CorMedix Inc.
Form 10-K
March 15, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended: December 31, 2015

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	(Zip

if changed since last report)	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

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 ý

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 ý

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 ý 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 ý 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 ý
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 ý

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 $118.0 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 36,118,323 as of March 11, 2016.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2016 Annual Meeting of Stockholders are incorporated herein by reference, as indicated in Part III.

CORMEDIX INC.

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

PART I

Forward-Looking Statements

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

Item 1. Business

Overview

We in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious and inflammatory diseases. We have in-licensed the worldwide rights to develop and commercialize our product candidate, CRMD003 (Neutrolin®), which we believe addresses potentially large market opportunities in the instances in which a central venous catheter is used, such as hemodialysis, intensive care units, oncology and patients receiving total parenteral nutrition, IV hydration, and/or IV medications.

Neutrolin is an anti-infective solution 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 (U.S.). There are 250,000 catheter related bloodstream infections (CRBSIs) in the United States per year. 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 468,000 hemodialysis patients in the United States. 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. These hemodialysis patients represent over 127 million catheter/dialysis treatment days per year in the U.S., which we believe represents a conservative market potential of $300 to $400 million. The market in the critical care/intensive care units is 28.5 million catheter days per year in the United States alone. There were over 14.5 million patients living with cancer in the United States as of 2014 with an estimated 7.7 million having a long-term central venous catheter. However, when stages of disease, chemotherapy regimens and catheter types are factored, the oncology market represents 90 million catheter days. 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.

International

In late 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 then 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 late 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.

In July 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, Bahrain, Qatar, Kuwait, United Arab Emirates and The Netherlands for such treatment.

We have entered into agreements with a German contract sales company and with 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 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.

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.

United States

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 plan to conduct at least one Phase 3 clinical trial in hemodialysis catheters and one Phase 3 clinical trial in oncology/total parenteral nutrition. We worked with the FDA to design the protocol for a 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 could be initiated in the U.S.

In December 2015, our Phase 3 clinical trial in hemodialysis catheters or Catheter Lock Solution Investigational Trial (“LOCK-IT-100”) began with the enrollment and dosing of the first patient. The LOCK-IT-100 trial is a prospective, multicenter, randomized, double-blind, placebo-controlled, active control trial which aims to demonstrate the efficacy and safety of Neutrolin in preventing CRBSIs in subjects receiving hemodialysis therapy as treatment for end stage renal disease. The primary endpoint for the trial is freedom from CRBSIs. The trial will evaluate whether Neutrolin is superior to the active control heparin or normal saline control by documenting the incidence of CRBSI and the time until the occurrence of CRBSI. Key secondary endpoints are catheter patency which is defined as required use of tissue plasminogen activating factor (tPA) or removal of catheter due to dysfunction and catheter removal for any

reason. An exploratory endpoint of biofilm analysis will be evaluated in the first 200 catheters removed.

The FDA has 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 provides an additional five years of market exclusivity in addition to the five years granted for a New Chemical Entity. In addition, in January 2015, the FDA granted Fast Track designation to Neutrolin® Catheter Lock Solution, pursuant to the Food and Drug Administration Safety and Innovation Act (FDASIA) highlighting the large unmet need to prevent infections in the U.S, healthcare system. 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 was CRMD004, which is the gel formulation of Neutrolin that was in the pre-clinical stage of development. In November 2015, we terminated the license agreement covering CRMD004 and all rights to CRMD004 reverted to the licensor.

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 licensing product candidates, developing clinical trials for our product candidates, seeking regulatory approvals for Neutrolin, establishing manufacturing for our product candidate, 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 their vascular system in order to perform treatments on a multiple scheduled basis each week. According to the 2015 United States Renal Disease System, there were 468,000 patients on hemodialysis. It has been reported that patients requiring a catheter represent over 127 million catheter/dialysis treatment days per year. In the United States, there were 5.7 million intensive care patients representing 28.5 million catheter days associated with ICU stays alone. As of 2014, there were over 14.5 million patients in the United States living with cancer, with an estimated 7.7 million having had a long-term central venous catheter when stages of disease and types of chemotherapy regime are considered, the number of catheter days are 90 million. Infections and thrombosis represent key complications among cancer patients with central venous catheters. One of the major and common complications for all patients requiring central venous catheters is catheter related blood stream infections, or CRBSIs, and the clinical complications associated with them. There are an estimated 250,000 CRBSIs each year. The U.S. Centers for Disease Control and Prevention stated in the Journal of American Medicine, the total annual cost in the United States of treating all CRBI episodes and their complications would amount to approximately $6 billion.

Biofilm build up is the pathogenesis of both infections and thrombotic complications in central venous catheters. Prevention of CRBIs and inflammatory complications requires both decontamination of the internal surface of the catheter to prevent the systemic dissemination of organisms contained within the biofilm as well as an anticoagulant to retain patency. Biofilm forms when bacteria adhere to surfaces in aqueous environments and begin to excrete a slimy, glue-like substance that can anchor them to various types of materials, including intravenous catheters. The presence of biofilm has many adverse effects, including the ability to release bacteria into the blood stream. The current standard of catheter care is to instill a heparin lock solution at a concentration of 1,000 u/mL into each catheter lumen immediately following treatment, in order to prevent clotting between dialysis treatments. However, a heparin lock solution provides no protection from the risk of infection.

Currently, there are no pharmacologic agents approved in the U.S. for the prevention of CRBIs in central venous catheters. As noted above, we received the CE Mark approval for Neutrolin from the Medical Evaluation Board, or MEB, at the EU in July 2013.

We believe there is a significant need for prevention of CRBIs in the hemodialysis patient population as well as for other patient populations utilizing central venous catheters and peripherally inserted central catheters, such as oncology/chemotherapy, total parenteral nutrition and intensive care unit patients.

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

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 plan 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 4 clinical trial in ICU-critical care. We have worked with the FDA to design the protocol for the 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 could be initiated in the U.S. The Phase 3 clinical trial in hemodialysis catheters began in December 2015. 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 catheters, oncology/total parenteral nutrition and ICU-critical care.

Sales and Marketing Strategy

After CE Mark approval, we launched Neutrolin for 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 formed a European subsidiary, CorMedix Europe GmbH. We have entered into agreements with a German contract sales company and with a Saudi Arabian company to market and sell Neutrolin for hemodialysis and oncolytic patients in Germany and Saudi Arabia, respectively, and with 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.

We are seeking FDA approval to market our product Neutrolin® in the United States, which will require the successful completion of clinical studies and the submission of a new drug application (NDA) as the agency has informed us that they will regulate the product as a drug, rather than as a device, in this country. As part of the approval process, we intend to seek product labeling that would authorize the use of Neutrolin for the prevention of CRBIs and the maintenance of catheter patency in hemodialysis and oncology/total parenteral nutrition patients, and we intend to launch the product and make it commercially available throughout the United States within six months following FDA approval.

Initially, we expect to sell the product directly to hospitals and also to key dialysis center operators. We anticipate that Medicare reimbursement could be available for Neutrolin in other catheter indications in intensive care, oncology and

total parenteral nutrition through relevant hospital inpatient diagnosis-related groups (DRGs) or outpatient ambulatory payment classifications (APCs), the End-Stage Renal Disease Prospective Payment System (ESRD PPS) base payment, or under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule, depending on the setting of care. We also plan to seek separate reimbursement as a drug, where available under Medicare, through mechanisms such as pass-through status under the Hospital Outpatient Prospective Payment System, the transitional drug add-on payment adjustment under the ESRD PPS, or reimbursement as a drug used with a DME infusion pump. We cannot fully anticipate changes in reimbursement requirements and mechanisms in the coming years, however, and we cannot be certain that Neutrolin will be granted separate reimbursement under any of these mechanisms.

Furthermore, we anticipate that the U.S. Centers for Medicare & Medicaid Services (CMS), and private payers will increasingly demand that manufacturers demonstrate the cost effectiveness of their product as part of the reimbursement review and approval process. With this in mind, we have incorporated health economic evaluations into our ongoing clinical studies to support this review in the context of the prospective use of Neutrolin in dialysis, the ICU and oncology settings. Our studies might not be sufficient to support coverage or reimbursement at levels that allow providers to use Neutrolin.

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

Drug:

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

TauroLock, manufactured by Tauro-Implant (Winsen, Germany). TauroLock has received a CE Mark and is distributed in 25 countries. It has anti-microbial and anti-coagulant activity and contains a combination of citrate 4% with (cyclo)-taurolidine and heparin or urokinase TauroLock has four formulations: TauroLock, Tauro_lock Heparin 100, TauroLock Heparin 500 and TauroLock Urokinase 2500IU.

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

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

DuraLock-C, manufactured by Medical Components, Inc. (Harleysville,PA). DuraLock-C received a CE Mark and is distributed in a number of European Union countries. It has anti-microbial and anti-thrombosis activity and contains trisodium citrate in 46.7%, 30% and 4% concentrations.

IntraLock, manufactured by Fresenius Medical Care AG & Co. (Bad Homburg, Germany). IntraLock received a CE Mark and is distributed in a number of European Union countries. It is an anticoagulant solution to prevent thrombus formation in catheters. IntraLock contains citrate (4%) for anticoagulation and a small amount of polyhexanide for preservation.

TauroSept, manufactured by Geistlich Pharma (Wolhusen, Switzerland). TauroSept received Class 3 CE Mark and is distributed in a number of European Union countries. TauroSept contains 2% taurolidine solution, 5% polyvinylpyrrolidone and traces of HCl and NaOH to adjust pH. It contains no anticoagulant substances.

Medical Devices:

Tego® Needlefree Connector, manufactured by ICU Medical Inc. (California, USA) Tego Needlefree Connector received 510(k) clearance from the FDA. The Tego connector creates a mechanical and microbiology closed system when attached to the hub of the catheter and works with all hemodialysis CVC related applications.

Curos® (Luer-lock caps twist on, stay on) disinfecting port protectors designed specifically for Tego Needlefree Connectors, manufactured by Ivera Medical Corporation. Curos received 510 (k) clearance from the FDA. Curos for Tego Needlefree Connectors contains 70% isopropyl alcohol-saturated, sponge-like foam that disinfects ports in three minutes and keeps ports clean for seven days.

ClearGuard® HD End Caps for Hemodialysis Catheters, manufactured by Pursuit Vascular, Inc. ClearGuard HD End Caps received 510 (k) clearance from the FDA. The ClearGuard HD End Cap consists of 1) a copolyester polymer plug, which has a rod extending from the tier region that is coated with the antimicrobial agent chlorhexidine acetate (CHA) and 2) a nylon lock ring with threads that are also coated with CHA.

BioFlo DuraMax Dialysis Catheter with Endexo Technology, manufactured by AngioDynamics. The product received 510(k) clearance by the FDA. The BioFlo DuraMax chronic dialysis catheter features Endexo Technology, a catheter material more resistant to thrombus accumulation. Endexo technology is permanent, non-eluting polymer "blended" into the polyurethane from which the catheter is made.

Some device companies have launched antibiotic or antimicrobial-coated catheters as short-term prevention of catheter infection. 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.

On April 9, 2015, we announced a program aimed at reducing the cost of goods of Neutrolin through a more efficient, custom synthesis of the active ingredient taurolidine. As part of that program, on April 8, 2015, we entered into a Preliminary Services Agreement with [RC]2 Pharma Connect LLC ("RC2"), pursuant to which RC2 will coordinate certain manufacturing services related to taurolidine, which is a key ingredient in Neutrolin. Specifically, RC2 will undertake a critical parameters evaluation for our manufacturing needs and coordinate the cGMP processes set forth in the agreement that we believe are necessary for the submission of our planned new drug application for Neutrolin to the FDA, as well as any foreign regulatory applications. The total cost for RC2's services under the preliminary services agreement is approximately $1.7 million which is expected to be incurred under the terms of this agreement through the second quarter of 2016. Through December 31, 2015, RC2 completed and we recognized expense of approximately $227,000 for its services related to this agreement.

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

Navinta LLC, a U.S.-based active pharmaceutical ingredient, or API, developer, provides API manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for CRMD003, pursuant to a supply agreement dated December 7, 2009 (the "Navinta Agreement"). On March 24, 2015, we and Navinta LLC entered into an amendment to the Navinta Agreement to extend the term of the Navinta Agreement to March 31, 2016 and to lower the price per kilogram of API that we purchase from Navinta LLC under the Navinta Agreement. We also agreed to purchase a minimum amount of product from Navinta LLC during 2015, which replaced the prior minimum purchase requirement. The Navinta Agreement may be terminated by either party upon 30 days written notice. The Navinta Agreement is set to expire in accordance with its terms upon the delivery of API in early April of 2016.

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 ten years or more to complete. The FDA may prevent clinical trials from beginning or may place clinical trials on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. Trials may also be prevented from beginning or may be terminated by institutional review boards, 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 ten 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 endpoints of product effectiveness, thus accelerating the normal approval process. Where the FDA approves a product on the basis of a surrogate endpoint, 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 those countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current United States law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do

not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. to take advantage of differing regulatory requirements. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

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

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

Intellectual Property

CRMD003 and CRMD004

On January 30, 2008, we entered into a License and Assignment Agreement, or the NDP License Agreement, with ND Partners, LLC, or NDP. Pursuant to the NDP License Agreement, NDP granted us exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the "NDP Technology"). We acquired such licenses and patents through our assignment and assumption of NDP's rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann, and Dr. Johannes Reinmueller. NDP also granted us exclusive licenses, with the right to grant sublicenses, to use and display certain trademarks in connection with the NDP Technology. As consideration in part for the rights to the NDP Technology, we paid NDP an initial licensing fee of $325,000 and granted NDP an equity interest in our company consisting of 365,534 shares of common stock as of December 31, 2010. In addition, we are required to make payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The maximum aggregate number of shares issuable upon achievement of milestones and the number of shares held in escrow is 145,543 shares of common stock. During the year ended December 31, 2014, a certain milestone was achieved resulting in the release of 36,386 shares held in escrow. The number of shares held in escrow as of December 31, 2015 is 109,157 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. There were no milestones achieved in 2015.

