CorMedix Inc.
Form 10-K
March 31, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

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FORM 10-K

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

For the fiscal year ended: December 31, 2013
OR

o 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.)
745 Rt. 202-206, Suite 303, Bridgewater, NJ	08807
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

Securities registered pursuant to Section 12(g) of the Act: none

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes o No þ

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 o No þ

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 þ No o

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 þ No o

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.

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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 o	Accelerated filer o
Non-accelerated filer o	Smaller reporting company þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes o No þ

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 $12.5 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 21,993,384 as of March 25, 2014.

DOCUMENTS INCORPORATED BY REFERENCE

None

CORMEDIX INC.

PART I

PART II

PART III

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

PART I

Forward-Looking Statements

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

Item 1. Business

Overview

We are a development stage company as of December 31, 2013 and are in the process of transitioning to a commercial pharmaceutical and medical device company. We seek to in-license, develop and commercialize therapeutic products for the treatment of cardiorenal and infectious diseases, including the dialysis and non-dialysis areas. As of the date of this report, we have in-licensed all of the product candidates in our pipeline.

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

Our primary product is Neutrolin for the prevention of catheter-related infections in dialysis and non-dialysis markets, which we believe addresses a medical need and a potentially large market opportunity. Neutrolin is a liquid formulation designed to prevent central venous catheter infection as well as catheter obstruction, also referred to as maintenance of catheter patency, in central venous catheters, which we initially plan for use in hemodialysis catheters. There are approximately 780,000 hemodialysis patients in the United States and the European Union, or EU. We believe the patients undergoing hemodialysis using a tunneled central vein catheter will be our initial target market. We project 91,000 patients in the European Union and 104,000 patients in the United States. These patients represent nearly 30 million hemodialysis sessions per year, which we believe represents a market potential of approximately $300 - $400 million.

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

notified body managing our CE Mark application. In the fourth quarter of 2011, we successfully completed our stage 1 audit with TÜV SÜD and we successfully completed the stage 2 audit in the third quarter of 2012.

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

On July 5, 2013, we received CE Mark approval for Neutrolin. As a result, we began the commercial launch of Neutrolin for the prevention of catheter-related bloodstream infections, or CRBI, and maintenance of catheter patency in hemodialysis patients in Europe in the fourth quarter of 2013.

We have four pillars to our Neutrolin strategy: (i) successfully launch the product in Germany; (ii) expand the product into additional applications; (iii) expand sales into other foreign countries; and (iv) apply for and receive marketing approval and launch the product in the United States.

In anticipation of receiving CE Mark approval, on January 10, 2013, we entered into an agreement with MKM Co-Pharma GmbH, or MKM, regarding Neutrolin, pursuant to which, MKM hired a national sales manager to market Neutrolin in Germany according to a negotiated work plan. While the plan may be revised, it currently provides that the sales manager will market Neutrolin in three phases. In the first phase, which began in January 2013, the sales manager visited hemodialysis centers and doctors to, among other things, provide them information. The sales manager also produced a market review of our product, negotiated wholesaler relationships for initial stocking of our product, and developed sales projections for the launch of Neutrolin. We transferred this work from MKM to human4farma GmbH, or human4farma, which hired the same sales manager who continued, after the receipt of CE Mark approval, with the launch Neutrolin in the fourth quarter of 2013 in Germany. human4farma will be responsible for growing Neutrolin sales and expanding the promotional plans.

In late 2013, we met with the FDA to determine the pathway for U.S. approval of Neutrolin, which will entail at least one Phase 3 clinical trial in hemodialysis catheters and potentially one Phase III clinical trial in another indication.

Platforms and Products

Our product candidates' technology seeks to utilize liquid and gel formulations of Neutrolin (CRMD003 and CRMD004, respectively) to prevent the infection and maintenance of catheter patency in central venous catheters and peripherally inserted central catheters. These catheters are frequently used for vascular access in hemodialysis (a form of dialysis where the patient's blood is circulated through a dialysis filter), for cancer chemotherapy, long term antibiotic therapy, total parenteral nutrition (complete or partial dietary support via intravenous nutrients) and intensive care patients.

The following table summarizes our current product candidates.

Product	Intended Indication	Status of Clinical Programs	Commercial Rights
CRMD003 (Neutrolin) (liquid formulation)	Prevention of catheter-related blood stream infections and maintenance of catheter patency in hemodialysis patients who are asymptomatic for catheter-related blood stream infections using both incident and prevalent catheters with any brand of central venous catheter. Additionally, we intend to pursue other indications in the future.	In Europe, Neutrolin (taurolidine 1.35%, citrate 3.5% and heparin 1,000 u/mL) is considered to be a Class III device requiring submission and approval of a CE Mark for marketing of the product. We received CE Mark approval in Europe in July 2013. In the U.S., Neutrolin is considered to be a drug product, requiring submission and approval of an Investigational New Drug ("IND") application to the FDA.	Worldwide
CRMD004 (gel formulation)	Prevention of catheter-related blood stream infections and maintenance of catheter patency in hemodialysis patients who are asymptomatic for catheter-related blood stream infections using both incident and prevalent catheters with any brand of central venous catheter.	In Europe, CRMD004 is considered to be a Class III device requiring submission and approval of a CE Mark for marketing of the product.	Worldwide

CRMD003 (Neutrolin)

Market Opportunity

Patients undergoing hemodialysis require access to the vascular system in order to perform treatments on a multiple scheduled basis each week. According to the American Journal of Kidney Diseases, February 2008, approximately 81,000 hemodialysis patients in the United States relied on a central venous catheter. One of the major complications in the use of a central venous catheter for hemodialysis treatment is catheter related blood stream infections, or CRBIs, and the inflammatory complications associated with them. Assuming an average of two episodes of CRBIs per year, there would be 162,000 episodes per 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. There are 15 million central venous catheter days in U. S. hospitals each year and an estimated 250,000 CRBI episodes across all hospitals. CRBIs and inflammatory complications are a primary cause of morbidity in the end-stage renal disease hemodialysis patient population, and the second most common cause of mortality.

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

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

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

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

Development Strategy

Our strategy is to obtain worldwide approval for Neutrolin. On July 5, 2013, the MEB, which is responsible for authorizing and monitoring safe and effective medicinal products on the Dutch market and shares responsibility for authorizing medicinal products throughout the European Union, issued final approval for the CE Mark certification for Neutrolin.

In 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, which will entail at least one Phase 3 clinical trial in hemodialysis catheters and one Phase III clinical trial in another indication. Based upon FDA guidance, we plan to approach the Center for Drug Evaluation and Research, or CDER, anti-infective division and submit our plan for a clinical trial program that would be acceptable to the FDA to allow the submission of an IND which, if successful, would in turn allow the submission of an NDA for full marketing approval for Neutrolin. Our plan is for one pivotal Phase III clinical trial, but it is possible the FDA might request an additional Phase IIb trial. We anticipate our clinical trial program would begin sometime during the second half of 2014 and be completed in 2015 or early 2016 with NDA submission and potential approval in late 2016 or late 2017.

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. We initially launched in Germany through our agreement with human4farma GmbH, or human4farma, to which we had transferred the work from MKM Co-Pharma GmbH. human4farma hired the same national sales manager who had been at MKM, to market Neutrolin in Germany according to a negotiated work plan. While the plan may be revised, it currently provides that the sales manager will market Neutrolin in three phases. In the first phase, from January to March 2013, the sales manager visited hemodialysis centers and doctors to, among other things, provide them information. The sales manager has also produced a market review of our product, negotiated wholesaler relationships for initial stocking of our product, and developed sales projections for the launch of Neutrolin. In the second phase, which began with the receipt of CE Mark approval, the sales manager initiated the process of launching Neutrolin in the fourth quarter of 2013, and is to generate sales on a best efforts basis and supervise the key account managers. The sales manager is responsible for growing Neutrolin sales and expanding the promotional plans. Additionally, to lead the commercialization of Neutrolin in the European Union, we have formed a European subsidiary, CorMedix Europe GmbH.

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

After we launch Neutrolin, we will consider developing it 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.

