify that:

1. I have reviewed this annual report on Form 10-K of CorMedix Inc. for the year ended December 31, 2014;

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

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

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

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

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

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

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

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

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

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

March 12, 2015

/s/ Randy Milby

Name: Randy Milby
Title: Chief Executive Officer
(Principal Executive Officer)

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

I, Harry O'Grady, certify that:

1. I have reviewed this annual report on Form 10-K of CorMedix Inc. for the year ended December 31, 2014;

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

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

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

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

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

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

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

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

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

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

March 12, 2015

/s/ Harry O'Grady

Name: Harry O'Grady
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the annual report of CorMedix Inc. (the "Company") on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Randy Milby, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

March 12, 2015

/s/ Randy Milby

Name: Randy Milby
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the annual report of CorMedix Inc. (the "Company") on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harry O'Grady, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

March 12, 2015

/s/ Harry O'Grady

Name: Harry O'Grady
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)