On April 11, 2013, we entered into an amendment to the NDP License Agreement. Under Article 6 of the NDP License Agreement, we were obligated to make a milestone payment of $500,000 to NDP upon the first issuance of a CE Mark for a licensed product, which payment was payable to NDP within 30 days after such issuance. Pursuant to the terms of the amendment, we and NDP agreed to delay such milestone payment to a time, to be chosen by us, anytime within twelve months after the achievement of such issuance. As consideration for the amendment, we issued NDP a warrant to purchase 125,000 shares of our common stock at an exercise price of $1.50 per share. The warrant is exercisable immediately upon issuance and has a term of five years. The warrant contains a cashless exercise feature and standard adjustment features in the event of a stock split, stock dividend, recapitalization or similar events. During the year ended December 31, 2013, a milestone payment of $500,000 was earned by NDP upon the first issuance of the CE Mark for Neutrolin, which was converted in January 2014 into 50,000 Series C-3 non-voting preferred stock and 250,000 warrants at an exercise price of $1.50 per share.

The NDP License Agreement will expire on a country-by-country basis upon the earlier of (i) the expiration of the last patent claim under the NDP License Agreement in a given country, or (ii) the payment of all milestone payments and release of all shares of our common stock held in escrow under the NDP License Agreement. Upon the expiration of

the NDP License Agreement in each country, we will have an irrevocable, perpetual, fully paid-up, royalty-free exclusive license to the NDP Technology in such country. The NDP License Agreement also may be terminated by NDP if we materially breach or default under the NDP License Agreement and that breach is not cured within 60 days following the delivery of written notice to us, or by us on a country-by-country basis upon 60 days prior written notice. If the NDP License Agreement is terminated by either party, our rights to the NDP Technology will revert back to NDP.

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

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

We believe that the patents and patent applications we have licensed pursuant to the NDP License Agreement cover effective solutions to the various problems discussed previously when using taurolidine in clinical applications, and specifically in hemodialysis applications. We intend to file additional patent applications to cover any additional related subject matter we develop. We filed five provisional patents covering additional applications using taurolidine in sutures, hydrogels and mesh products.

Employees

As of March 11, 2016, we had nine 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.

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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 2016.

We were established in July 2006 and have only a limited operating history. 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 $18.2 million for the year ended December 31, 2015. As of December 31, 2015, we had an accumulated deficit of approximately $94.4 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trial and commercialization activities increase as we develop and commercialize Neutrolin. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Neutrolin was launched in December 2013 and is currently available for distribution in Germany, Austria, The Netherlands, Malta, Italy, The Kingdom of Saudi Arabia, Bahrain, Qatar, Kuwait and United Arab Emirates. We have not generated any significant commercial revenue and do not expect to generate substantial revenues from Neutrolin until it is approved by the FDA and launched in the U.S. market, and might never generate significant revenues from the sale of Neutrolin or any other products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following: successfully marketing Neutrolin in Germany and other countries in which it is approved for sale; obtaining necessary regulatory approvals for Neutrolin from the other applicable European and Middle East agencies, other foreign agencies and the FDA and international regulatory agencies for any other products; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We 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 and generate substantial earnings from it, 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 including the ongoing and planned clinical trials, seek regulatory approvals for Neutrolin, 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, Malta, the Kingdom of Saudi Arabia, Bahrain, Qatar, Kuwait and the United Arab Emirates but to date have no other approved product on the market and have not generated significant product revenue from Neutrolin to date. Unless and until we receive applicable regulatory approval for Neutrolin in the U.S., we cannot sell Neutrolin in the U.S. Therefore, for the foreseeable

future, we will have to fund all of our operations and capital expenditures from Neutrolin sales in Europe and other foreign markets, if approved, cash on hand, additional financings, licensing fees and grants.

We believe that our cash resources as of December 31, 2015, will be sufficient to enable us to fund our projected operating requirements for at least the next twelve months following the balance sheet date. However, we need to raise additional funds during 2016 to fund our ongoing hemodialysis clinical trial and our planned Phase 3 oncology/total parenteral nutrition clinical trial in the U.S. If we are unable to raise additional funds when needed, we may not be able to complete our ongoing and planned Phase 3 clinical trials or commercialize Neutrolin and we could be required to delay, scale back or eliminate some or all of our research and development programs. We can provide no assurances that any financing or strategic relationships will be available to us on acceptable terms, or at all. We expect to incur increases in our cash used in operations as we continue to commercialize Neutrolin in Europe and other markets, prepare for and undertake our ongoing and planned Phase 3 clinical trials, pursue business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S.

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

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

In March 2015, the Board commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. The Board engaged the investment bank Evercore Group L.L.C. to provide financial advice and assist the Board with its evaluation process. No transaction has materialized to date and there can be no assurance that any transaction will result. 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. We continue to retain Evercore and will work with them as potential opportunities are presented to us. 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 only product is only recently 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 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 candidate is 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; and

CRMD003 (Neutrolin) - Phase 3 trial in hemodialysis catheters initiated in December 2015; planned Phase 3 trial in oncology/total parenteral nutrition expected to initiate in fourth quarter of 2016, 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.

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 a German company to market and sell Neutrolin in Germany, which launched in Germany in the fourth quarter of 2013. We also have entered into agreements with a Saudi Arabian company to market and sell Neutrolin in Saudi Arabia, and with a South Korean company to market, sell and distribute Neutrolin in South Korea upon receipt of regulatory approval in that country. We also have independent sales representatives in the United Arab Emirates 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 2 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. We have received approval from the FDA to proceed with our ongoing Phase 3 clinical trial for Neutrolin in hemodialysis catheters and our planned Phase 3 trial in oncology/total parenteral nutrition. In December 2015, we initiated the Phase 3 trial in hemodialysis catheters however, we will not initiate the oncology/total parenteral nutrition trial until we receive sufficient funding. We are seeking one or more strategic partners or other sources of capital to complete the Phase 3 trial in hemodialysis and to start the Phase 3 trial for oncology/total parenteral nutrition. However, we might not obtain any commercial partner or financing and may never start the Phase 3 clinical trial for oncology/total parenteral nutrition.

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

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

Once a product is approved, numerous post-approval requirements apply in the United States and abroad. Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA, foreign and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA or a foreign regulatory body to modify or withdraw product approval.

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

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and/or private health insurers, both in the U.S. and abroad. Further, significant uncertainty exists as to the reimbursement status of newly approved health care products. We initially expect to sell Neutrolin directly to hospitals and key dialysis center operators, but also plan to expand its usage into intensive care, oncology and total parenteral nutrition patients needing catheters, including Medicare patients. All of these potential customers are healthcare providers who depend upon reimbursement by government and commercial insurance payors for dialysis and other treatments. Reimbursement is strictly governed by these insurance payors. We believe that Neutrolin would be eligible for coverage under various reimbursement programs, including hospital inpatient diagnosis-related groups (DRGs), outpatient ambulatory payment classification (APCs) and the End-Stage Renal Disease Prospective Payment System (ESRD PPS) or under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule, depending on the treatment setting. However, coverage by any of these reimbursement programs is not assured, and even if coverage is granted it could later be revoked or modified under future regulations. Further, the U.S. Centers for Medicare & Medicaid Services (CMS), which administers Medicare and works with states to administer Medicaid, has adopted and will continue to adopt and/or amend rules governing reimbursement for specific treatments, including those we intend to address such as dialysis and ESRD PPS. We anticipate that CMS and private insurers will increasingly demand that manufacturers demonstrate the cost effectiveness of their products as part of the reimbursement review and approval process. Rising healthcare costs have also lead many European and other foreign countries to adopt healthcare reform proposals and medical cost containment measures. Any measures affecting the reimbursement programs of these governmental and private insurance payors, including any uncertainty in the medical community regarding their nature and effect on

reimbursement programs, could have an adverse effect on purchasing decisions regarding Neutrolin, as well as limit the prices we may charge for Neutrolin. The failure to obtain or maintain reimbursement coverage for Neutrolin or any other products could materially harm our operations.

Physicians and patients may not accept and use our products.

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

perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product;

cost-effectiveness of our product relative to competing products;

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

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

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

Risks Related to Our Business and Industry

We are subject to a putative securities class action, which may require significant management time and attention and significant legal expenses and may result in an unfavorable outcome, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We and certain of our officers have been named as defendants in a putative securities class action lawsuit that generally alleges that we and certain of our current and former officers violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act by making materially false or misleading statements and omissions concerning among other things, the competitor landscape for our Neutrolin product, and the alleged use of stock promoters. While we believe that we have substantial legal and factual defenses to the claims in the class action and intend to vigorously defend the case, this lawsuit could divert management's attention from our ordinary business operations, the outcome of the pending litigation is difficult to predict and quantify, and the defense against the underlying claims could be costly. The ultimate resolution of this matter could result in payments of monetary damages or other costs, materially and adversely affect our business, financial condition, results of operations and cash flows, or adversely affect our reputation, and consequently, could negatively impact the trading price of our common stock.

We have various insurance policies related to the risks associated with our business, including directors' and officers' liability insurance policies. However, there is no assurance that our insurance coverage will be sufficient or that our insurance carriers will cover all claims in that litigation. If we are not successful in our defense of the claims asserted in the putative class action and those claims are not covered by insurance or exceed our insurance coverage, we may have to pay damage awards, indemnify our officers from damage awards that may be entered against them and pay the costs and expenses incurred in defense of, or in any settlement of, such claims.

In addition, there is the potential for additional shareholder litigation, and we could be similarly materially and adversely affected by such matters.

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

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

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

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

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

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

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

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

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

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

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

Market acceptance and sales of Neutrolin or any other product candidates that we develop will depend on reimbursement policies and may be affected by health care reform measures in the United States and abroad. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for Neutrolin or any other product candidates that we develop. Also, we cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize Neutrolin or any other product candidates that we develop.

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

In addition to the Healthcare Reform Act, we expect that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Certain of these changes could impose limitations on the prices we will be able to charge for any products that are approved or the amounts of reimbursement available for these products from governmental agencies or other third-party payors or may increase the tax requirements for life sciences companies such as ours. While it is too early to predict what effect the Healthcare Reform Act or any future legislation or regulation will have on us, such laws could have an adverse effect on our business, financial condition and results of operations.

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

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

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

We are highly dependent on the principal members of our management and scientific staff, specifically, Randy Milby, a director and our Chief Executive Officer, and Dr. Antony Pfaffle, a director and Chief Scientific Officer. Mr. Milby is expected to transition out of his role as Chief Executive Officer and we have begun a search for his replacement. Our future success will depend in part on our ability to identify, hire, and retain additional personnel including a new Chief Executive Officer. We experience intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of our business. Moreover, our work force is located in the New Jersey metropolitan area, where competition for personnel with the scientific and technical skills that we seek is extremely high and is likely to remain high. Because of this competition, our compensation costs may increase significantly. In addition, we have only limited ability to prevent former employees from competing with us.

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

Over time, we expect to hire additional qualified personnel with expertise in clinical testing, clinical research and testing, government regulation, formulation and manufacturing, and sales and marketing. We compete

for qualified individuals with numerous pharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining such qualified personnel will be critical to our success.

We may not successfully manage our growth.

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

Risks Related to Our Intellectual Property

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

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

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

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

U.S. Patent No. 8,541,393 (expiring in November 2024) (the “Prosl Patent”) - use of Neutrolin for preventing infection and maintenance of catheter patency in hemodialysis catheters (for CRMD003);

U.S. Patent No. 6,166,007 (expiring May 2019) (the “Sodemann Patent”) - a method of inhibiting or preventing infection and blood coagulation at a medical prosthetic device (for CRMD003); and

European Patent EP 1 814 562 B1 (expiring October 12, 2025) (the “Prosl European Patent”) - a low heparin catheter lock solution for maintaining and preventing infection in a hemodialysis catheter.

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

patents that may be issued or licensed may be challenged, invalidated, or circumvented, or otherwise may not provide any competitive advantage;

our competitors, many of which have substantially greater resources than we have and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets;

there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful as a matter of public policy regarding worldwide health concerns; and

countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

In addition, the United States Patent and Trademark Office, or PTO, and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated.

The above mentioned patents and patent applications are exclusively licensed to us. To support our patent strategy, we have engaged in a review of patentability and certain freedom to operate issues, including performing certain searches. However, patentability and certain freedom to operate issues are inherently complex, and we cannot provide assurances that a relevant patent office and/or relevant court will agree with our conclusions regarding patentability issues or with our conclusions regarding freedom to operate issues, which can involve subtle issues of claim interpretation and/or claim liability. Furthermore, we may not be aware of all patents, published applications or published literature that may affect our business either by blocking our ability to commercialize our product candidates, preventing the patentability of our product candidates to us or our licensors, or covering the same or similar technologies that may invalidate our patents, limit the scope of our future patent claims or adversely affect our ability to market our product candidates.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we take measures to protect this information by entering into confidentiality and inventions agreements with our employees, scientific advisors, consultants, and collaborators, we cannot provide any assurances that these agreements will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure if they are breached, or that our trade secrets will not otherwise become known or be independently discovered by competitors. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of our intellectual property may be greatly reduced.