Competitive Landscape

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

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

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

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

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

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

Antibiotic or antimicrobial coated catheters have been launched by some device companies as short term prevention of catheter infection. These are not effective for hemodialysis catheters due to the long term use and high blood flow associated with hemodialysis.

Manufacturing

All of our manufacturing processes currently are, and we expect them to continue to be, outsourced to third parties. We rely on third-party manufacturers to produce sufficient quantities of drug product for use both commercially and in clinical trials. We intend to continue this practice in the future.

Navinta LLC, a U.S.-based active pharmaceutical ingredient, or API, developer, provides API manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for CRMD003, pursuant to a supply agreement dated December 7, 2009 (the "Navinta Agreement"). The Navinta Agreement provides that Navinta will supply taurolidine (the API for CRMD003) to us on an exclusive worldwide basis in the field of the prevention and treatment of human infection and/or dialysis so long as we purchased a minimum of $350,000 of product from Navinta by December 30, 2010, which we achieved, and following our first commercial sale of a product incorporating taurolidine (which occurred in December 2013), purchase a minimum of $2,250,000 of product on an annual basis for five years. We are also required to make certain cash payments to Navinta upon the achievement of certain sales-based milestones. The maximum aggregate amount of such payments, assuming achievement of all milestones, is $1,975,000. The Navinta Agreement has a term of five years, but may be terminated by either party upon 30 days written notice.

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 IND application, which must become effective before human clinical trials may commence;
- preliminary human clinical studies to evaluate the drug's safety and effectiveness for its intended uses;
- FDA review of whether the facility in which the drug is manufactured, processed, packaged, or held meets standards designed to assure the product's continued quality; and
- submission of a new drug application, or NDA, to the FDA, and approval of the application by the FDA to allow sales of the drug.

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

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

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

Before proceeding with a study, sponsors may seek a written agreement known as a Special Protocol Assessment, or SPA, from the FDA regarding the design, size, and conduct of a clinical trial. Among other things, SPAs can cover clinical studies for pivotal trials whose data will form the primary basis to establish a product’s efficacy. SPAs help establish up-front agreement with the FDA about the adequacy of a clinical trial design to support a regulatory approval, but the agreement is not binding if new circumstances arise. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

United States law requires that studies conducted to support approval for product marketing be “adequate and well controlled.” In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with good clinical practice requirements, and informed consent must be obtained from all study subjects.

The clinical trial process for a new compound can take 10 years or more to complete. The FDA may prevent clinical trials from beginning or may place clinical trials on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. Trials may also be prevented from beginning or may be terminated by institutional review boards, who must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product’s use and, potentially, withdrawal of the product from the market.

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

Each domestic and foreign manufacturing establishment, including any contract manufacturers that we may decide to use, must be listed in the NDA and must be registered with the FDA. The application generally will not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug product, and determines that the facility is in compliance with current Good Manufacturing Practices, or cGMP, requirements.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing an NDA, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant.

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

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

The regulatory framework applicable to the production, distribution, marketing, and/or sale, of our products may change significantly from the current descriptions provided herein in the time that it may take for any of our products to reach a point at which a NDA is approved.

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

Drugs for Serious or Life-Threatening Illnesses

The Federal Food, Drug, and Cosmetic Act, as amended, and FDA regulations provide certain mechanisms for the accelerated “Fast Track” approval of products intended to treat serious or life-threatening illnesses which have been studied for safety and effectiveness and which demonstrate the potential to address unmet medical needs. The procedures permit early consultation and commitment from the FDA regarding the preclinical and clinical studies necessary to gain marketing approval. Provisions of this regulatory framework also permit, in certain cases, New Drug Applications to be approved on the basis of valid surrogate markets of product effectiveness, thus accelerating the normal approval process. Where the FDA approves a product on the basis of a surrogate market, it requires the

sponsor to perform post-approval, or Phase 4, studies as a condition of approval, and may withdraw approval if post-approval studies do not confirm the intended clinical benefit or safety of the product. Special rules would also apply to the submission to the FDA of advertising and promotional materials prior to use.

Controlled Substances

Compounds that have a potential for patient dependence and abuse are classified as controlled substances under the Controlled Substances Act, regulations of the Drug Enforcement Administration, or DEA, and similar state and foreign laws. In the United States, for new chemical entities under development for medicinal use, designated staff at the FDA make recommendations about whether a drug should be scheduled as a controlled substance, and the DEA makes the final determination. States then either follow the federal classification or make their own determination. In the case of a new drug approved by the FDA, the final DEA scheduling determination generally occurs several months or longer after the FDA's approval.

Drugs that are scheduled as controlled substances are subject to stringent regulatory requirements, including requirements for registering manufacturing and distribution facilities, security controls and employee screening, recordkeeping, reporting, product labeling and packaging, import and export. There are five federal schedules for controlled substances, known as Schedule I, II, III, IV and V. The regulatory requirements that apply to a drug vary depending on the particular controlled substance schedule into which a drug is placed, based on consideration of its potential for dependence and abuse and its medicinal uses. Schedules I and II contain the most stringent restrictions and requirements, and Schedule V the least. No products with recognized medicinal uses are in Schedule I. For substances in Schedule I and II, quotas must be obtained from the DEA in order to manufacture, procure, and distribute inventory. For all controlled substances, there are potential criminal and civil penalties that apply for the failure to meet applicable legal requirements. Healthcare professionals must have special DEA licenses in order to prescribe controlled substances.

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 would commercialize a product following regulatory approval, 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. For example, in the case of Medicare coverage for physician-administered oncology drugs, the Omnibus Budget Reconciliation Act of 1993, with certain exceptions, prohibits Medicare carriers from refusing to cover unapproved uses of an FDA-approved drug if the unapproved use is supported by one or more citations in the American Hospital Formulary Service Drug Information the American Medical Association Drug Evaluations, or the United States Pharmacopoeia Drug Information. Another commonly cited compendium, for example under Medicaid, is the DRUGDEX Information System.

Foreign Regulatory Requirements

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

of products not approved by the FDA, depending on the country involved and the status of the product in that country.

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

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

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

Intellectual Property

CRMD003 and CRMD004

On January 30, 2008, we entered into a License and Assignment Agreement, or the NDP License Agreement, with ND Partners, LLC, or NDP. Pursuant to the NDP License Agreement, NDP granted us exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the "NDP Technology"). We acquired such licenses and patents through our assignment and assumption of NDP's rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann, and Dr. Johannes Reinmueller. NDP also granted us exclusive licenses, with the right to grant sublicenses, to use and display certain trademarks in connection with the NDP Technology. As consideration in part for the rights to the NDP Technology, we paid NDP an initial licensing fee of $325,000 and granted NDP an equity interest in us 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 as of December 31, 2013. The maximum aggregate amount of cash payments upon achievement of milestones is $3,000,000. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval processes and certain worldwide net sales amounts.

On April 11, 2013, we entered into an amendment to the NDP License Agreement. Under Article 6 of the NDP License Agreement, we were obligated to make a milestone payment of $500,000 to NDP upon the first issuance of a CE Mark for a licensed product, which payment was payable to NDP within 30 days after such issuance. Pursuant to the terms of the amendment, we and NDP agreed to delay such milestone payment to a time, to be chosen by us, anytime within 12 months after the achievement of such issuance. As consideration for the amendment, we issued NDP a warrant to purchase 125,000 shares of our common stock at an exercise price of $1.50 per share. The warrant is exercisable immediately upon issuance and has a term of five years. The warrant contains a cashless exercise feature and standard adjustment features in the event of a stock split, stock dividend, recapitalization or similar events. As of December 31, 2013, a milestone payment of $500,000 was earned by NDP upon the first issuance of the CE Mark for Neutrolin.