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

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may initiate or become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or we may become subject to proceedings initiated by our competitors or other third parties or the PTO or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. In addition, litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others.

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

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland (“Geistlich”) brought an action against the European Sodemann Patent covering our Neutrolin product candidate, which is owned by ND Partners, LLC (“NDP”) and licensed to us pursuant to the License and Assignment Agreement between us and NDP. This action was brought at the Board of the European Patent Office (“EPO”) opposition division (the “Opposition Board”) based upon alleged lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions of the prior art. The Opposition Board rejected the opposition by Geistlich. 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 requesting a dismissal of the appeal and maintenance of the patent as granted. On November 28, 2012, the Board of Appeals of the EPO (the “Appeals Board”) 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 claims of the counterpart of the Sodemann Patent. We received the Appeals Board’s 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 EPO reopened the proceedings before the first instance and gave their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfills the requirements of clarity, novelty, and inventive step, and invited the parties to provide their comments and/or requests by February 10, 2014. We filed 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 Opposition

Board 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 became final as no further appeal was lodged by Geistlich.

On September 9, 2014, we filed in the District Court of Mannheim, Germany a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of our European Patent EP 1 814 562 B1, which was granted by the EPO on January 8, 2014 (the "Prosl European Patent"). The Prosl European Patent covers a low dose heparin catheter lock solution for maintaining patency and preventing infection in a hemodialysis catheter. In this action, we claim that the Defendants infringe on the Prosl European Patent by manufacturing and distributing catheter locking solutions to the extent they are covered by the claims of the Prosl European Patent. We believe that our patent is sound, and are seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. Separately, TauroPharm has filed an opposition with the EPO against the Prosl European Patent alleging that it lacks novelty and inventive step. We cannot predict what other defenses the Defendants may raise, or the ultimate outcome of either of these related matters. In the same complaint against the same Defendants, we also alleged an infringement (requesting the same remedies) of NDP's utility model DE 20 2005 022 124 U1 (the "Utility Model"), which we believe is fundamentally identical to the Prosl European Patent in its main aspects and claims. The Court separated the two proceedings and the Prosl European Patent and the Utility Model claims are now being tried separately. TauroPharm has filed a cancellation action against the Utility Model before the German Patent and Trademark Office based on the similar arguments as those in the opposition against the Prosl European Patent.

On March 27, 2015, the District Court held a hearing to evaluate whether the Utility Model has been infringed by TauroPharm in connection with the manufacture, sale and distribution of its TauroLock-HEP100TM and TauroLock-HEP500TM products. A hearing before the same court was held on January 30, 2015 on the separate, but related, question of infringement of the Prosl European Patent by TauroPharm. The Court issued its decisions on May 8, 2015 staying both proceedings. In its decisions, the Court found that the commercialization by TauroPharm in Germany of its TauroLock catheter lock solutions Hep100 and Hep500 infringes both the Prosl European Patent and the Utility Model and further that there is no prior use right that would allow TauroPharm to continue to make, use or sell its product in Germany. However, the Court declined to issue an injunction in favor of us that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the EPO, in the case of the Prosl European Patent, or the German Patent and Trademark Office (the "German PTO"), in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by us for injunctive and other relief until such time as the EPO or the German PTO has ruled on the underlying validity of the Prosl European Patent and the Utility Model.

Both the opposition proceedings against the Prosl European Patent before the EPO and the cancellation action against the Utility Model before the German PTO are ongoing. In its preliminary consideration of the matter, the EPO (and the German Patent and Trademark Office) regarded the patent as not inventive or novel due to publication of prior art. Oral proceedings before the Opposition Division at the EPO were held on November 25, 2015, at which the three judge patent examiner panel considered arguments related to the validity of the Prosl European Patent. As with the unfair competition matter, we expect that this matter will be under review and consideration by the Office for some time, with a determination not likely to be made before mid-2016. While we continue to believe that the referenced publication and instructions for use do not, in fact, constitute prior art and that the Prosl European Patent and the Utility Model validly claim inventions that will be found to be such by the EPO and the German PTO, there can be no assurance that we will prevail in this matter. We do not expect a decision from the German PTO in the Utility Model matter before the middle of 2016, with any such decision being subject to appeal.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture

of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider our claims. On January 14, 2016, the court issued an interim order seeking to clarify the facts and to substantiate the assertions made, in particular with regard to establishing the specific know-how that was provided to TauroPharm, and the details as to its provision. We expect to reply and produce the respective documentation. A date for a further oral hearing has not been scheduled as yet.

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

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

obtain licenses, which may not be available on commercially reasonable terms, if at all;

abandon an infringing product candidate;

redesign our products or processes to avoid infringement;

stop using the subject matter claimed in the patents held by others;

pay damages; or

defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Risks Related to Dependence on Third Parties

If we are not able to develop and maintain collaborative marketing relationships with licensees or partners, or create an effective sales, marketing, and distribution capability, we may be unable to market our products or market them successfully.

Our business strategy for Neutrolin relies on collaborating with larger firms with experience in marketing and selling medical devices and pharmaceutical products; for other products we may also rely on such marketing collaborations or out-licensing of our product candidates. Specifically, for Neutrolin, we have entered into an agreement with a German company to market and sell Neutrolin in Germany and a distributor agreement with each of a Saudi Arabian and a South Korean company for sales and marketing in those two countries (upon receipt of approval to market in South Korea). In addition, we have independent sales representatives marketing and selling in the Middle East 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 currently rely and intend to continue to rely on third parties to market and sell Neutrolin. If we are unable to enter into or maintain agreements with third parties to market and sell Neutrolin or any other product after approval or are unable to establish our own marketing and sales capabilities, we may not be able to generate significant or any product revenues.

We do not have an internal sales organization. To date we have relied, and intend to continue to rely, on third parties for the marketing, sales and distribution of Neutrolin and any other product we might develop. However, we may not be able to maintain current and future arrangements or enter into new arrangements with third parties to sell Neutrolin or any other product on favorable terms or at all. In that event, we would have to develop our own marketing and sales force. The establishment and development of our own sales force would be expensive and time consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capability. In addition, the use of third parties to commercialize our approved products reduces the revenues that we would receive if we commercialized these products ourselves.

We have entered into agreements with independent companies to market Neutrolin in Germany and in Saudi Arabia and, upon regulatory approval, South Korea. We also have independent sales representatives in the Middle East and The Netherlands. We intend to seek a sales partner in the U.S. if Neutrolin receives FDA approval. Consequently, we will be dependent on these firms and individuals for the success of sales in these and any other countries in which approval is granted. If these firms or individuals do not perform for whatever reason, our business, prospects and results of operations will be materially adversely affected. Finding a new or replacement organization for sales and marketing could be difficult, which would further harm our business, prospects and results of operations.

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

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

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

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

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

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

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

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

Risks Related to our Common Stock

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

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

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

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

During the period from the completion of our initial public offering, or IPO, on March 30, 2010 through March 11, 2016, the high and low sales prices for our common stock were $10.40 and $0.15, respectively. There is a limited public market for our common stock and we cannot provide assurances that an active trading market will develop. As a result of low trading volume in our common stock, the purchase or sale of a relatively small number of shares could result in significant share price fluctuations.

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

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

our need for additional capital;

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

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

our entry into or the loss of a significant collaboration;

regulatory or legal developments in the United States and other countries, including changes in the healthcare payment systems;

changes in financial estimates or investment recommendations by securities analysts relating to our common stock;

announcements by our competitors of significant developments, strategic partnerships, joint ventures or capital commitments;

changes in key personnel;

variations in our financial results or those of companies that are perceived to be similar to us;

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

general economic, industry and market conditions;

developments or disputes concerning patents or other proprietary rights;

future sales or anticipated sales of our securities by us or our stockholders; and

any other factors described in this "Risk Factors" section.

In addition, the stock markets in general, and the stock of pharmaceutical and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

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

As of February 29, 2016, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

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

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

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

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 per share that expire on March 24, 2016;

options to purchase an aggregate of 775,000 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 $0.78 per share;

options to purchase an aggregate of 3,530,045 shares of our common stock issued to our officers, directors and non-employee consultants under our 2013 Stock Plan, with a weighted average exercise price of $2.08 per share;

warrants issued to investors in our 2012 private placement to purchase an aggregate of 337,500 shares of our common stock with an exercise price of $0.40 per share, of which 312,500 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;

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

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

Series C-3 Preferred Stock convertible into 1,365,000 shares of common stock;

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

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

warrants for 682,500 shares of common stock issued in March 2014 with an exercise price of $2.50 per shares that expire on September 9, 2019;

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

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

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

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

We anticipate that we will incur operating losses for the foreseeable future. Additionally, we will require substantial funds in the future to support our operations. We expect to seek equity or debt financings in the future to fund our operations. The issuance of additional equity securities, or convertible debt or other derivative securities, likely will dilute some if not all of our then existing stockholders, depending on the financing terms.

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

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

Pursuant to our 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 29, 2016, options to purchase 775,000 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of $0.78 per share, and options to purchase 3,530,045 shares of common stock issued under our 2013 Stock Plan at a weighted average exercise price of $2.08 per share were outstanding. In addition, at February 29, 2015, there were outstanding warrants to purchase an aggregate of 4,422,188 shares of our common stock at prices ranging from $0.40 to $7.00, and shares of our outstanding Series B, C-2, C-3, D and E preferred stock convertible into an aggregate of 6,303,999 shares of our common stock. Stockholders will experience dilution in the event that additional shares of common stock are issued under our 2006 Stock Plan or 2013 Stock Plan, or options issued under our 2006 Stock Plan or 2013 Stock Plan are exercised, or any warrants are exercised for, or preferred stock shares are converted to, common stock.

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

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

authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

prohibiting our stockholders from fixing the number of our directors; and

establishing advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board of Directors.

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

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

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

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

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

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

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

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

the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

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

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located in approximately 4,700 square feet of office space in Bedminster, New Jersey. We sublease this office space pursuant to a sublease agreement dated December 2014 which runs from April 1, 2015 until March 31, 2018. Rent is $5,000 per month plus occupancy costs such as utilities, maintenance and taxes. 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 remaining sublease obligation is approximately $135,000 as of December 31, 2015.

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 €4,400 as of December 31, 2015.

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

Item 3. Legal Proceedings

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland (“Geistlich”) brought an action against the European Sodemann Patent covering our Neutrolin product candidate, which is owned by ND Partners, LLC (“NDP”) and licensed to us pursuant to the License and Assignment Agreement between us and NDP. This action was brought at the Board of the European Patent Office (“EPO”) opposition division (the “Opposition Board”) based upon alleged lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions of the prior art. The Opposition Board rejected the opposition by Geistlich. 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 requesting a dismissal of the appeal and maintenance of the patent as granted. On November 28, 2012, the Board of Appeals of the EPO (the “Appeals Board”) 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 claims of the counterpart of the Sodemann Patent. We received the Appeals Board’s 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 EPO reopened the proceedings before the first instance and gave their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfills the requirements of clarity, novelty, and inventive step, and invited the parties to provide their comments and/or requests by February 10, 2014. We filed 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 Opposition Board 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 became final as no further appeal was lodged by Geistlich.

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

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

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

The Court issued its decisions on May 8, 2015 staying both proceedings. In its decisions, the Court found that the commercialization by TauroPharm in Germany of its TauroLock catheter lock solutions Hep100 and Hep500 infringes both the Prosl European Patent and the Utility Model and further that there is no prior use right that would allow TauroPharm to continue to make, use or sell its product in Germany. However, the Court declined to issue an injunction in favor of us that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the EPO, in the case of the Prosl European Patent, or the German Patent and Trademark Office (the "German PTO"), in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by us for injunctive and other relief until such time as the EPO or the German PTO has ruled on the underlying validity of the Prosl European Patent and the Utility Model.

Both the opposition proceedings against the Prosl European Patent before the EPO and the cancellation action against the Utility Model before the German PTO are ongoing. In its preliminary consideration of the matter, the EPO (and the German Patent and Trademark Office) regarded the patent as not inventive or novel due to publication of prior art. Oral proceedings before the Opposition Division at the EPO were held on November 25, 2015, at which the three judge patent examiner panel considered arguments related to the validity of the Prosl European Patent. The hearing was adjourned due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in another hearing. A date for such further hearing has not been scheduled yet. As with the unfair competition matter, we expect that this matter will be under review and consideration by the Office for some time, with a determination not likely to be made before mid-2016. While we continue to believe that the referenced publication and instructions for use do not, in fact, constitute prior art and that the Prosl European Patent and the Utility Model validly claim inventions that will be found to be such by the EPO and the German PTO, there can be no assurance that we will prevail in this matter. The German PTO has scheduled a hearing in the cancellation proceeding for May 11, 2016 which will, however, likely be rescheduled due to conflicting court

appointments of some members of the legal team. We therefore do not expect a decision from the German PTO in the Utility Model matter before mid- 2016, with any such decision also being subject to appeal.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider our claims. The judge made no decision on the merits of our complaint. On January 14, 2016, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. We are in the process of preparing the requested reply and produce the respective documentation. A date for a further oral hearing has not been scheduled yet.

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

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

On February 1, 2016, the Cormedix Defendants filed a motion to dismiss all claims asserted against them in the Amended Complaint on the grounds, among others, that the Amended Complaint fails to adequately allege: (1) material misstatements or omissions; (2) scienter by any of the Cormedix Defendants; or (3) loss causation. The parties are in the process of briefing that motion and oral argument currently is scheduled for May 2, 2016.

The Company believes that it has substantial legal and factual defenses to the claims in the class action and intends to continue vigorously defending the case.

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:

	2015		2014	
	High	Low	High	Low
First Quarter	$9.90	$1.63	$3.20	$1.24
Second Quarter	$10.40	$3.62	$2.56	$1.05
Third Quarter	$4.31	$1.72	$2.15	$1.69
Fourth Quarter	$2.96	$1.72	$1.97	$1.25

Based upon information furnished by our transfer agent, at March 8, 2016, we had approximately 68 holders of record of our common stock.

Stock Performance Graph

The following performance graph shall not be deemed to be "soliciting material" or "filed" or incorporated by reference in future filings with the SEC, or subject to the liabilities of Section 18 of the Exchange Act except as shall be expressly set forth by specific reference in such filing. The performance graph compares the performance of our common stock to the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph covers the most recent five-year period ended December 31, 2015. The graph assumes that the value of the investment in our common stock and each index was $100.00 at December 31, 2010, and that all dividends are reinvested.

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, 2015 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)	3,600,045	$ 1.82	1,780,000
Equity compensation plans not approved by security holders (2)	125,795	1.49	--
Total	3,725,840	$ 1.81	1,780,000

(1) Our Amended and Restated 2006 Stock Incentive Plan was approved by our stockholders on February 19, 2010. Our 2013 Stock Incentive Plan was approved by our stockholders on July 30, 2013.

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

Item 6. Selected Financial Data

The consolidated statement of income data set forth below with respect to the years ended December 31, 2015, and December 31, 2014, and the consolidated balance sheet data at December 31, 2015 and December 31, 2014 are derived from the audited consolidated financial statements included in Item 8 of this Annual Report and should be read in conjunction with those financial statements and notes thereto. The consolidated statement of income data for the years ended December 31, 2013 and December 31, 2012 and December 31, 2011 and the consolidated balance sheet data at December 31, 2013, December 31, 2012 and December 31, 2011 are derived from audited consolidated financial statements not included herein.

(amounts in thousands, except for per share amounts)	2015	2014	2013	2012	2011
RESULTS OF OPERATIONS					
Net sales	$210	$189	$2	$-	$-
Gross (loss)	(109)	(257)	(200)	-	-
(Loss) from operations	(16,654)	(8,903)	(4,915)	(3,000)	(7,247)
(Loss) before income taxes	(18,187)	(20,453)	(9,133)	(3,381)	(7,205)
State income tax benefit	-	-	-	-	494
Net (loss)	(18,187)	(20,453)	(9,133)	(3,381)	(6,711)
Comprehensive income (loss)	(37)	108	(9)	-	-
Comprehensive (loss)	(18,224)	(20,345)	(9,142)	(3,381)	(6,711)
(LOSS) PER SHARE					
Basic and diluted	$(0.58)	(0.96)	(0.69)	(0.30)	$(0.59)

BALANCE SHEET DATA					
Total cash and marketable securities	$35,386	$4,340	$2,374	$835	$1,985
Total assets	37,102	5,098	2,968	1,153	2,556
Total liabilities	3,090	1,463	6,990	1,489	1,319
Total stockholders' equity (deficiency)	34,011	3,634	(4,022)	(335)	1,237

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 in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious and inflammatory diseases. As of the date of this report, we have in-licensed the worldwide rights to develop and commercialize our product CRMD003 (Neutrolin®), which we believe addresses 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, IV hydration, and/or IV medications.

Neutrolin is an anti-infective solution for the prevention of catheter-related infections and thrombosis in the central venous catheter markets such as dialysis, critical care, and oncology. Catheter related blood stream infections cause extensive morbidity and mortality, prolonged hospital stays and cost the U.S. healthcare system over $11 billion per year. 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 in order to reduce infection and thrombosis and thereby keep catheters operating optimally in clinical settings in hemodialysis, critical care/intensive care and oncology. Our initial target market for Neutrolin was hemodialysis using a tunneled central vein catheter, and we launched Neutrolin as a medical device in our first geographical market, Germany, in December 2013.

According to the United States Renal Disease System, there were approximately 468,000 patients on dialysis in 2015. It has been reported that patients requiring catheter represent over 127 million catheter days annually. The market in the critical care/intensive care units is approximately 28.5 million catheter days per year in the United States alone. There were over 14.5 million patients living with cancer in the United States in 2014 with an estimated 7.7 million having a long-term central venous catheter. However, when stages of disease, chemotherapy regimens and catheter types are factored, we believe the oncology market is approximately 90 million catheter days. 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 intravenous ("IV") antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the central venous catheter, related treatment costs and increased mortality when they occur.

In July 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 ("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, Bahrain, Qatar, Kuwait, United Arab Emirates and The Netherlands for such treatment.

We have entered into agreements with a German contract sales company to market and sell Neutrolin for hemodialysis, critical care/intensive care and oncolytic patients in Germany, with a Saudi Arabian company to market and sell Neutrolin in the Middle East, and with 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 the Middle East.

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

In late 2013, we met with the U.S. Food and Drug Administration (the "FDA") to determine the pathway for U.S. approval of Neutrolin. Based on our discussions with the FDA, we plan 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 clinical trial in hemodialysis patients with a central venous catheter; this protocol was accepted in August 2014 and we filed an investigational new drug application ("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 the Phase 3 clinical trial in hemodialysis patients was initiated in the U.S. in December 2015.

On June 17, 2015, we received guidance from the FDA on the acceptable design of the second planned pivotal Phase 3 trial in oncology/total parenteral nutrition patients and are working with the FDA to finalize the details. We plan to initiate the Phase 3 trial in oncology/total parenteral nutrition in the fourth quarter of 2016, depending on our ability to raise additional capital and our ability to complete the hemodialysis catheters trial within our expected budget, although we also plan to continue to seek one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

Our other product candidate was CRMD004, which is the gel formulation of Neutrolin that we were seeking to develop for a variety of indications including 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 anti-infective solution. On November 5, 2015, we gave notice of our termination of the Polaschegg Exclusive License and Consulting Agreement, dated January 30, 2008, covering the CRMD004 gel formulation, which termination was effective in January 2016. We determined that the CRMD004 gel technology patent targeting catheter locks was narrow in scope and limited in market potential. Based on technical analysis of the other patents under the Polaschegg License Agreement, we determined that extensive investment would be required to strengthen the patents. Upon termination of the Polaschegg License Agreement, all rights to the Polaschegg CRMD004 gel technology patent reverted to the patent originators. CRMD004 was in preclinical development.

We are evaluating opportunities for the possible expansion of indications for taurolidine. Provisional patents have been submitted in four areas, antimicrobial sutures, nanofiber webs, wound management, and osteoarthritis and visco-supplementation. There exists a need to control and protect against surgical site infections upon closure with sutures. We believe taurolidine could offer benefits not currently available in marketed antimicrobial sutures. We also believe that the nanofiber webs used for absorbable meshes could benefit from taurolidine's minimal inflammatory response and infection control. Taurolidine incorporated into webs or hydrogels could also be used for wound management especially wounds in less sterile environments and burn patients. Lastly, incorporating taurolidine into formulations for osteoarthritis and visco-supplementation may benefit from taurolidine's anti-inflammatory and anti-infection properties.

In March 2015, we commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. We engaged investment bank Evercore Group L.L.C. to provide financial advice and assist us with our evaluation process. After the process with Evercore, we announced in July 2015 that we expect to continue to pursue product development and commercialization opportunities as we move forward with the planned Phase 3 clinical trials, rather than pursuing a possible sale of our company as this time. We continue to retain Evercore and will work with them as potential opportunities are presented to us.

Since our inception, we have not generated enough revenue from product sales to be profitable. Our operations to date have been primarily limited to licensing product candidates, developing clinical trials for our product candidates, establishing manufacturing for our product candidates, performing business and financial planning, performing research and development, seeking regulatory approval for our products, initial commercialization activities for Neutrolin, and maintaining and improving our patent portfolio. We have funded our operations primarily with debt and equity financings. We have generated significant losses to date, and we expect to incur increases in our cash used in operations as we continue to commercialize Neutrolin in Europe and other markets, prepare for and undertake our ongoing and planned Phase 3 clinical trials, pursue business development activities, incur additional legal costs to defend our intellectual property, and seek FDA approval of Neutrolin in the U.S. As of December 31, 2015, we had an accumulated deficit of approximately $94.4 million. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

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Financial Operations Overview

Revenue

We have not generated substantial revenue since our inception. Through December 31, 2015, we have funded our operations primarily through debt and equity financings and our initial public offering, and to a lesser extent, the receipt from Federal grants under the Qualifying Therapeutic Discovery Project program and the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program.

Research and Development Expense

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

Conducting a significant amount of development is central to our business model. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. We plan to increase our R&D expenses for the foreseeable future in order to complete development of Neutrolin in the U.S., especially for the ongoing Phase 3 trial in hemodialysis patients and the planned Phase 3 trial in oncology/total parenteral nutrition.

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

	Year Ended December 31,			
	2015		2014	
CRMD003	98	%	98	%
CRMD004	2	%	2	%

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

Development timelines, probability of success and development costs vary widely. Our current focus is on clinical development efforts in the U.S. and optimization of sales in markets where Neutrolin is approved and gaining

utilization. We are seeking to develop Neutrolin in the U.S. Based on our discussions with the FDA, we plan to conduct at least one Phase 3 clinical trial in hemodialysis catheters and, subject to finalization of the protocol, one Phase 3 clinical trial in oncology/total parenteral nutrition. We initiated the Phase 3 clinical trial in hemodialysis catheters in December 2015 and we plan to initiate the Phase 3 trial in oncology/total parenteral nutrition in the fourth quarter of 2016 depending on our ability to raise additional capital and our ability to complete the hemodialysis catheters trial within our expected budget. We expect that the ongoing Phase 3 trial for hemodialysis catheters will cost approximately $26 million to $30 million and will take 18 months to complete after initiation. We are still finalizing the details of the protocol for the planned second Phase 3 trial for oncology/total parenteral nutrition and are unable to provide a cost estimate at this time. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

On July 5, 2013, we received CE Mark approval for Neutrolin. As a result, in late 2013, we 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, Bahrain, Qatar, Kuwait, United Arab Emirates and The Netherlands for such treatment.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expense includes costs related to commercial personnel, medical education professionals, marketing and advertising, salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, sales, finance and accounting functions. Other SG&A expense includes facility-related costs not included in R&D expense, promotional expenses, costs associated with industry and trade shows, and professional fees for legal services and accounting services. We expect that our SG&A expenses will increase due to marketing of our Neutrolin product in Europe and other markets in which it is approved.

Loss on Issuance of Preferred Stock, Convertible Notes and Warrants

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

Change in Fair Value of Derivative Liabilities

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

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

Loss on Modification of Equity Instruments and Extinguishment of Derivative Liabilities

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

Foreign Currency Exchange Transaction Gain (Loss)

Foreign currency exchange transaction gain (loss) is the result of re-measuring transactions denominated in a currency other than our functional currency and is reported in the consolidated statement of operations as a separate line item within other income (expense). In 2014, foreign currency exchange transaction gain (loss) consists of foreign exchange transaction gains and losses on intercompany loans that are in place between our company, which is based in New Jersey and our German subsidiary. Effective October 1, 2014, we determined that the intercompany loans outstanding are not expected to be repaid in the foreseeable future and the nature of the funding advanced is of a long-term investment nature. As such, beginning October 1, 2014, unrealized foreign exchange movements related to long-term intercompany loans are recorded in other comprehensive income (loss).

Interest Income

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

Interest Expense

Interest expense consists of interest incurred on financing of expenses.

Results of Operations

Comparison of the Years Ended December 31, 2015 and December 31, 2014

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

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

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

Cost of Sales. Cost of sales was $319,000 for the year ended December 31, 2015 compared to $446,000 in the same period last year, a decrease of $127,000. The decrease was primarily due to decreases in ongoing stability studies and services performed in the management of manufacturing of $131,000 and other manufacturing expenses mainly due to costs in transitioning Neutrolin to new labels and packaging of $13,000, offset by an increase in direct cost of materials of $67,000 due to the use of new commercial batches as compared to the use of old previously expensed

research and development batches in 2014. In addition, we recorded a charge of $125,000 associated with pre-launch inventory build-up and start-up related manufacturing inefficiencies in 2015 as compared to $175,000 in 2014, a decrease of $50,000.

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

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

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

Change in Fair Value of Derivative Liabilities. The change in the value of derivative liabilities for the year ended December 31, 2014 of $8,849,000 consists of increases in the fair value of preferred stock conversion options and warrants between December 31, 2013 and September 15, 2014 of $7,138,000 and $1,711,000, respectively. Due to the modification of certain terms within the preferred stock which resulted in the reclassification of the remaining derivative liability to equity in September 2014, there was no charge to earnings during the year ended December 31, 2015.

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

Foreign Exchange Transaction Gain (Loss). Foreign exchange transaction loss of $7,000 for the year ended December 31, 2105 was due to the foreign exchange rate fluctuations for the payment of invoices paid in foreign currency. Foreign exchange transaction loss was $151,000 for the year ended December 31, 2014 due to additional funding to our German subsidiary through September 30, 2014 and the corresponding fluctuation in the exchange rates. Effective October 1, 2014, we considered the intercompany loans to be of long-term investment nature. Foreign exchange gains or losses subsequent to October 1, 2014 have been recorded in other comprehensive income.

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

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

Other Comprehensive Income (Loss). Unrealized foreign exchange movements related to long-term intercompany loans and the translation of the foreign affiliate financial statements to U.S. dollars and unrealized movements related

to short-term investment are recorded in other comprehensive income totaling a $37,000 loss for the year ended December 31, 2015 and a $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.