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

On January 30, 2008, we also entered into an Exclusive License and Consulting Agreement with Dr. Polaschegg. Pursuant to the Polaschegg License Agreement, Dr. Polaschegg granted us an exclusive, worldwide license for a gel lock invention and certain taurolidine treatments and the corresponding United States patent applications (the "Polaschegg Technology"). The Polaschegg Technology serves as a basis for CRMD004, which is the gel formation of Neutrolin. As consideration for the rights to the Polaschegg Technology, in addition to an initial fee of $5,000, we agreed to pay Dr. Polaschegg certain royalty payments ranging from 1% to 3% of the net sales of the Polaschegg

Technology. The Polaschegg License Agreement also sets forth certain minimum royalty payments (on an annual basis) to be made to Dr. Polaschegg in connection with the Polaschegg Technology, which payments range from $10,000 to $45,000. Additional minimum royalty payments will become payable to Dr. Polaschegg if he develops new intellectual property that is applied to the Polaschegg Technology. As of December 31, 2013, we recorded an aggregate of approximately $230,000 in licensing and minimum royalty payments under the Polaschegg License Agreement.

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

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

Employees

As of March 1, 2014, we have two employees, our CEO and our customer service representative in Germany, and had one independent contractor working in the finance area in the U.S. Two of our directors serve as the Interim Chief Financial Officer and the Acting Chief Scientific Officer, respectively. 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 745 Route 202-206, Suite 303, Bridgewater, New Jersey 08807. Our telephone number is (908) 517-9500.

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

Item 1A. Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and a history of operating losses, and expect to incur additional operating losses in 2014.

We were established in July 2006 and have only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in the early stages of operation. We incurred a net loss of approximately $9.1 million for the year ended December 31, 2013. As of December 31, 2013, we had an accumulated deficit of approximately $55.8 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trial and commercialization activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Having only launched Neutrolin in December 2013, we have no products that have generated any significant commercial revenue, do not expect to generate substantial revenues from Neutrolin until at least 2015, 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; obtaining necessary regulatory approvals for Neutrolin from the other applicable European and Middle East agencies, other foreign agencies and the FDA and international regulatory agencies for any other products; successful completion of the development of our other product candidates; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur losses and negative operating cash flow in 2014, and we may never achieve or maintain profitability. Until we successfully commercialize Neutrolin or other product candidates, we expect to incur losses and may never become profitable. We also expect to continue to incur significant operating and capital expenditures as we pursue the U.S. development of Neutrolin and anticipate that our expenses will increase substantially in the foreseeable future as we continue to undertake development and commercialization of Neutrolin and our other product candidates, undertake clinical trials of our product candidates, seek regulatory

approvals for product candidates, implement additional internal systems and infrastructure, and hire additional personnel.

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

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

We launched Neutrolin in Germany in the fourth quarter of 2013, but to date have no other approved product on the market and have not generated significant product revenue from Neutrolin to date. Unless and until we receive applicable regulatory approval for Neutrolin in the U.S. and for any other product candidates, we cannot sell those products in the U.S. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from Neutrolin sales in Europe and other foreign markets, if approved, cash on hand, additional financings, licensing fees and grants.

Based on the funds we have raised through March 31, 2014, we believe that existing cash will be sufficient to enable us to fund our projected operating requirements into 2015. However, we may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them if the conditions for raising capital are favorable.

We may seek to sell additional equity or debt securities, obtain a bank credit facility, or enter into a corporate collaboration or licensing arrangement. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in 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.

Risks Related to the Development and Commercialization of Our Product Candidates

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

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

CRMD003 (Neutrolin) - received CE Mark approval in Europe on July 5, 2013, with launch is begun in Germany late in the fourth quarter of 2013;

CRMD003 (Neutrolin) – pre-IND meeting with the FDA held in November 2013; and

CRMD004 - currently in the pre-clinical phase.

Our product development efforts may not lead to commercially viable products for any of several reasons. For example, our product candidates may fail to be proven safe and effective in clinical trials, or we may have inadequate financial or other resources to pursue development efforts for our product candidates. Even if approved, our products may not be accepted in the marketplace. Neutrolin will require significant additional development, clinical trials, regulatory clearances and/or investment by us or our collaborators as we continue its commercialization, as will any of our other products. Specifically, we plan to expand marketing of Neutrolin in other foreign countries and to develop Neutrolin for sale in the U.S., which will take time and capital.

We have entered into an agreement with human4farma to sell Neutrolin in Germany, which launched in Germany in the fourth quarter of 2013. Consequently, we will be dependent on human4farma for the success of sales in Germany. If human4farma does not perform for whatever reason, our business, prospects and results of operations will me materially adversely affected. Finding a suitable replacement organization 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.

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.

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

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

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

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

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

Physicians and patients may not accept and use our products.

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

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

cost-effectiveness of our product relative to competing products;

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

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

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

Risks Related to Our Business and Industry

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

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

There can be no assurance that any of our product candidates 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, our former Chief Operating Officer and, effective January 1, 2013, our Chief Executive Officer, Steven Lefkowitz, a director and, effective August 15, 2013, our Interim Chief Financial Officer, and Dr. Antony Pfaffle, a director and, effective January 1, 2013, our Acting Chief Scientific Officer. We do not have any employment agreements with any of our officers. Even if we were to enter into an employment agreement, such an agreement cannot ensure our retention of any person covered by such agreement. Furthermore, our future success will also depend in part on our ability to identify, hire, and retain additional personnel. We experience intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of our business. Moreover, our work force is located in the New Jersey metropolitan area, where competition for personnel with the scientific and technical skills that we seek is extremely high and is likely to remain high. Because of this competition, our compensation costs may increase significantly. In addition, we have only limited ability to prevent former employees from competing with us.

Recent changes in our management may lead to instability and may negatively affect our business.

In September 2011, John Houghton, our former President and Chief Executive Officer, left the Company and, in April 2012, Brian Lenz, our former Chief Financial Officer and Chief Operating Officer resigned. In May 2012, our board of directors appointed then director Richard Cohen to serve as our Interim Chief Executive Officer and Interim Chief Financial Officer. Mr. Cohen resigned all positions on August 14, 2013, and the board of directors appointed director Steven Lefkowitz to serve as our Interim Chief Financial Officer, effective August 15, 2013. In May 2012, the board of directors also engaged Randy Milby to serve as our Chief Operating Officer. On December 21, 2012, we appointed Mr. Milby as our Chief Executive Officer, effective January 1, 2013. At that time, Mr. Milby's responsibilities as our Chief Operating Officer terminated. Effective January 1, 2013, we also appointed our director Dr. Antony Pfaffle as our Acting Chief Scientific Officer. Dr. Mark Klausner, our former part-time Chief Medical Officer, ceased employment on February 28, 2013. We cannot be certain that the changes in management will not negatively affect our business in the future or that additional changes in management and in the composition of our board of directors will not occur. Additionally, we may be negatively impacted by a lack of accounting expertise, lack of internal control processes (which include lack of segregation of duties for cash disbursements and cash reconciliations), lack of accuracy and timeliness of financial reporting as a result of the changes in our Chief Financial Officer, Chief Operating Officer and other positions.

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

Over time, we expect to hire additional qualified personnel with expertise in clinical testing, clinical research and testing, government regulation, formulation and manufacturing, and sales and marketing. We compete for qualified individuals with numerous pharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining such qualified personnel will be critical to our success.

We may not successfully manage our growth.

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

Risks Related to Our Intellectual Property

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

Our commercial success will depend in part on the maintenance of our license agreements. Each of our license agreements provides the licensor with a right to terminate the license agreement for our material breach or default under the agreement, including the failure to make any required milestone or other payments. Additionally, our license agreement with Dr. Hans-Dietrich Polaschegg (referred to herein as the Polaschegg License Agreement) provides for a right of termination for, among other things, our failure to make a product with respect to either of the licensed technologies available to the market within eight years after (i) the effective date of the Polaschegg License Agreement, which was January 20, 2008, or (ii) the priority date of any new patent, whichever is later. Our intellectual property licensed under the Polaschegg License Agreement serves as a basis for CRMD004, the gel formation of Neutrolin. Should the licensor under any of our license agreements exercise such a termination right, we would lose our right to the intellectual property under the respective license agreement, which loss may materially harm our business.