During the year ended December 31, 2015, we received net proceeds of $43,603,000 from the following:

- sales of our common stock in an at-the-market program resulting in the issuance of 5,310,037 shares of common stock at a weighted average price of $5.55 per share;
- exercise of 4,581,783 warrants at a weighted average exercise price of $3.20 per share, which resulted in the issuance of 4,581,783 shares of common stock; and
- exercise of 499,955 stock options at a weighted average exercise price of $0.99 per share, which resulted in the issuance of 499,955 shares of common stock.

Net Cash Used in Operating Activities

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

Net Cash Used in Investing Activities

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $43,629,000 for the year ended December 31, 2015 as compared to $8,358,000 for the same period last year, an increase of $35,271,000. During the year ended December 31, 2015, we received net proceeds of $28,452,000 from the sale of our common stock in an at-the-market program, $14,658,000 from the exercise of warrants and $493,000 from the exercise of stock options. Additionally, we received $27,000 from short swing profit recovery. In comparison for the same period last year, we received net proceeds from the sale of common stock of $6,723,000, Series C-3 preferred stock of $1,319,000, and exercise of stock options of $318,000.

Funding Requirements and Liquidity

Our total cash on hand and short-term investments as of December 31, 2015 was $35,386,000 excluding restricted cash of $172,000, compared to approximately $4,340,000 at December 31, 2014. Because our business has not currently generated 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 activities and our business development activities, as well as to fund operations generally. Our continued operations and completion of our ongoing Phase 3 clinical trial for Neutrolin in hemodialysis catheters in the U.S. which was initiated in December 2015 and is expected to take 18 months to complete will depend on whether we are able to raise sufficient additional funds through various potential sources, such as equity, debt financings, and/or strategic relationships. We also plan to conduct an oncology/total parenteral nutrition patient Phase 3 clinical trial in the U.S. for which additional funds over and above the funds needed for the hemodialysis Phase 3 clinical trial will be required to complete that study. However, we can provide no assurances that financing or strategic relationships will be available on acceptable terms, or at all.

We expect to continue to fund operations from cash on hand and through 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. At December 31, 2015, we had approximately $10.5 million available for sale under our at-the market program, however, we may seek to sell additional equity or debt securities, obtain a bank credit facility, or enter into a corporate collaboration or licensing arrangement, but can provide no assurances that any 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. 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 actual cash requirements may vary materially from those now planned, however, because of a number of factors including any change in the focus and direction of our research and development programs, any acquisition or pursuit of development of new product candidates, competitive and technical advances, costs of commercializing any of our product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights.

While we expect to grow product sales, we do not anticipate that we will generate significant product sales revenue in the foreseeable future. In the absence of such revenue, we would experience continuing operating cash flow deficits. We expect to incur increases in our cash used in operations as we continue to commercialize Neutrolin in Europe and other foreign markets, prepare for and undertake our ongoing and planned Phase 3 clinical trials, pursue business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S.

Based on our cash resources at December 31, 2015, our expectations for sales of Neutrolin in the currently approved markets and the expected cost of the Phase 3 clinical trial in hemodialysis catheters in the U.S., we believe that our existing cash will be sufficient to fund our operations for at least the next twelve months following the balance sheet date. However, if we are unable to raise additional funds when needed, we may not be able to complete our ongoing and planned Phase 3 clinical trials or market our products and 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.

Contractual Obligations

We 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, we deposited $5,000 with the landlord, the equivalent of one month rent.

Our German subsidiary entered into a lease agreement for its offices in Fulda, Germany 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 ($20,000).

Under our current lease agreements, the total remaining lease obligation as of December 31, 2015 is set forth below:

2016	65,364
2017	60,784
2018	15,000
Total	$141,148

Critical Accounting Estimates

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

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

Stock-Based Compensation

We account for stock options according to the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") No. 718, "Compensation — Stock Compensation" ("ASC 718"). 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 No. 505-50, "Equity-Based Payments to Non-Employees" ("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 use 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 ASC 505.

Valuations incorporate several variables, including expected term, expected volatility, expected dividend yield and a risk-free interest rate. We estimate the expected term of the options granted based on anticipated exercises in future periods. Prior to 2015, the expected volatility used in the valuation of our stock options was based on the historical volatility of publicly traded peer group companies due to the limited trading history of our common stock. Beginning in the first quarter of 2015, the expected stock price volatility for our stock options is calculated based on the historical volatility since the initial public offering of our common stock in March 2010. 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. For an upfront payment related to an exclusive distribution agreement, we record it as deferred revenue and recognize revenue on a straight-line basis over the contractual term of the agreement

In October 2015, we shipped product with less than 75% of its remaining shelf life to a customer and issued a guarantee that any product shipped with less than 75% of its shelf life remaining would be replaced by us if the customer was not able to sell the product before it expired. As a result of this warranty, we may have an additional performance obligation (i.e. accept returned product and deliver new product to the customer) if the customer is unable to sell the short-dated product. Due to limited sales experience with the customer, we are unable to estimate the amount of the warranty obligation that may be incurred as a result of this shipment. Therefore, we have deferred the revenue and related cost of sales associated with the shipment of this product. Since we will be unable to resell the expired product if returned by the customer, the deferred revenue and related cost of sales is presented net as "Deferred revenue" on the consolidated balance sheet. At December 31, 2015, deferred income on shipment to distributor was $121,384.

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

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

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

Short-Term Investments

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

Fair Value Measurements

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

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

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

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

Embedded Derivative Liabilities:

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

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

Recent Authoritative Pronouncements:

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

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

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

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

will have on the determination or reporting of our financial results.

On August 27, 2014 ASU No. 2014-15 – Presentation of Financial Statements, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern was issued. The ASU requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued and if management's plans will alleviate that doubt. Management will be required to make this evaluation for both annual and interim reporting periods. The guidance is effective beginning in the first quarter of 2016.

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

In February 2016, the FASB issued new guidance related to how an entity should lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for us beginning in the first quarter of 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. We are evaluating the impact of adopting this guidance on our consolidated financial 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

See our disclosure in our Current Report on Form 8-K filed with the SEC on May 16, 2014.

Item 9A. Controls and Procedures

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

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the year ended December 31, 2015 other than the remediation of previously identified material weakness outlined below that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

Our management previously determined that as of December 31, 2014, 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 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 fully remediated our material weakness in internal control over financial reporting (as disclosed in Form 10-K for the year ended December 31, 2014) by implementing additional internal controls and improved monitoring of financial reporting transactions, analyses and disclosures.

Management's Annual Report on Internal Controls Over Financial Reporting

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

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

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

In connection with the preparation of our annual consolidated financial statements, management, including, our Chief Executive Officer (who is our principal executive officer and principal financial officer), has undertaken an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2015, based on the criterial established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, in 2013, or the COSO Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2015.

Friedman LLP, the independent registered public accounting firm that audited our consolidated financial statements included in this report, has issued their report on the effectiveness of internal control over financial reporting as of December 31, 2015, a copy of which is included herein.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited CorMedix, Inc. and subsidiary's (the "Company") internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013, or COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, CorMedix, Inc. and subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by COSO in 2013.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of CorMedix, Inc. and subsidiary as of December 31, 2015, and 2014, and the related consolidated statements of operations, comprehensive income (loss), cash flows, and stockholder's equity for each of the years in the two-year period ended December 31, 2015, and our report dated March 15, 2016 expressed an unqualified opinion on those consolidated financial statements.

/s/ Friedman LLP
East Hanover, NJ
March 15, 2016

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Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

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

The other information required by this Item concerning our directors is incorporated by reference from the section captioned "Proposal No. 1—Election of Directors" and "Corporate Governance" contained in our proxy statement related to the 2016 Annual Meeting of Stockholders scheduled to be held on June 7, 2016 which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K. The information required by this Item concerning compliance with Section 16(a) of the Exchange Act by our directors, executive officers and persons who own more than 10% of our outstanding common stock is incorporated by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the proxy statement.

Item 11. Executive Compensation

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

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

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

Item 13. Certain Relationships and Related Transactions and Director Independence

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

Item 14. Principal Accountant Fees and Services

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

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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 8, 2014.	8-K	1/09/2014	3.12

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
3.13	Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.8	
3.14	Certificate of Amendment to Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.13	
4.1	Specimen of Common Stock Certificate.	S-1/A	3/19/2010	4.1	
4.2	Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC.	S-1	11/25/2009	4.7	
4.3	Form of Registration Rights Agreement.	10-Q	11/13/2012	4.5	
4.4	Form of Warrant issued on February 19, 2013.	8-K	2/19/2013	4.13	
4.5	Form of Warrant issued on May 30, 2013.	8-K	5/24/2013	4.20	
4.6	Form of Warrant issued on July 30, 2013.	8-K	7/26/2013	4.21	
4.7	Form of Warrant issued on October 22, 2013.	8-K	10/18/2013	4.22	
4.8	Form of Warrant issued on January 8, 2014.	8-K	1/09/2014	4.23	
4.9	Form of Warrant issued on March 10, 2014.	8-K	3/05/2014	4.24	
4.10	Form of Warrant issued on March 3, 2015.	8-K	3/04/2015	4.1	
4.11	Amended and Restated Warrant originally issued May 30, 2013.	8-K	3/04/2015	4.3	
4.12	Amended and Restated Warrant originally issued March 24, 2010.	8-K	3/04/2015	4.2	
4.13	Form of Convertible Note.	8-K	3/04/2015	4.4	
4.14	Registration Rights Agreement, dated March 3, 2015, by and between CorMedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	4.5	
10.1*	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC.	S-1/A	12/312009	10.5	
10.2	Escrow Agreement, dated as of January 30, 2008, among the Company, ND Partners LLC and the Secretary of the Company, as Escrow Agent.	S-1	11/25/2009	10.6	
10.3*	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	
10.4	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl.	S-1	11/25/2009	10.12	
10.5*	Supply Agreement, dated as of December 7, 2009, between the Company and Navinta,	8-K	2/06/2015	10.1	

	LLC.			
10.6*	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
10.7	Amended and Restated 2006 Stock Incentive Plan.	S-1/A	3/01/2010	10.8
10.8	Form of Indemnification Agreement between the Company and each of its directors and executive officers.	S-1/A	3/01/2010	10.17
10.9	Subscription Agreement by and between the Company and certain accredited investors (with attached schedule of parties thereto).	8-K	11/15/2012	10.1
10.10	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
10.11	2013 Stock Incentive Plan	10-K	3/27/2013	10.27
10.12	Form of Securities Purchase Agreement, dated January 7, 2014, between CorMedix Inc. and the investors named therein.	8-K	1/09/2014	10.36

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.13	Backstop Agreement, dated March 3, 2015, by and between CorMedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	10.1	
10.14	Amendment No. 2, dated as of March 10, 2015, to Taurolodine Supply Agreement.*	10-Q	5/07/2015	10.1	
10.15	Preliminary Services Agreement dated April 8, 2015, between CorMedix Inc. and [RC]2 Pharma Connect LLC.	10-Q	8/06/2015	10.1	
10.16	Release of Claims and Severance Modification, dated July 17, 2015, between Randy Milby and CorMedix Inc.				X
21.1	List of Subsidiaries	10-K	3/27/2013	21.1	
23.1	Consent of Independent Registered Public Accounting Firm.				X
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following materials from CorMedix Inc. Form 10-K for the year ended December 31, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2015 and 2014, (ii) Statements of Operations for the years ended December 31, 2015 and 2014, (iii) Statements of Changes in Stockholders' Equity for the years ended December 31, 2015 and 2014, (iv) Statements of Cash Flows for the years ended December 31, 2015 and 2014 and (v) Notes to the Financial Statements.**				X

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

** 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 15, 2016	By:	/s/ Randy Milby Randy Milby Chief Executive Officer (Principal Executive Officer and Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ Randy Milby Randy Milby	Chief Executive Officer and Director (Principal Executive Officer and Principal Financial and Accounting Officer)	March 15, 2015
/s/ Cora Tellez Cora Tellez	Chairman of the Board and Director	March 15, 2015
/s/ Janet Dillione Janet Dillione	Director	March 15, 2015
/s/ Matthew Duffy Matthew Duffy	Director	March 15, 2015
/s/ Michael George Michael George	Director	March 15, 2015
/s/ Steven Lefkowtiz Steven Lefkowitz	Director	March 15, 2015
/s/ Taunia Markvicka Taunia Markvicka	Director	March 15, 2015
/s/ Antony E. Pfaffle Antony E. Pfaffle	Chief Scientific Officer and Director	March 15, 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 sheets of CorMedix, Inc. and subsidiary (the "Company") as of December 31, 2015, and 2014, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2015. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2015, in conformity with U.S. generally accepted principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013 and our report dated March 15, 2016 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Friedman LLP
East Hanover,
March 15, 2016

CORMEDIX INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
December 31, 2015 and 2014