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

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

U.S. Registration No. 7,696,182 (expiring in May 2025) - use of Neutrolin for preventing infection and maintenance of catheter patency in hemodialysis catheters (for CRMD003);

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

European Registration No. 1442753 (expiring February 2023) - use of a thixotropic gel as a catheter locking composition, and method of locking a catheter (for CRMD004); and

European Patent EP 1 814 562 B1 (expiring October 12, 2025), 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 patent applications in our patent portfolio are exclusively licensed to us. To support our patent strategy, we have engaged in a review of patentability and freedom to operate issues, including performing certain searches. However, patentability and 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.

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

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement or invalidity claims or litigation arising out of patents and pending applications of our competitors, or additional proceedings initiated by third parties or the PTO or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. The defense and prosecution of 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. 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. An adverse determination in litigation or PTO or foreign proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, restrict or prevent us from selling our products in certain markets, or invalidate or render unenforceable our licensed or owned patents. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland, or Geistlich, brought an action against the Sodemann patent covering our Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to us pursuant to the License and Assignment Agreement between us and ND Partners LLC. The action that was brought against the Sodemann patent in Germany at the Board of the European Patent Office opposition division was for lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions described in the Lehner patent. The Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. We filed a response to the appeal of Geistlich on March 25, 2009 where we requested a dismissal of the appeal and to maintain the patent as granted. As of March 27, 2014, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, we became aware that the Board of Appeals of the European Patent Office issued, on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the Sodemann patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the Sodemann patent claims. We received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. In a letter dated September 30, 2013, we were notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils the requirements of Clarity, Novelty, and Inventive Step, and invited the parties to provide their comments and/or requests by February 10, 2014. We filed our response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division has granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. We intend to continue to vigorously defend the patent in a restricted form. However, we can provide no assurances regarding the outcome of this matter.

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

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

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

abandon an infringing product candidate;

redesign our products or processes to avoid infringement;

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

pay damages; or

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

Risks Related to Dependence on Third Parties

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

Our business strategy for Neutrolin relies on collaborating with larger firms with experience in marketing and selling medical devices and pharmaceutical products; for other products we may also rely on such marketing collaborations or out-licensing or our product candidates. Specifically, for Neutrolin, we have entered into an agreement with human4farma to market Neutrolin, initially in Germany and letters of intent with two distributors in the Middle East (Saudia Arabia, Oman and Yemen as of the date of this report). 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 establish marketing, sales, or distribution relationships, that such relationships, if established, such as with human4farma, will be maintained and/or be successful, or that we will be successful in gaining market acceptance for our products. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third-parties.

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

We currently have no internal marketing and sales organization and have no experience as a company in marketing medical devices or drug products. If we are unable to establish our own marketing and sales capabilities, or enter into agreements with third parties, to market and sell our products after they are approved, we may not be able to generate product revenues.

We do not have an internal sales organization for the marketing, sales and distribution of any drug products. In order to commercialize any products, we must develop these capabilities on our own or make arrangements with third parties for the marketing, sales and distribution of our products. The establishment and development of our own sales force would be expensive and time consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capability. As a result, we may seek one or more third party organizations to handle some or all of the sales and marketing of Neutrolin, which we have done with human4farma for the initial launch in Germany and letters of intent with two distributors in the Middle East (Saudia Arabia, Oman and Yemen as of the date of this report). However, we may not be able to enter into or maintain arrangements with third parties to sell Neutrolin on favorable terms or at all. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize Neutrolin or any other product candidates that we develop, which would negatively impact our ability to generate product revenues. Further, whether we commercialize products on our own or rely on a third party to do so, our ability to generate revenue will be dependent on the effectiveness of the sales force. In addition, to the extent we rely on third

parties to commercialize our approved products, we will likely receive less revenues than if we commercialized these products ourselves.

We have entered into an agreement with human4farma to market Neutrolin in Germany. Consequently, we will be dependent on human4farma for the success of sales in Germany and any continued success of the marketing and sales of Neutrolin in Germany. If human4farma does not perform for whatever reason, our business, prospects and results of operations will be materially adversely affected. Finding a replacement organization 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 our product candidates 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 our product candidates on our own, we must obtain regulatory approval of the manufacturing facility and process. The manufacture of drugs for clinical and commercial purposes must comply with cGMP and applicable non-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements would require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. We would also have to pass a pre-approval inspection prior to FDA or non-U.S. regulatory agency approval. Failure to pass a pre-approval inspection may significantly delay regulatory approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products. As a result, our business, financial condition, and results of operations could be materially adversely affected.

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

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

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

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

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

Risks Related to our Common Stock

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

We have identified a material weakness in our internal control over financial reporting related to our limited finance staff and the resulting ineffective management review over financial reporting, coupled with increasingly complex accounting treatments associated with our financing activities and European expansion. We have taken initial measures to remediate this weakness by increasing internal review processes, in addition to the previously established accounting oversight committee, which is comprised of members of our senior management and third party GAAP advisor. We expect to be able to add to our finance staff in 2014 as we build our infrastructure, which we believe will remediate this weakness. However, we cannot be assured that this weakness will be remediated or that other material weaknesses will not be discovered.

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

impact on our financial condition and stock price.

Our 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 14, 2014, the high and low sales prices for our common stock were $4.00 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:

our need for additional capital;

the receipt of additional regulatory approvals for Neutrolin;

results of clinical trials of our product candidates 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, you should consider an investment in our securities as 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 March 14, 2014, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

227,273 shares of common stock issuable upon exercise of a warrant issued in July 2013 with an exercise price of $1.50 that expire on July 30, 2018;

454,546 shares of common stock issuable upon conversion of the Series B Preferred Stock;

1,000,000 shares of common stock issuable upon exercise of the warrants issued in May 2013 with an exercise price of $1.00 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 4,043,569 shares of our common stock issued in connection with our IPO with an exercise price of $3.4375 per share that expire on March 24, 2015;

a warrant to purchase 2,406 units with an exercise price of $7.80 per unit issued to the underwriters of our IPO that, if exercised, would result in the issuance of an additional 4,812 shares of common stock and warrants to purchase an additional 2,406 shares of common stock with an exercise price of $3.90 that expire on March 24, 2015;

warrants for 503,034 shares of our common stock issued in our 2009 private placement, which warrants have an exercise price of $3.4375 per share and expire on October 29, 2014;

warrants for 18,250 shares of common stock with an exercise price of $7.84 per share issued to co-placement agents in connection with our previous convertible note financings;

options to purchase an aggregate of 1,594,630 shares of our common stock issued to our officers, directors, employees and non-employee consultants under our Amended and Restated 2006 Stock Incentive Plan, or the 2006 Stock Plan, with a weighted average exercise price of $1.27 per share;

options to purchase an aggregate of 2,484,000 shares of our common stock issued to our officers, directors and non-employee consultants under our 2013 Stock Plan, with a weighted average exercise price of $1.29 per share;

warrants issued to investors in our 2012 private placement to purchase an aggregate of 1,712,500 shares of our common stock with an exercise price of $0.40 per share, of which 1,687,500 expire on September 20, 2017 and 25,000 expire on November 13, 2017;

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

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

1,500,000 shares of common stock issuable upon exercise of warrants with an exercise price of $1.25 that expire on October 22, 2019;

1,000,000 shares of common stock issuable upon exercise of warrants with an exercise price of $1.25 that expire on January 8, 2020;

1,500,000 shares of common stock issuable upon conversion of the Series C-2 Preferred Stock;

2,000,000 shares of common stock issuable upon conversion of the Series C-3 Preferred Stock;

1,148,000 shares of common stock issuable upon conversion of the Series D Preferred Stock;

1,104,280 shares of common stock issuable upon conversion of the Series E Preferred Stock; and

1,036,000 shares of common stock issuable upon exercise of warrants issued in March 2014 with an exercise price of $3.10 per shares that expire on September 9, 2019.