	December 31, 2015	2014
ASSETS		
Current assets		
Cash and cash equivalents	$11,817,418	$4,339,540
Restricted cash	171,553	-
Short-term investments	23,568,386	-
Trade receivables	315,771	80,183
Inventories, net	376,569	463,029
Prepaid research and development expenses	430,162	-
Other prepaid expenses and current assets	379,004	155,210
Total current assets	37,058,863	5,037,962
Property and equipment, net	37,866	41,458
Security deposit	5,000	18,342
TOTAL ASSETS	$37,101,729	$5,097,762
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$1,709,397	$893,385
Accrued expenses	1,221,557	521,525
Deferred revenue	130,409	10,477
Total current liabilities	3,061,363	1,425,387
Deferred revenue and rent, long term	28,878	37,903
TOTAL LIABILITIES	3,090,241	1,463,290
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 450,085 and 949,948 shares issued and outstanding at December 31, 2015 and 2014, respectively (See Note 8)	450	950
Common stock - $0.001 par value: 80,000,000 shares authorized; 35,963,348 and 22,461,668 shares issued and outstanding at December 31, 2015 and 2014, respectively	35,964	22,461
Deferred stock issuances	(110)	(110)
Accumulated other comprehensive gain	62,130	98,972
Additional paid-in capital	128,304,649	79,716,265
Accumulated deficit	(94,391,595)	(76,204,066)
TOTAL STOCKHOLDERS' EQUITY	34,011,488	3,634,472
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$37,101,729	$5,097,762

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

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

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

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

	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 Issuances	Accumulated Other Comprehen-sive Gain (Loss)	Additional Paid-in Capital	Accumulated Deficit	Total Stockholder Equity (Deficiency
	Shares	Amount	Shares	Amount					
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
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					36		(36)		-

certain milestone									
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)	(20,453,42
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
Conversion of Series B non-voting preferred stock to common stock	454,546	455	(454,546)	(455)			-		-
Conversion of Series C-3 non-voting preferred stock to common stock	425,000	425	(42,500)	(42)			(383)		-
Conversion of Series E non-voting preferred stock to common stock	61,598	62	(2,817)	(3)			(59)		-
Stock issued in connection with warrants exercised	4,581,783	4,582					14,653,579		14,658,161
Stock issued in connection with warrants cashless exercised	2,158,033	2,158					(2,158)		-
Stock issued in connection with	499,955	500					492,460		492,960

stock options exercised									
Stock issued in connection with sale of common stock	5,310,037	5,310					28,446,538		28,451,848
Stock issued in connection with conversion of wages	10,728	11					49,989		50,000
Value of warrants in connection with backstop financing							1,583,252		1,583,252
Modification of warrant agreement							112,982		112,982
Short swing profit recovery							26,525		26,525
Stock-based compensation							3,225,659		3,225,659
Other comprehensive loss						(36,842)	-		(36,842
Net loss							-	(18,187,529)	(18,187,52
Balance at December 31, 2015	35,963,348	$35,964	450,085	$450	$(110)	62,130	$128,304,649	$(94,391,595)	$34,011,488

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

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

	December 31, 2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(18,187,529)	$(20,453,427)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,225,659	2,168,303
Value of warrants issued in connection with backstop financing	1,583,252	-
Modification of warrant agreement	112,982	-
Loss on foreign exchange transactions	-	150,803
Loss on issuance of preferred stock, convertible notes and warrants	-	89,590
Loss on modification of equity instruments and extinguishment of derivative liabilities	-	2,462,588
Inventory reserve	125,000	175,000
Revaluation of derivative liabilities	-	8,848,953
Depreciation	15,076	15,074
Changes in operating assets and liabilities:		
Restricted cash	(171,553)	220,586
Trade receivables	(248,186)	(85,412)
Inventory	(38,540)	(558,008)
Prepaid expenses and other current assets	(645,356)	72,958
Accounts payable	825,105	8,055
Accrued expenses and accrued interest	764,114	522,995
Deferred revenue	113,078	41,123
Net cash used in operating activities	(12,526,898)	(6,320,819)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term investments	(23,592,625)	-
Purchase of equipment	(15,446)	(25,402)
Net cash used in investing activities	(23,608,071)	(25,402)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock from at-the-market program	28,451,848	-
Proceeds from Series C-3 preferred stock, net	-	743,884
Proceeds from Series C-3 preferred stock, related party	-	575,000
Proceeds from exercise of warrants	14,658,161	-
Proceeds from exercise of stock options	492,960	318,150
Payment of deferred financing costs	-	(2,366)
Proceeds from sale of equity securities	-	6,723,248
Proceeds from short swing profit recovery	26,525	-
Net cash provided by financing activities	43,629,494	8,357,916
Foreign exchange effect on cash	(16,647)	(46,048)
NET INCREASE IN CASH AND CASH EQUIVALENTS	7,477,878	1,965,647
CASH AND CASH EQUIVALENTS – BEGINNING OF YEAR	4,339,540	2,373,893
CASH AND CASH EQUIVALENTS – END OF YEAR	$11,817,418	$4,339,540

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

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

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

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

CORMEDIX INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business:

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

The Company's primary activities since incorporation have been acquiring licenses for its pharmaceutical product candidates, performing business and financial planning, performing research and development, seeking regulatory approval for its products and conducting initial commercialization activities for its product Neutrolin® in certain markets. The Company has in-licensed Neutrolin and CRMD004 (see Note 6 related to CRMD004) and filed provisional patents for the other product candidates in its pipeline.

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 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, Bahrain, Qatar, Kuwait, United Arab Emirates and The Netherlands.

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

The Company launched its Phase 3 clinical trial in hemodialysis catheters in the U.S. in December 2015 and plans to conduct a Phase 3 clinical trial in oncology/total parenteral nutrition that is estimated to start in the fourth quarter of 2016

Note 2 — Liquidity and Uncertainties:

To date, the Company's commercial operations have not generated enough revenues to make the Company profitable. As of December 31, 2015, the Company has an accumulated deficit of $94.4 million, and has incurred losses from operations of $18.2 million for the year then ended. Based on the current development plans for Neutrolin in both the United States ("U.S.") and foreign markets (including the ongoing hemodialysis Phase 3 clinical trial in the U.S.) and on the current revenue assumptions for Neutrolin in approved markets, management believes that the existing cash at December 31, 2015 will be sufficient to fund its operations for at least the next twelve months following this balance sheet date. The Company will need additional funding thereafter to complete the hemodialysis clinical trial in the U.S. which commenced in December 2015. The Company also plans to initiate an oncology/total parenteral nutrition trial in the U.S. in the fourth quarter of 2016 and will need to raise additional funds to complete this trial. If the Company is unable to raise additional funds when needed, they will not be able to complete the ongoing hemodialysis Phase 3 clinical trial or the planned Phase 3 oncology/total parenteral nutrition clinical trial.

The Company's continued operations will depend on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products, 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. Without this funding, the Company could be required to delay, scale back or eliminate some or all of its research and development programs which would likely have a material adverse effect on the Company's business.

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's product candidates; the ability to obtain regulatory approval to market the Company's products; 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 amongst others.

CORMEDIX INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 3 — Summary of Significant Accounting Policies:

Use of Estimates:

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

Basis of Consolidation:

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

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.

Short-Term Investments

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation as of each balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair values of the Company's investments are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in other comprehensive income (loss). Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in income (expense) on the consolidated statements of operations and comprehensive income (loss). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. For declines in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other (income) expense, net. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. There were no deemed permanent impairments at December 31, 2015.

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

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Fair Value
Money Market Funds included in Cash Equivalents	$3,353,067	$-	$-	$3,353,067

U.S. Government Agency Securities	6,531,914	(3,014)	-	6,528,900
Corporate Securities	15,065,595	(21,637)	412	15,044,370
Commercial Paper	1,995,116	-	-	1,995,116
Subtotal	23,592,625	(24,651)	412	23,568,386
	$26,945,692	$(24,651)	$412	$26,921,453

CORMEDIX INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Fair Value Measurements

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

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

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

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

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

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

	Carrying Value	Level 1	Level 2	Level 3
Money Market Funds	$3,353,067	$3,353,067	$-	$-
US Government Agency Securities	6,528,900	-	6,528,900	-
Corporate Securities	15,044,370	-	15,044,370	-
Commercial Paper	1,995,116	-	1,995,116	-
Subtotal	$23,568,386	$-	$23,568,386	$-
	$26,921,453	$3,353,067	$23,568,386	$-

Foreign Currency Translation and Transactions:

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

The Company has intercompany loans between the parent company based in New Jersey and its German subsidiary. Effective October 1, 2014, the Company assessed and determined that the intercompany loans outstanding are not expected to be repaid in the foreseeable future and the nature of the funding advanced is of a long-term investment nature. As such, beginning October 1, 2014, unrealized foreign exchange movements related to long-term intercompany loans are recognized in other comprehensive income (loss).

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

Segment and Geographic Information:

The Company reported revenues of $210,130 and $189,274 for the years ended December 31, 2015 and 2014, respectively. Of the Company's 2015 and 2014 revenues, $201,306 and $185,598, respectively, were attributable to its European and Mideast operations, which are based in Germany. Total assets at December 31, 2015 and 2014 were $37,101,729 and $5,097,762, respectively, of which $36,190,835 and $4,416,074 were located in the United States at December 31, 2015 and 2014, respectively, with the remainders in Germany. Net property and equipment at December 31, 2015 and 2014 were $37,866 and $41,458, respectively, of which $12,093 and $1,089 were located in the United States at December 31, 2105 and 2014, respectively, with the remainders located in Germany.

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Restricted Cash:

As of December 31, 2015, the Company's restricted cash is in connection with the patent and utility model infringement proceedings against TauroPharm (see Note 6). The Company was required by the District Court Mannheim to provide a security deposit of approximately $132,000−−−−−−−−−−−−−−−−−− to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The Company furthermore had to provide a deposit in the amount of $40,000 in connection with the unfair competition proceedings in Cologne.

Prepaid Research and Development and Other Prepaid Expenses:

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

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,	
	2015	2014
Raw materials	$244,459	$293,976
Work in process	424,622	341,807
Finished goods	7,488	2,246
Inventory reserve	(300,000)	(175,000)
Total	$376,569	$463,029

Property and Equipment:

Property and equipment consist primarily of furnishings, fixtures, leasehold improvements, office equipment and computer equipment which are recorded at cost. Depreciation is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. Property and equipment, as of December 31, 2015 and 2014 were $37,866 and $41,458, respectively, net of accumulated depreciation of $92,353 and $77,277, 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:

	2015	2014
Professional and consulting fees	$282,975	$225,726
Accrued payroll and payroll taxes	532,084	13,393
Clinical trial and manufacturing development	226,042	-
Market research	3,225	137,345
Monitoring program fees	65,076	82,861
Statutory taxes	67,236	34,548
Other	44,919	27,652
Total	$1,221,557	$521,525

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Revenue Recognition:

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

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

Deferred Revenue:

In October 2015, the Company shipped product with less than 75% of its remaining shelf life to a customer and issued a guarantee that the specific product shipped would be replaced by the Company if the customer was not able to sell the product before it expired. As a result of this warranty, the Company may have an additional performance obligation (i.e. accept returned product and deliver new product to the customer) if the customer is unable to sell the short-dated product. Due to limited sales experience with the customer, the Company is unable to estimate the amount of the warranty obligation that may be incurred as a result of this shipment. Therefore, the Company has deferred the revenue and related cost of sales associated with the shipment of this product. Since the Company will be unable to resell the expired product if returned by the customer, the deferred revenue and related cost of sales is presented net as Deferred Revenue on the consolidated balance sheet which amounted to $121,000 at December 31, 2015.

In August 2014, the Company entered into an exclusive distribution agreement (the "Wonik Agreement") with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis and oncolytic patients upon receipt of regulatory approval in Korea. Upon execution of the Wonik 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 Wonik Agreement commenced on August 8, 2014 and will continue for three years after the first commercial sale of Neutrolin in the Territory. The non-refundable up-front payment has been recorded as deferred revenue and will be recognized as revenue on a straight-line basis over the contractual term of the Agreement.

Loss Per Common Share:

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

	December 31,	
	2015	2014
Series B non-voting preferred stock	-	454,546
Series C non-voting preferred stock	2,865,000	3,290,000

Series D non-voting preferred stock	1,479,240	1,479,240
Series E non-voting preferred stock	1,959,759	2,021,358
Shares underlying outstanding warrants	4,422,188	11,520,762
Shares underlying outstanding stock options	3,600,045	3,664,500
Total	14,326,232	22,430,406

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Stock-Based Compensation:

The Company accounts for stock options granted to employees, officers and directors according to ASC No. 718, "Compensation — Stock Compensation" ("ASC 718"). Share-based compensation cost is measured at grant date, based on the estimated fair value of the award using the Black-Scholes option pricing model, and is recognized as expense net of expected forfeitures, over the employee's requisite service period on a straight-line basis.

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 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 historical forfeitures.

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

Research and Development:

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

Income Taxes:

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

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 the Company beginning in the first quarter of 2017. Early adoption is not permitted and retrospective application is required. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial 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.

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In April 2015, the FASB issued new guidance which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance requires retrospective adoption and will be effective for the Company beginning in the first quarter of 2016. Early adoption is permitted. The Company does not expect this adoption to have a material impact on its financial statements.

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

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

On August 27, 2014 ASU No. 2014-15 – Presentation of Financial Statements, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern was issued. The ASU requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the financial statements are issued and if management’s plans will alleviate that doubt. Management will be required to make this evaluation for both annual and interim reporting periods. The guidance is effective beginning in the first quarter of 2016.

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

In February 2016, the FASB issued new guidance related to how an entity should lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for the Company beginning in the first quarter of 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The Company is evaluating the impact of adopting this guidance on our consolidated financial condition, results of operations and cash flows.