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

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

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

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

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may 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 March 14, 2014, options to purchase 1,594,630 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of $1.27 per share, and options to purchase 2,484,000 shares of common stock issued under our 2013 Stock Plan at a weighted average exercise price of $1.29 per share were outstanding. In addition, at March 14, 2014, there were outstanding warrants to purchase an aggregate of 10,571,233 shares of our common stock at prices ranging from $0.40 to $7.84, and shares of our outstanding Series B, C-2, C-3, D and E preferred stock convertible into an aggregate of 6,206,826 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. On April 20, 2012, and April 5, 2013, the NYSE MKT notified us that we were not in compliance with certain listing standards relating to our financial condition and stockholders' equity, respectively, and we had to submit a plan to regain compliance with the listing standards, which required and received several extensions. We regained compliance on October 20, 2013. We will need to satisfy NYSE MKT Rule 1003(a)(ii) by having a minimum of $4.0 million in stockholders' equity as of December 31, 2013 and maintain that amount during 2014. We anticipated being in compliance on December 31, 2013, however, due to complex derivative accounting and equity financing transactions that closed in January and March of 2014, we were not in compliance at December 31, 2013. Based on the equity financing transactions that closed in January and March of 2014, conversions of preferred stock to common stock, stock option exercises and the reclassification of derivative liabilities to equity accounts, we believe we now have stockholders' equity in excess of $4 million. There can be no assurance that we will 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. As a result, our common stock is 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.

Our management is aware of the abuses that have occurred historically in the penny stock market.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located in approximately 3,500 square feet of office space in Bridgewater, New Jersey. We lease this office space pursuant to a lease agreement dated March 18, 2010 with UA Bridgewater Holdings, LLC (the "Lease Agreement"). The Lease Agreement has an initial term of 60 months, commencing on April 1, 2010 and expiring on March 31, 2015, and lease payments began on July 1, 2010. We have been granted the option to extend the lease term for one additional period of three years, commencing the day following the then-current expiration date of the term, March 31, 2015, provided we deliver notice to the landlord no later than nine months prior to March 31, 2015. The total 60 month lease obligation is approximately $389,000. Our total remaining lease obligation was approximately $104,000 as of December 31, 2013.

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 €442. The total 36 month lease obligation is approximately €15,900 and the remaining lease obligation was approximately €14,100 as of December 31, 2013.

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Item 3. Legal Proceedings

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland, or Geistlich, brought an action against the Sodemann patent covering our Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to us pursuant to the License and Assignment Agreement between us and ND Partners LLC. The action that was brought against the Sodemann patent in Germany at the Board of the European Patent Office opposition division was for lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions described in the Lehner patent. The Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. We filed a response to the appeal of Geistlich on March 25, 2009 where we requested a dismissal of the appeal and to maintain the patent as granted. As of March 27, 2014, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, we became aware that the Board of Appeals of the European Patent Office issued, on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the Sodemann patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the Sodemann patent claims. We received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. In a letter dated September 30, 2013, we were notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils the requirements of Clarity, Novelty, and Inventive Step, and invited the parties to provide their comments and/or requests by February 10, 2014. We filed our response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division has granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. We intend to continue to vigorously defend the patent in a restricted form. However, we can provide no assurances regarding the outcome of this matter.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market for Common Equity

Our common stock trades on the NYSE MKT under the symbol “CRMD.” The following table sets forth the high and low sales prices for our common stock for the periods indicated as reported by NYSE MKT:

Fiscal Year 2013	High	Low
First Quarter	$1.11	$0.71
Second Quarter	$1.00	$0.48
Third Quarter	$1.29	$0.75
Fourth Quarter	$1.37	$0.66

Fiscal Year 2012	High	Low

First Quarter	$ 0.62	$ .23
Second Quarter	$ 0.50	$ .15
Third Quarter	$ 0.35	$ .16
Fourth Quarter	$ 1.25	$ .24

Based upon information furnished by our transfer agent, at March 14, 2014, we had approximately 234 holders of record of our common stock.

Dividend Policy

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Further, pursuant to the terms of our Series D and 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, 2013 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)	3,453,630	$1.06	3,256,000
Equity compensation plans not approved by security holders (2)	123,649	1.63	--
Total	3,577,279	$1.08	3,256,000

(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 2,406 units consisting of two shares of common stock issuable pursuant to a warrant issued to the underwriters of our IPO in 2010 (with an exercise price of $7.80 per unit), 18,250 shares of common stock issuable pursuant to warrants issued to the co-placement agents of our convertible note financings prior to our IPO (with an exercise price of $7.84 per share), and 100,587 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).

Item 6. Selected Financial Data

Not applicable.

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

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

Overview

We are a development stage company as of December 31, 2013 and are in the process of transitioning to a commercial pharmaceutical and medical device company. We seek to in-license, develop and commercialize therapeutic products for the treatment of cardiorenal and infectious diseases, including the dialysis and non-dialysis areas. As of the date of this report, we have in-licensed all of the product candidates in our pipeline.

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

Our primary product is Neutrolin for the prevention of catheter-related infections in dialysis and non-dialysis markets, which we believe addresses a medical need and a potentially large market opportunity. Neutrolin is a liquid formulation designed to prevent central venous catheter infection as well as catheter obstruction, also referred to as maintenance of catheter patency, in central venous catheters, which we initially plan for use in hemodialysis catheters. There are approximately 780,000 hemodialysis patients in the United States and the EU. We believe the patients undergoing hemodialysis using a tunneled central vein catheter will be our initial target market. We project 91,000 patients in the European Union and 104,000 patients in the United States. These patients represent nearly 30 million hemodialysis sessions per year, which we believe represents a market potential of approximately $300 - $400 million.

During the third quarter of 2011, we received a notice from the FDA that Neutrolin had been assigned to the CDER for review as a drug rather than a device. As a result of this, and given our limited resources, we decided to change our business strategy and focus the majority of our resources on the research and development of Neutrolin, rather than CRMD004 and to seek regulatory and commercialization approval for Neutrolin in Europe through a CE Mark application rather than pursue FDA approval at that time.

On July 5, 2013, we received CE Mark approval for Neutrolin. As a result, we began the commercial launch of Neutrolin for the prevention of catheter-related bloodstream infections, or CRBI, and maintenance of catheter patency in hemodialysis patients in Europe in the fourth quarter of 2013.

We have four pillars to our Neutrolin strategy: (i) successfully launch the product in Germany; (ii) expand the product into additional applications; (iii) expand sales into other foreign countries; and (iv) apply for and receive marketing approval and launch the product in the United States.

In anticipation of receiving CE Mark approval, on January 10, 2013, we entered into an agreement with MKM Co-Pharma GmbH, or MKM, regarding Neutrolin, pursuant to which, MKM hired a national sales manager, to market Neutrolin in Germany according to a negotiated work plan. While the plan may be revised, it currently provides that the sales manager will market Neutrolin in three phases. In the first phase, which began in January 2013, the sales manager visited hemodialysis centers and doctors to, among other things, provide them information. The sales

manager has also produced a market review of our product, negotiated wholesaler relationships for initial stocking of our product, and developed sales projections for launching Neutrolin. We transferred this work from MKM to human4farma GmbH, or human4farma, which hired the same sales manager who continued, after the receipt of CE Mark approval, with the launch of Neutrolin in the fourth quarter of 2013 in Germany. Human4farma will be responsible for growing Neutrolin sales and expanding the promotional plans.

In late 2013, we met with the FDA to determine the pathway for U.S. approval of Neutrolin, which will entail at least one Phase III clinical trial in hemodialysis catheters and potentially one Phase III clinical trial in another indication.

Financial Operations Overview

Revenue

We have not generated substantial revenue since our inception. As of December 31, 2013, we have funded our operations primarily through debt and equity financings and the IPO, and our receipt of a total of approximately $490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program, a total of approximately $775,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and approximately $35,000 from the State of New York's Research and Development Tax Credit Program.

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. Through December 31, 2013, we incurred $24.4 million in R&D expenses since our inception in July 2006. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. We plan to increase our R&D expenses for the foreseeable future in order to complete development of Neutrolin in the U.S.

The following table summarizes the percentages of our R&D payments related to our two most advanced product candidates and other projects. The percentages summarized in the following table reflect payments directly attributable to each development candidate, which are tracked on a project basis. A portion of our internal costs, including indirect costs relating to our product candidates, are not tracked on a project basis and are allocated based on management's estimate.

	Year Ended December 31,		Period from July 28, 2006 (Inception) through December 31,
	2013	2012	2013
CRMD001	0%	6%	44%
CRMD002	0%	0%	0%
CRMD003	97%	88%	53%
CRMD004	3%	6%	3%

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

or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates.

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

We received CE Mark approval in July 2013 and launched Neutrolin for the prevention of CRBI and maintenance of catheter patency in hemodialysis patients in Germany in the fourth quarter of 2013. We intend to seek U.S. approval of Neutrolin, which we expect to entail a Phase 3 trial, based on guidance from the FDA.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expense include 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 otherwise 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 as a result of the reporting obligations applicable to public companies. From our inception on July 28, 2006 through December 31, 2013, we incurred $16.3 million of SG&A expense.

Loss on Issuance of Convertible Notes and Warrants

As discussed in Note 6, we sold convertible notes and warrants during the year ended December 31, 2013. We elected to account for the convertible notes and warrants under the fair value option. The loss on the issuance of convertible notes and warrants represents the difference on the issuance date between the combined fair value of the convertible notes and the warrants, and the proceeds that were received net of all fees and expenses related to the issuance.

Change in Fair Value of Convertible Notes and Warrants

The change in the value of convertible notes and warrants represents the change in the fair value of the convertible notes for which we elected the fair value option, and the change in the fair value of warrants that are required to be recorded at fair value on a recurring basis under generally accepted accounting principles. This includes any reductions in fair value resulting from the redemption or conversion of the convertible notes and the exercise of warrants.

Loss on Extinguishment of Convertible Notes

The loss on extinguishment of convertible notes represents the difference between the fair value of convertible notes redeemed and converted and the cash paid or fair value of shares issued to noteholders in connection with the redemptions and conversions.

Other Income (Expense)

Other income consists mainly of federal research grants awarded and research and development tax refunds, net of application fees. From our inception on July 28, 2006 through December 31, 2013, we received $0.4 million of other income, net of application fees and related filing costs.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash and cash equivalents. Interest expense consists of interest incurred on our pre-IPO convertible notes (up to their automatic conversion into units or common stock upon the completion of the IPO on March 30, 2010), and on our convertible notes issued in September and November 2012 and in May 2013, as well as the amortization and write-off of deferred financing costs and debt discounts and a charge for the beneficial conversion relating to certain of our convertible notes. From our inception on July 28, 2006 through December 31, 2013, we received $0.1 of interest income through interest bearing savings accounts and incurred $13 million of interest expense, which consists of interest incurred in debt issued to note holders, amortization and write-off of deferred financing costs and debt discounts and a beneficial conversion feature charge related to the conversion of certain of our convertible notes.

Results of Operations

Comparison of the Years Ended December 31, 2013 and December 31, 2012

Research and Development Expense. R&D expense was $1,226,874 for the year ended December 31, 2013, an increase of $84,243 from $1,142,631 for the same period last year. The increase was primarily attributable to the license fee of $500,000 as a result of the CE Mark approval for Neutrolin in the EU and the non-cash value of the warrants issued to ND Partners, LLC as a result of the April 2013 amendment to the License and Assignment Agreement, dated January 30, 2008 between the Company and ND Partners, LLC, partially offset by a decrease in personnel costs.

Selling, General and Administrative Expense. SG&A expense was $3,488,917 for the year ended December 31, 2013, an increase of $1,631,837 from $1,857,080 for the same period last year. The increase was primarily attributable to stock-based compensation expense and costs related to the launch and commercialization of Neutrolin in the EU.

Loss on Issuance of Convertible Notes and Warrants. The loss on the issuance of convertible notes and warrants represents the difference on the issuance date between the combined fair value of the convertible notes and the warrants of $2,231,100, and the proceeds received, net of all issuance-related fees and expenses, of $1,285,208.

Change in Fair Value of Convertible Notes, Preferred Stock and Warrants. The change in the value of convertible notes, preferred stock and warrants of $363,919 consists of an increase in the fair value of warrants between the issuance date and December 31, 2013 of $141,573, reduction in the fair value of convertible notes of $44,642 and increase in the fair value of preferred stock of $266,988. The change in the fair value of the convertible notes and preferred stock include the combined changes in (i) the fair value of the converted and redeemed amounts between the issuance date and the relevant conversion and redemption dates and (ii) the change in fair value of the outstanding

convertible notes and preferred stock at December 31, 2013 between the issuance date and December 31, 2013. The change in fair value of the warrants is the difference between the fair value at the issuance date and December 31, 2013.

Loss on Extinguishment of Convertible Notes. The $1,459,661 loss on extinguishment of convertible notes for the year ended December 31, 2013 represents the excess of the fair value of shares issued in connection with the conversions and redemptions over the fair value of the convertible notes that were converted or redeemed for shares.

Other Income (Expense). Other income (expense) for the year ended December 31, 2013 increased by $4,513 as compared to the same period last year due to the foreign currency loss.

Interest Income. Interest income was $668 for the year ended December 31, 2013, a decrease of $1,297 from $1,965 for the year ended December 31, 2012. The decrease was attributable to having lower interest-bearing cash balances during the year ended December 31, 2013 compared to the same period last year.

Interest Expense. Interest expense was $1,444,386 for the year ended December 31, 2013, an increase of $1,061,450 from $382,936 for the same period last year, primarily due to the amortization of beneficial conversion feature and warrants valuation related to the senior convertible notes and warrants issued in 2012 and 2013, amortization of deferred financing fees and accrued interest related to the senior convertible notes.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our lack of revenues and significant R&D expenditures, we have not been profitable and have generated significant operating losses since we were incorporated in July 2006. We received CE Mark approval in July 2013 and launched our product in the EU. Prior to the IPO in 2010, we had funded our operations principally with $14,364,973 in convertible notes sold in private placements and $625,464 in related party notes, which were also convertible. All of our convertible notes were automatically converted into 1,237,293 shares of common stock and 2,338,576 Units (comprised of 4,677,152 shares of common stock and 2,841,603 warrants at an exercise price of $3.4375). We received net proceeds of $10,457,270 from the IPO, after deducting underwriting discounts, commissions and offering expenses payable by us upon the closing of the IPO on March 30, 2010. Additionally, we received a total of approximately $490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program and a total of approximately $775,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and a total of approximately $35,000 from qualified R&D expenditures refunded to us through the New York State Department of Taxation and Finance under the Qualifying Emerging Technology Incentive Program.

During the year ended December 31, 2012, we completed two tranches of a private placement for a total of 1,324 units, each unit consisting of (i) a one-year $1,000 aggregate principal amount 9% senior convertible note, convertible into shares of common stock, at a conversion price of $0.35 per note, and (ii) a five-year redeemable warrant to purchase 2,500 shares of common stock at an initial exercise price of $0.40 per share. We received gross proceeds of $1,324,000 or net proceeds of approximately $1,095,600 from the private placement. The notes issued matured in 2013, 924 units were converted to common stock during the year ended December 31, 2013.

During the year ended December 31, 2013, we sold 761,429 shares of our Series A non-voting convertible preferred stock and a warrant to purchase up to 400,000 shares of our common stock for gross proceeds of $533,000 in February 2013; we sold $1,500,000 of convertible notes and warrants to purchase up to 750,000 shares of our common stock in May 2013; we sold 454,546 shares of Series B non-voting convertible preferred stock and a warrant to purchase up to 227,273 shares of our common stock for gross proceeds of $500,000 in July 2013; and we sold 150,000 shares of our Series C-1 and 150,000 shares of our Series C-2 non-voting convertible preferred stock and warrants to purchase up to 1,500,000 shares of our common stock for gross proceeds of $3,000,000 in October 2013. Also in October 2013, we exchanged $400,000 in principal amount of September 2012 convertible notes for 57,400 shares of our Series D non-voting convertible preferred stock and also exchanged $750,000 in principal amount of May 2013 convertible notes for 53,537 shares of our Series E non-voting convertible preferred stock. All of the Series A and Series C-1 non-voting convertible preferred stock were converted to common stock during the year ended December 31, 2013.