Note 4 — Related Party Transactions:

On March 3, 2015, the Company entered into a backstop agreement with an existing institutional investor, Manchester Securities Corp., a wholly owned subsidiary of Elliott Associates, L.P., and a beneficial holder of more than 5% of the Company's outstanding common stock. Pursuant to the backstop agreement, Manchester agreed to lend the Company, at its request, up to $4,500,000 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 IPO on or before April 30, 2015, provided that the loan could not exceed $3,000,000. The Company issued two warrants exercisable for an aggregate of up to 283,400 common shares with an exercise price of $7.00 per share and a term of five years as a result of entering into the backstop agreement. The Company had received approximately $5.7 million through March 31, 2015 from the exercise of warrants issued in connection with its IPO and therefore the Company did not access the loan and the loan expired on April 30, 2015. Additionally, the Company granted Manchester the right for as long as it or its affiliates hold any of the Company's common stock or securities convertible into its common stock the right to appoint up to two members to the Company's board of directors and/or to have up to two observers attend board meetings in a non-voting capacity. As of December 31, 2015, one board member had been appointed to the Company's board of directors under this provision.

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

Note 5 — Income Taxes:

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

	December 31,	
	2015	2014
United States	$(16,690,084)	$(18,653,576)
Foreign	(1,497,445)	(1,799,851)
Total	$(18,187,529)	$(20,453,427)

There was no current or deferred income tax provision for the year ended December 31, 2015 or 2014.

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

	December 31,	
	2015	2014
Net operating loss carryforwards – Federal	$18,282,000	$12,928,000
Net operating loss carryforwards – state	2,522,000	1,531,000
Net operating loss carryforwards –foreign	1,103,000	655,000
Capitalized licensing fees	1,915,000	2,135,000
Stock-based compensation	2,349,000	1,457,000
Accrued compensation	206,000	-
Other	150,000	38,000
Totals	26,527,000	18,744,000
Less valuation allowance	(26,527,000)	(18,744,000)
Deferred tax assets	$-	$-

At December 31, 2015, the Company had potentially utilizable Federal, state and foreign net operating loss tax carryforwards of approximately $56,429,000, $45,113,000 and $3,678,000, 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. Our federal and state operating loss carryforwards include windfall tax deductions from stock option exercises. The amount of windfall tax benefit recognized in additional paid-in capital is limited to the amount of benefit realized currently in income taxes payable. As of December 31, 2015, the Company had suspended additional paid-in capital credits of $1,060,000 related to windfall tax deductions. Upon realization of the net operating loss carryforwards from such windfall tax deductions, the Company would record a benefit of $1,062,000 in additional paid-in capital.

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

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

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

	December 31,	
	2015	2014
Statutory Federal tax rate	(34.0)%	(34.0)%
State income tax rate (net of Federal)	(6.2)%	(0.6)%
Effect of foreign operations	(2.5)%	0.4 %
Non-deductible expenses associated with derivative liabilities	0.0 %	23.5 %
Warrent related expenses	3.2 %	0.0 %
Prior year return to provision adjustment	(3.1)%	0.0 %
Other permanent differences	(0.1)%	(0.1)%
Effect of valuation allowance	42.7 %	10.8 %
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, 2015 and 2014, the Company maintained a full valuation allowance against its net deferred tax assets. The Company will continue to assess all available evidence during future periods to evaluate the realization of its deferred tax assets.

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

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

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

The Company files income tax returns in the U.S. federal, state and foreign jurisdictions. Tax years 2012 to 2015 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:

Contingency Matters

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland (“Geistlich”) brought an action against the European Sodemann Patent covering the Company’s Neutrolin product candidate, which is owned by ND Partners, LLC (“NDP”) and licensed to the Company pursuant to the License and Assignment Agreement between the Company and NDP. This action was brought at the Board of the European Patent Office (“EPO”) opposition division (the “Opposition Board”) based upon alleged lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions of the prior art. The Opposition Board rejected the opposition by Geistlich. 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 requesting a dismissal of the appeal and maintenance of the patent as granted. On November 28, 2012, the Board of Appeals of the EPO (the “Appeals Board”) 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 claims of the counterpart of the Sodemann Patent. The Company received the Appeals Board’s 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 EPO reopened the proceedings before the first instance and gave their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfills the requirements of clarity, novelty, and inventive step, and invited the parties to provide their comments and/or requests by February 10, 2014. The Company filed its response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not provide any filing by February 10, 2014; however, the Opposition Board 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 became final as no further appeal was lodged by Geistlich.

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

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

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

The Court issued its decisions on May 8, 2015 staying both proceedings. In its decisions, the Court found that the commercialization by TauroPharm in Germany of its TauroLock catheter lock solutions Hep100 and Hep500 infringes both the Prosl European Patent and the Utility Model and further that there is no prior use right that would allow TauroPharm to continue to make, use or sell its product in Germany. However, the Court declined to issue an injunction in favor of the Company that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the EPO, in the case of the Prosl European Patent, or the German Patent and Trademark Office (the "German PTO"), in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by the Company for injunctive and other relief until such time as the EPO or the German PTO has ruled on the underlying validity of the Prosl European Patent and the Utility Model.

Both the opposition proceedings against the Prosl European Patent before the EPO and the cancellation action against the Utility Model before the German PTO are ongoing. The EPO held a hearing in the opposition proceeding on November 25, 2015. In its preliminary consideration of the matter, the EPO (and the German Patent and Trademark Office) had regarded the patent as not inventive or novel due to publication of prior art. However, the EPO did not issue a decision at the end of the hearing but adjourned the matter due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in a further hearing in order to close some gaps in the documentation presented by TauroPharm as regards the publication of the prior art. No date has yet been scheduled for such hearing. While the Company continues to believe that the referenced publication and instructions for use do not, in fact, constitute prior art and that the Prosl European Patent and the Utility Model validly claim inventions that will be found to be such by the EPO and the German PTO, there can be no assurance that the

Company will prevail in this matter. The German PTO has scheduled a hearing for May 11, 2016 which will, however, likely be rescheduled due to conflicting court appointments of some members of the legal team. The Company therefore does not expect a decision from the German PTO in the Utility Model matter before mid-2016, with any such decision also being subject to appeal.

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On January 16, 2015, the Company filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, the Company alleges violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. The Company alleges that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. The Company seeks a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. A hearing in this matter was scheduled for July 2, 2015, but was postponed by the Court to November 19, 2015. In this hearing, the presiding judge explained that the court needed more information with regard to several aspects of the case. As a consequence, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. The Company's legal team is in the process of preparing the requested reply and produce the respective documentation. A date for a further oral hearing has not been scheduled yet.

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

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

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

On February 1, 2016, the Cormedix Defendants filed a motion to dismiss all claims asserted against them in the Amended Complaint on the grounds, among others, that the Amended Complaint fails to adequately allege: (1) material misstatements or omissions; (2) scienter by any of the Cormedix Defendants; or (3) loss causation. The parties are in the process of briefing that motion and oral argument currently is scheduled for May 2, 2016. The Company believes that it has substantial legal and factual defenses to the claims in the class action and intends to continue vigorously defending the case.

Commitments

Manufacturing

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

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On March 24, 2015, the Company and Navinta LLC entered into an amendment to the Navinta Agreement to extend the term of the Navinta Agreement to March 31, 2016 and to lower the price per kilogram of API that the Company purchases from Navinta LLC under the Navinta Agreement. The Company also agreed to purchase a minimum amount of product from Navinta LLC during 2015, which replaced the prior minimum purchase requirement. The Navinta Agreement may be terminated by either party upon 30 days written notice. The Navinta Agreement is set to expire in accordance with its terms upon the delivery of API in early April of 2016.

The Company announced a program aimed at reducing the cost of goods of Neutrolin through a more efficient, custom synthesis of the active ingredient taurolidine. As part of that program, on April 8, 2015, the Company entered into a Preliminary Services Agreement with [RC]2 Pharma Connect LLC ("RC2"), pursuant to which RC2 will coordinate certain manufacturing services related to taurolidine. Specifically, RC2 will undertake a critical parameters evaluation for the Company's manufacturing needs and coordinate the cGMP processes set forth in the agreement that the Company believes are necessary for the submission of its planned new drug application for Neutrolin to the FDA, as well as any foreign regulatory applications. The total cost for RC2's services under the preliminary services agreement is expected to be approximately $1.7 million which is expected to be incurred through the second quarter of 2016. Through December 31, 2015, the Company recognized expense of approximately $227,000 for its services related to the agreement.

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

Clinical and Regulatory

On December 3, 2015 CorMedix signed a Master Service Agreement and Work Order (the "Master Service Agreement") with PPD Development, LP ("PPD") for a $19.2 million Phase 3 multicenter, double-blind, randomized active control study (the "Phase 3 Clinical Trial") to demonstrate the safety and effectiveness of Neutrolin in preventing catheter-related bloodstream infections and blood clotting in subjects receiving hemodialysis therapy as treatment for end stage renal disease. The Phase 3 Clinical Trial is expected to run for 18 months and accrue up to 632 patients in 70 sites in the US. The Phase 3 Clinical Trial will stop when there are 162 incidences and an interim analysis will be performed after 81 incidences to determine whether additional sites and patients are required to complete the study. Prior to the signing of the Master Service Agreement, CorMedix signed a Letter of Agreement ("LOA") with PPD in July 2015. The original LOA was subsequently amended later in July 2015 for a total of $2.75 million, to revise and expand the scope of services provided by PPD in connection with the identification, activation and management of 70 U.S. sites for the Phase 3 Clinical Trial described above. When the Master Service Agreement was signed in December 2015, the amended LOA was rolled into the $19.2 million Phase 3 Clinical Trial. During the year ended December 31, 2015, the Company recognized $1,019,000 research and development expense related to this agreement.

In-Licensing

In 2008, the Company entered into a License and Assignment Agreement (the "NDP License Agreement") with NDP. Pursuant to the NDP License Agreement, NDP granted the Company exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a

taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the "NDP Technology"). The Company acquired such licenses and patents through its assignment and assumption of NDP's rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann and Dr. Johannes Reinmueller. As consideration in part for the rights to the NDP Technology, the Company paid NDP an initial licensing fee of $325,000 and granted NDP a 5% equity interest in the Company, consisting of 39,980 shares of the Company's common stock.

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In addition, the Company is required to make payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The maximum aggregate number of shares issuable upon achievement of milestones is 145,543 shares. During the year ended December 31, 2014, a certain milestone was achieved resulting in the release of 36,386 shares held in escrow. The number of shares held in escrow as of December 31, 2015 is 109,157 shares of common stock. The maximum aggregate amount of cash payments upon achievement of milestones is $3,000,000 with $2,500,000 remaining at December 31, 2015. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval and upon achieving certain worldwide net sales amounts. There were no milestones achieved in 2015.

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

On January 30, 2008, the Company also entered into an Exclusive License and Consulting Agreement with Dr. Polaschegg (the "Polaschegg License Agreement"). 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 set forth certain minimum royalty payments (on an annual basis) to be made to Dr. Polaschegg in connection with the Polaschegg Technology, which payments range from $10,000 to $45,000. The Company could terminate the Polaschegg License Agreement with respect to any piece of the Polaschegg Technology upon 60 days notice. If the Polaschegg License Agreement is terminated with respect to any piece of the Polaschegg Technology by either party, all rights with respect to such portion of the Polaschegg Technology revert to Dr. Polaschegg. On November 5, 2015, the Company gave notice of its termination of the Polaschegg License Agreement. During the years ended December 31, 2015 and 2014, the Company expensed $30,000 and $40,000, respectively, in connection with the Polaschegg License Agreement.

Other

On August 3, 2015, the Company entered into a Release of Claims and Severance Modification with Randy Milby, its Chief Executive Officer, due to the anticipated termination of Mr. Milby's employment. In exchange for the release of various claims by Mr. Milby against the Company, including claims related to his employment with Company and the termination of same and claims for additional compensation or benefits other than the compensation and benefits set forth in his employment agreement, the Company agreed to amend Mr. Milby's employment agreement, dated as of March 31, 2014, to specify that Mr. Milby may not compete against the Company by engaging in any business involving the development or commercialization of (i) a preventive anti-infective product that would be a direct competitor of Neutrolin or (ii) a product containing taurolodine. The non-compete term did not change and remains at twelve months following termination of his employment. The employment agreement was also amended to allow Mr. Milby a period in which to exercise all vested options and warrants until the later of 60 months following the termination date of his employment or 60 months following the date on which his service on the Company's Board of

Directors ends, provided in no event shall he be able to exercise after the respective expiration date of any stock option or warrant. During the year ended December 31, 2015, the Company recorded non-cash expense of $507,341 as a result of this modification.

Pursuant to the terms of his employment agreement, Mr. Milby will be entitled to receive his base salary and benefits for a period of twelve months following the effective date of the termination of his employment, or, in the case of benefits, until such time as he receives equivalent coverage and benefits under plans and programs of a subsequent employer if such receipt is prior to the expiration of the twelve month period. 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. The Company accrued $325,000 of severance pay during the year ended December 31, 2015.

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.

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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 ($20,000).

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

Under the Company's current lease agreements, the total remaining lease obligation as of December 31, 2015 is set forth below:

2016	$65,364
2017	60,784
2018	15,000
Total	$141,148

Note 7 — Equity Instruments Modification and Fair Value Measurements:

The following table presents the fair value hierarchy and the change in fair values of the Company's derivative liabilities measured at fair value on a recurring basis.

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

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, 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.

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

1. Decrease the exercise price of the warrants issued in May 2013 from $1.00 to $0.65, decrease the exercise price of the warrants issued in October 2013 from $1.25 to $0.90, decrease the exercise price of the warrants issued in January 2014 from $1.25 to $0.90, and decrease the exercise price of the warrants issued in March 2014 from $3.10 to $2.50;

2. Extend the existing right of the two institutional investors in our May and October 2013 financings to participate in future financings to the later of two years 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 on September 15, 2015. 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 fair value was re-measured immediately prior to the modification date with the original terms and immediately after the modification date with the amended terms. The change in fair value resulting from the modifications made to those instruments on September 15, 2014 was recorded as loss on modification of equity instruments and extinguishment of derivative liabilities in the amount of approximately $2,463,000.