In January 2014, we sold 200,000 shares of our Series C-3 non-voting convertible preferred stock and warrants to purchase up to 1,000,000 shares of our common stock for gross proceeds of $2,000,000.

In March 2014, we sold 2,960,000 units, each unit consisted of one share of our common stock and 0.35 of a warrant to purchase one share of our common stock, for gross proceeds of $7,400,000. We received net proceeds of approximately $6,600,000.

Net Cash Used in Operating Activities

Net cash used in operating activities was $3,618,532 million for the year ended December 31, 2013. The net loss of $9,133,098 for the year ended December 31, 2013 was higher than cash used in operating activities by $5,514,566. The difference is attributable primarily to a non-cash loss on extinguishment of debt and issuance of

convertible notes and warrants, change in value of convertible notes and warrants, amortization of debt discount and deferred financing costs, stock-based compensation charge and an increase in accrued expenses.

Net Cash Used in Investing Activities

Net cash used in investing activities was $35,683 for the year ended December 31, 2013 as compared to $0 for the same period last year due to the purchase of operating equipment and software for our German subsidiary, which was established in 2013.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $5,204,082 for the year ended December 31, 2013 as compared to $1,126,397 provided by financing activities for the same period last year. The increase was attributable to the proceeds of $3,000,000 from the sales of Series C-1 and C-2 non-voting preferred stock, net of expenses of $73,122; $1,500,000 from the sale of the 8% senior convertible notes, net of discount and expenses of $127,500, proceeds of $1,033,000 from the sale of Series A and Series B preferred stock, and proceeds of $62,400 from the exercise of warrants and stock options, partially offset by the payment of deferred financing costs and private placement expenses of $157,696 and repurchase of outstanding warrants of $33,000. In comparison, we received $1,324,000 of gross proceeds in 2012 from the sale of 9% senior convertible notes, net of expenses of $127,400, offset by the payment of deferred financing costs of $70,203.

Funding Requirements

Our total cash on hand as of December 31, 2013 was $2,373,893, compared to $835,471 at December 31, 2012. Because our business to date does not generate positive operating cash flow, we may need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development, as well as to fund operations generally. Our continued operations will depend on whether we are able to generate substantial revenue from the sale of Neutrolin or raise additional funds through various potential sources, such as equity, debt financing, strategic relationships, out-licensing or distribution arrangements of our products. Through December 31, 2013, all of our financing has been through the issuance of convertible notes in 2012 and 2013, the issuances of preferred stock in 2013, our 2010 IPO, previous debt financings and our receipt of a total of approximately $490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program, a total of approximately $775,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and approximately $35,000 from the State of New York's Research and Development Tax Credit Program, net of application fees. We expect to continue to fund operations from cash on hand and through either capital raising sources as previously described, which may be dilutive to existing stockholders, or through generating revenues from the licensing of our products or strategic alliances. We plan to seek additional debt and/or equity financing, but can provide no assurances that such financing will be available on acceptable terms, or at all. Moreover, the incurrence of indebtedness in connection with a debt financing would result in increased fixed obligations and could also result in covenants that would restrict our operations. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors including the changes in the focus and direction of our research and development programs, the acquisition and pursuit of development of new product candidates, competitive and technical advances, costs of commercializing any of our product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights.

While we expect to grow product sales substantially, we do not anticipate that we will generate significant product sales revenue for 2014. In the absence of such revenue, we would experience continuing operating cash flow losses. We expect to incur increases in our cash used in operations over the next several quarters as we continue to commercialize Neutrolin and seek FDA approval of Neutrolin in the U.S.

Based on our cash resources at December 31, 2013, and the proceeds from the private placement in the first quarter of 2014 of our Series C-3 non-voting convertible preferred stock and common stock and warrants, our expectations on product sales and our current plan of expenditure on continuing development of Neutrolin, we believe that we have sufficient capital to fund our operations into 2015, but will need additional financing thereafter until we can achieve profitability, if ever. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our products, or we could be required to delay, scale back or eliminate some or all of our research and development programs. Each of these alternatives would likely have a material adverse effect on our business.

Critical Accounting Policies

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

While our significant accounting policies are more fully described in Note 2 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 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 method in accordance with ASC 718. The non-cash charge to operations for non-employee options with vesting are revalued at the end of each reporting period based upon the change in the fair value of the options and amortized to consulting expense over the related vesting period.

We granted options to purchase 1,814,000 shares of common stock to our employees, non-employees and directors and officers during the year ended December 31, 2013. For the purpose of valuing options and warrants granted to our employees, directors and officers during the year ended December 31, 2013, we used the Black-Scholes option pricing model. For the purpose of valuing performance based options granted to non-employees during the year ended December 31, 2013, we used the guidelines in accordance with FASB ASC No. 505-50 ("ASC 505"), "Equity-Based Payments to Non-Employees", of which if the performance condition is outside of the control of the non-employee, the cost to be recognized is the lowest aggregate fair value prior to the achievement of the performance condition, even if we believe it is probable that the performance condition will be achieved. As of December 31, 2013, the performance conditions of an aggregate of 410,000 stock options were achieved, resulting in non-employee stock options vesting and we recorded an expense of $333,977 during the period ended December 31, 2013. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of our awards. We estimated the expected term of the options granted based on anticipated exercises in future periods assuming the success of our business model as currently forecasted. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for the stock options was calculated by examining historical volatilities for publicly traded industry peers, since we do not have a significant trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for our common stock becomes available. We have experienced forfeitures of stock options issued to our former employees, officers, directors and board members. Since the stock options currently outstanding are primarily held by our senior management and directors, we will continue to evaluate the effects of such future potential forfeitures, as they may arise, to ascertain an estimated forfeiture rate.

Accounting Standards Updates

There are no recent accounting pronouncements that are expected to have an effect on our consolidated financial position or consolidated statement of operations.

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

None.

Item 9A. Controls and Procedures

We have identified a material weakness in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) related to our limited finance staff and the resulting ineffective management review over financial reporting, coupled with increasingly complex accounting treatments associated with our financing activities and European expansion. We have taken initial measures to remediate this weakness by increasing internal review processes, in addition to the previously established accounting oversight committee, which is comprised of members of our senior management and third party GAAP advisor. We expect to be able to add to our finance staff in 2014 as we build our infrastructure, which we believe will remediate this weakness. However, we cannot be assured that this weakness will be remediated or that other material weaknesses will not be discovered.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. As of the end of the period covered by this report, our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. Based on their evaluation of our disclosure controls and procedures, and as a result of the material weakness described above, our management, including our principal executive officer and principal financial officer, have concluded that our disclosure controls and procedures were not effective as of December 31, 2013 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (b) accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow for timely decisions regarding required disclosure.

Management's Annual Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. All internal control systems, no matter how well designed, have inherent limitations and may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Our management, including our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2013. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (1992). Our management concluded that based on its assessment, and as a result of the material weakness described above, our internal control over financial reporting was not effective as of December 31, 2013.

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

Changes in Internal Control Over Financial Reporting

Other than as described above, there were no changes in our internal control over financial reporting during the quarter ended December 31, 2013, or in other factors that could significantly affect these controls, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

We intend to hold our 2014 Annual Meeting of Stockholders on June 25, 2014.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock to file with the Securities and Exchange Commission ("SEC") initial reports of ownership and reports of changes in the ownership of our common stock and other equity securities. Such persons are required to furnish us copies of all Section 16(a) filings. Based solely upon a review of the copies of the forms furnished to us, we believe that our officers, directors and holders of more than 10% of our common stock complied with all applicable filing requirements during the fiscal year ended December 31, 2012, with the exception of Antony E. Pfaffle for whom a Form 4 to report the sale of 125 shares on September 24, 2013 was due on September 26, 2013 and that was filed on September 30, 2013.

Directors and Executive Officers

The following table sets forth the name, age and position of each of our directors and executive officers as of March 14, 2014.