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

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

Note 8 — Stockholders' Equity:

Common Stock:

On April 8, 2015, the Company entered into an At-the-Market Issuance Sales Agreement (the "Sales Agreement") with MLV & Co. LLC ("MLV") under which the Company may issue and sell up to $40.0 million of shares of its common stock from time to time through MLV acting as agent, subject to limitations imposed by the Company, such as the number or dollar amount of shares registered under the registration statement to which the offering relates. When the Company wishes to issue and sell common stock under the Sales Agreement, it notifies MLV of the number of shares to be issued, the dates on which such sales are anticipated to be made, any minimum price below which sales may not be made and other sales parameters as the Company deems appropriate. MLV is entitled to a commission of up to 3% of the gross proceeds from the sale of common stock sold under the Sales Agreement. The shares of common stock to be sold under the Sales Agreement are registered under an effective registration statement filed with the SEC. During the year ended December 31, 2015, the Company issued 5,310,037 shares of common stock under the Sales Agreement and realized net proceeds of approximately $28,451,848.

During the year ended December 31, 2015, the Company also issued shares of its common stock, resulting in gross proceeds of $14,658,161:

150,000 shares of common stock upon exercise of warrants with an exercise price of $0.90 per share;

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125,000 shares of common stock upon exercise of warrants with an exercise price of $0.40 per share;
353,500 shares of common stock upon exercise of warrants with an exercise price of $2.50 per share; and
3,953,283 shares of common stock upon exercise of warrants with an exercise price of $3.4375 per share.

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

2,158,033 shares upon cashless exercise of 2,597,591 warrants;
499,955 shares upon exercise of 499,955 stock options at a weighted average exercise price of $0.99 per share, resulting in gross proceeds of $492,960 to the Company;
454,546 shares upon conversion of 454,546 shares of the Series B non-voting preferred stock;
425,000 shares upon conversion of an aggregate of 42,500 shares of the Series C-3 non-voting preferred stock;
61,598 shares upon conversion of 2,817 shares of the Series E non-voting preferred stock; and
10,728 shares upon conversion of wages by an officer of the Company in an aggregate amount of $50,000 at prices per share of $3.10 - $8.55.

During the year ended December 31, 2015, the Company also issued 774 warrants upon the exercise of a unit warrant related to the IPO. These warrants were subsequently exercised resulting in the issuance of 774 shares of common stock and gross proceeds of $2,661 to the Company.

In March 2014, the Company sold an aggregate of 2,960,000 units in a registered direct offering at a purchase price of $2.50 per unit, for net proceeds of $6,723,248. Each unit consisted of one share of the Company's common stock and 0.35 of a warrant, each to purchase one share of the Company's common stock. Upon issuance, the warrants had an exercise price of $3.10 per share, are exercisable commencing six months from the date of issuance, and have a term of five years from the date of exercisability. Under certain circumstances, the warrants may be settled in cash and were therefore were initially classified as derivative liabilities (See Note 7). The Company used the Black Scholes option pricing model to value the warrants, of which $1,728,450 was the ascribed value calculated at the issuance date. These warrants were revalued at each balance sheet date and the resulting changes were recorded in other income (expense) in the statement of operations. On September 15, 2014, the exercise price of these warrants was decreased to $2.50 in exchange for the removal of the cash settlement provisions of the warrant. 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, the Company issued the following shares of common stock:

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

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

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

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

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

35,886 shares held in escrow was released upon achievement of certain milestones.

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

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, 2015:

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

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

Redemption – The Company is not obligated to redeem or repurchase any shares of Series B, Series C, Series D or Series E non-voting preferred stock. Shares of Series B, Series C, series D and Series E Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

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

Series B Non-Voting Convertible Preferred Stock and Warrants

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

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

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. In the event of the Company's liquidation, dissolution, or winding up, holders of the Series C Stock will receive a payment equal to $10.00 per share of Series C Stock, subject to adjustment, before any proceeds are distributed to the holders of common stock. Shares of the Series C Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors.

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

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. The warrants are exercisable one year after issuance, had an exercise price of $1.25 per share (decreased to $0.90 per

share in September 2014 – See Note 7), subject to adjustment, and a term of five years from the date they are first exercisable. The Company received net proceeds of $1,318,884.

The Series C-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; 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, 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.

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

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

The Series C-1 non-voting convertible preferred stock, Series C-2 non-voting convertible preferred stock, Series D non-voting convertible preferred stock and Series E non-voting convertible preferred stock all contained a prohibition on its respective conversion (in the case of the Series C-1 and Series C-2, in the aggregate for both series) if, as a result of such conversion, the Company would have issued in each case shares of its common stock in an aggregate amount equal to 3,190,221 shares, which is 20% of the shares of common stock outstanding on October 17, 2013, unless the Company received the approval of its stockholders for such overage. On February 28, 2014, the shareholders approved the issuance of such overage.

Series D Non-Voting Convertible Preferred Stock

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

The Series D non-voting convertible preferred stock ranks senior to the Company's common stock; senior to any class or series of capital stock created after the issuance of the Series D non-voting convertible preferred stock; senior to the Series C-2 non-voting convertible preferred stock and the Series C-3 non-voting convertible preferred stock; and on parity with the Series E non-voting convertible preferred stock. 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

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

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The Series E non-voting convertible preferred stock ranks senior to the Company's common stock; senior to any class or series of capital stock created after the issuance of the Series E non-voting preferred stock; senior to the Series C-2 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 the Series E non-voting convertible preferred stock is outstanding , the Company cannot, among others things: create, incur, assume or suffer to exist any encumbrances on any of our assets or property; redeem, repurchase or pay any cash dividend or distribution on any of our capital stock (other than as permitted); redeem, repurchase or prepay any indebtedness; or engage in any material line of business substantially different from our current lines of business.

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

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 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.

Stock Options:

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

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

During the year ended December 31, 2014, the Company granted ten-year non-qualified stock options under the 2013 Plan covering an aggregate of 1,185,000 shares of its common stock to its officers, directors and employees and an aggregate of 396,000 shares of its common stock to its consultants.

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

The fair value of the grants at grant dates is determined using the Black-Scholes option pricing model with the following assumptions:

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

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. Prior to 2015, the expected volatility used in the valuation of the Company's stock options was based on the historical volatility of publicly traded peer group companies due to the limited trading history of the Company's common stock. Beginning in the first quarter of 2015, the expected stock price volatility for the Company's stock options is calculated based on the historical volatility since the initial public offering of the Company's common stock in March 2010. The expected dividend yield of 0.0% reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards.

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

	Year Ended December 31, 2015		Year Ended December 31, 2014	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	3,664,500	$1.25	3,453,630	$1.06
Granted	640,000	$4.60	1,581,000	$1.98
Exercised	(499,955)	$0.99	(455,000)	$0.70
Expired/Cancelled	(25,000)	$2.97	(574,630)	$2.65

Forfeited	(179,500)	$2.20	(340,500)	$1.13
Outstanding at end of year	3,600,045	$1.82	3,664,500	$1.25
Options exercisable	3,172,212	$1.46	3,092,250	$1.15
Weighted-average fair value of options granted during the year		$3.46		$1.50

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	December 31, 2015	2014
Weighted average remaining contractual life of stock options outstanding (years)	7.6	8.2
Weighted average remaining contractual life of stock options exercisable (years)	7.4	8.0
Weighted average vesting period over which total compensation expense related to non-vested options not yet recognized (years)	0.5	0.5
Compensation expense related to non-vested options not yet recognized	$543,089	$308,005
Aggregate intrinsic value of stock options exercised	$3,260,728	$636,250
Aggregate intrinsic value of stock options outstanding	$2,405,321	$2,659,665

The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying options and the quoted closing price of the common stock of the Company at the end of the reporting period for those options that have an exercise price below the quoted closing price.

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

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

Warrants:

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

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

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

In March 2015, the Company issued two warrants exercisable for an aggregate of up to 283,400 common shares with an exercise price of $7.00 per share and a term of five years as a result of entering into a backstop agreement with Manchester Securities Corp. ("Manchester") (See Note 4). Additionally, the expiration date of March 24, 2015 of warrants to purchase 390,720 shares of common stock issued to Manchester in connection with the Company's initial

public offering ("IPO") was extended by one year to March 24, 2016. The Company recorded non-cash other expense of $1,583,252 for these warrants using the Black-Scholes option pricing model with the following assumptions:

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

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

	2015			2014		
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at beginning of year	11,520,762	$1.99	2.57	10,422,525	$2.00	3.12
Granted	284,174	$6.99	4.19	2,036,000	$2.19	5.11
Expired	(203,374)	$3.44	-	(18,250)	-	-
Exercised	(7,179,374)	$2.28	-	(919,513)	$0.41	-
Outstanding at end of year	4,422,188	$1.80	3.07	11,520,762	$1.99	2.57

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, 2015 and 2014, the amount of compensation that was deferred under this plan was $79,200 and $21,826, respectively.

Short Swing Profit Recovery

In June 2015, a member of the board of directors of the Company paid a total of $26,525 to the Company representing the disgorgement of short swing profits under Section 16(b) under the Exchange Act. The amount was recorded as additional paid in capital.

Note 9 — Concentrations:

During the year ended December 31, 2015, the Company had revenues of $100,000 from one customer which represented 48% of the Company's total revenue. At December 31, 2015, approximately 93% of net accounts receivable was due from this same customer.

Note 10 — Subsequent Events:

In January and February 2016, the Company issued the following shares of common stock:

74,975 shares under the at-the-market sales agreement with a weighted average sale price of $2.05 per share, resulting in net proceeds of approximately $149,000 to the Company; and

80,000 shares upon exercise of 80,000 stock options at a weighted average exercise price of $1.23 per share, resulting in gross proceeds of $98,700 to the Company.

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	2/27/2013	3.3	
3.4	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on February 18, 2013, as corrected on February 19, 2013.	8-K	2/19/2013	3.3	
3.5	Certificate of Designation of Series B Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on July 26, 2013.	8-K	7/26/2013	3.4	
3.6	Certificate of Designation of Series C-1 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.5	
3.7	Certificate of Amendment to Certificate of Designation of Series C-1 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.10	
3.8	Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.6	
3.9	Certificate of Amendment to Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.11	
3.10	Certificate of Designation of Series C-3 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.9	
3.11	Certificate of Designation of Series D Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 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	8-K	1/09/2014	3.12	

	State on January 8, 2014.			
3.13	Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.8
3.14	Certificate of Amendment to Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.13
4.1	Specimen of Common Stock Certificate.	S-1/A	3/19/2010	4.1
4.2	Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC.	S-1	11/25/2009	4.7

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
4.3	Form of Registration Rights Agreement.	10-Q	11/13/2012	4.5	
4.4	Form of Warrant issued on February 19, 2013.	8-K	2/19/2013	4.13	
4.5	Form of Warrant issued on May 30, 2013.	8-K	5/24/2013	4.20	
4.6	Form of Warrant issued on July 30, 2013.	8-K	7/26/2013	4.21	
4.7	Form of Warrant issued on October 22, 2013.	8-K	10/18/2013	4.22	
4.8	Form of Warrant issued on January 8, 2014.	8-K	1/09/2014	4.23	
4.9	Form of Warrant issued on March 4, 2014.	8-K	3/05/2014	4.24	
4.10	Form of Warrant issued on March 3, 2015.	8-K	3/04/2015	4.1	
4.11	Amended and Restated Warrant originally issued May 30, 2013.	8-K	3/04/2015	4.3	
4.12	Amended and Restated Warrant originally issued March 24, 2010.	8-K	3/04/2015	4.2	
4.13	Form of Convertible Note.	8-K	3/04/2015	4.4	
4.14	Registration Rights Agreement, dated March 3, 2015, by and between CorMedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	4.5	
10.1*	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC.	S-1/A	12/31/2009	10.5	
10.2	Escrow Agreement, dated as of January 30, 2008, among the Company, ND Partners LLC and the Secretary of the Company, as Escrow Agent.	S-1	11/25/2009	10.6	
10.3*	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	
10.4	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl.	S-1	11/25/2009	10.12	
10.5*	Supply Agreement, dated as of December 7, 2009, between the Company and Navinta, LLC.	8-K	2/06/2015	10.1	
10.6*	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	
10.7	Amended and Restated 2006 Stock Incentive Plan.	S-1/A	3/01/2010	10.8	
10.8	Form of Indemnification Agreement between the Company and each of its directors and executive officers.	S-1/A	3/01/2010	10.17	
10.9	Subscription Agreement by and between the Company and certain accredited investors (with attached schedule of parties thereto).	8-K	11/15/2012	10.1	

10.10	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
10.11	2013 Stock Incentive Plan	10-K	3/27/2013	10.27
10.12	Form of Securities Purchase Agreement, dated January 7, 2014, between CorMedix Inc. and the investors named therein.	8-K	1/09/2014	10.36
10.13	Backstop Agreement, dated March 3, 2015, by and between CorMedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	10.1
10.14	Amendment No. 2, dated as of March 10, 2015, to Taurolodine Supply Agreement.*	10-Q	5/07/2015	10.1
10.15	Preliminary Services Agreement dated April 8, 2015, between CorMedix Inc. and [RC]2 Pharma Connect LLC.	10-Q	8/06/2015	10.1

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.16	Release of Claims and Severance Modification, dated July 17, 2015, between Randy Milby and CorMedix Inc.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following materials from CorMedix Inc. Form 10-K for the year ended December 31, 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

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

** 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.