Name	Age	Position
Randy Milby	60	Chief Executive Officer, Director
Steven Lefkowitz (1) (3)	58	Interim Chief Financial Officer, Director
Gary A. Gelbfish, M.D. (1) (2) (3)	55	Chairman of the Board
Antony E. Pfaffle, M.D. (1) (3)	50	Director and Acting Chief Scientific Officer
Matthew Duffy (1) (2) (3) (4)	51	Director
Michael George (3) (4)	65	Director

(1) Member of the Compensation Committee.
(2) Member of the Audit Committee.
(3) Member of the Nominating and Corporate Governance Committee
(4) Member of the Sales and Marketing Oversight Committee

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

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

serve as a director of our company in light of our business and structure.

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

Gary A. Gelbfish, M.D. has been a director of CorMedix since December 2009. Dr. Gelbfish has been in private practice as a vascular surgeon since 1990. Dr. Gelbfish has practiced vascular surgery at Beth Israel Hospital since 1990, and has practiced vascular surgery at New York University Downtown Hospital since 2003. Since 1997, Dr. Gelbfish has served as an Assistant Clinical Professor of Surgery at Mt. Sinai Hospital. Dr. Gelbfish received a B.S. from Brooklyn College, holds an M.D. from Columbia University, and completed his fellowship in vascular surgery at Maimonides Medical Center. Among other experience, qualifications, attributes and skills, Dr. Gelbfish's in-depth knowledge of the practice of medicine and understanding of the science behind our product candidates led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

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

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

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

Board Committees

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

Audit Committee

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

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

The Audit Committee monitors our corporate financial statements and reporting and our external audits, including, among other things, our internal controls and audit functions, the results and scope of the annual audit and other services provided by our independent registered public accounting firm and our compliance with legal matters that have a significant impact on our financial statements. The Audit Committee also consults with our management and our independent registered public accounting firm prior to the presentation of financial statements to stockholders and, as appropriate, initiates inquiries into aspects of our financial affairs. The Audit Committee is responsible for

establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters, and for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters. In addition, the Audit Committee is directly responsible for the appointment, retention, compensation and oversight of the work of our independent registered public accounting firm, including approving services and fee arrangements. All related party transactions will be approved by the Audit Committee before we enter into them.

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

Compensation Committee

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

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

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

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee consists of Dr. Gelbfish (Chair), Dr. Pfaffle and Mr. Duffy, and Mr. George each of whom satisfies the independence requirements of NYSE MKT rules and regulations.

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

Sales and Marketing Oversight Committee

The Sales and Marketing Oversight Committee consists of Mr. Duffy (Chair), and Mr. George, each of whom satisfies the independence requirements of NYSE MKT rules and regulations.

The primary function of the Sales and Marketing Oversight Committee is to provide expert input and guidance to the Chief Executive Officer and the Sales and Marketing teams of CorMedix.

The Sales and Marketing Oversight Committee will review the status of the current and future strategies related to marketing, distribution, and sales.

In practice these responsibilities are carried out by performing the following functions:

Review and provide input on product positioning, pricing and sales performance;

Providing specific input on sales strategy;

Providing insights on distribution strategy, where required, guidance on development of new or alternate distribution systems and approaches; and

Provide oversight for compliance with Foreign Corrupt Practices Act (FCPA) in accordance with guidelines.

Code of Ethics

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

A copy of the Code of Ethics is available in the Investor Relations; Corporate Governance, portion of our website, www.cormedix.com. Additional copies of the Code of Ethics may be obtained without charge, from us by writing or calling: 745 Rt. 202-206, Suite 303, Bridgewater, NJ 08807, Attn: Chief Executive Officer; Telephone: (908) 517-9500.

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Item 11. Executive Compensation

Summary Compensation Table

The following table sets forth information with respect to compensation earned by our named executive officers in the years ended December 31, 2013 and 2012:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards (1) ($)	All Other Compensation ($)	Total ($)
Randy Milby (2)	2013	223,500	-	368,500	-	592,000
Chief Executive Officer	2012	58,800	-	67,750	-	126,550
Richard M. Cohen (3)	2013	60,000	-	80,559	-	140,559
Interim Chief Executive Officer and Interim Chief Financial Officer	2012	86,250	-	39,200	-	125,450
Steven W. Lefkowitz (4)	2013	30,000	-	88,440	39,650(5)	158,090
Interim Chief Financial Officer	2012	-	-	-	-	-
Antony E. Pfaffle (6)	2013	120,000	-	154,770	37,500(5)	312,270
Acting Chief Scientific Officer	2012	-	-	-	-	-

(1) The amounts included in this column are the dollar amounts representing the full grant date fair value of, and in the case of Mr. Cohen, the incremental fair value of modifications in August 2013 to his then outstanding options, of each stock option award calculated in accordance with FASB ASC Topic 718 and do not represent the actual value that may be recognized by the named executive officers upon option exercise. For information on the valuation assumptions used in calculating this amount, see Note 2 to our audited financial statements included in this Annual Report on Form 10-K.

(2) Mr. Milby became our Chief Operating Officer in May 2012. Effective January 1, 2013, the Board appointed Mr. Milby our Chief Executive Officer. The amount of salary reported for 2013 includes $36,000 paid in consulting fees to MW Bridges LLC, of which Mr. Milby is Managing Partner; all salary reported for 2012 was paid to MW Bridges. Mr. Milby became an employee on April 1, 2013.

(3) Mr. Cohen resigned as a director and our Interim Chief Financial Officer in August 2013. As our Interim Chief Executive Officer, Mr. Cohen did not receive Board fees and Board stock options grants in 2012 or 2013.

(4) Mr. Lefkowitz became our Interim Chief Financial Officer in August 15, 2013.

(5) Consists of director fees.

(6) Dr. Pfaffle became our Acting Chief Scientific Officer on January 1, 2013.

Compensation Objectives and Philosophy

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

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

The Compensation Committee seeks to achieve these objectives by:

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

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

Setting Executive Compensation

The Compensation Committee oversees the design, development and implementation of the compensation program for the Chief Executive Officer and the other named executive officers. The Compensation Committee evaluates the performance of the Chief Executive Officer and determines the Chief Executive Officer's compensation in light of the goals and objectives of the compensation program. The Chief Executive Officer and the Compensation Committee together assess the performance of the other named executive officers and determine their compensation, based on initial recommendations from the Chief Executive Officer. Our Chief Executive Officer provided the Compensation Committee with a detailed review of the performance of the other named executive officers and made recommendations to the Compensation Committee with respect to the compensation packages for those officers for 2013.

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

We did not use the services of any compensation consultant in matters affecting the compensation of named executive officers or directors during 2012 or 2013. In the future, we, or the Compensation Committee, may engage or seek the advice of a compensation consultant.

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

Components of Compensation

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

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

given performance year, actual salary increases may range from 0% to 10% of the salary guidelines based on individual performance. This broad range allows for meaningful differentiation on a pay for performance basis.

The base salary information for our named executive officers for 2013 is set forth in the table above. As a result of our financial condition as well as changes in our management in 2013, the Chief Executive Officer and the Compensation Committee recommended to the Board that no merit increases be granted to our named executive officers for 2013.

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

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

As a result of our financial condition, our Interim Chief Executive Officer and the Compensation Committee determined not to grant bonuses to the named executive officers for 2011 or 2012.

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

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

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

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

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

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

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

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

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

Restricted Stock. Our 2013 Stock Plan (and formerly our 2006 Stock Plan) authorizes us to grant restricted stock. No restricted stock grants were awarded during 2012 or 2013. In order to implement our long-term incentive goals, we may grant shares of restricted stock in the future.

Restricted Stock. Our 2013 Stock Plan (and formerly our 2006 Stock Plan) authorizes us to grant restricted stock. No restricted stock grants were awarded during 2012 or 2013. In order to implement our long-term incentive goals, we may grant shares of restricted stock in the future.

Executive Benefits and Perquisites

Our named executive officers, some of whom may be parties to employment or consulting agreements, will continue to be parties to such agreements in their current form until the expiration or termination of the employment or consulting agreement or until such time as the Compensation Committee determines in its discretion that revisions to

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

Employment Agreements and Arrangements

Randy Milby

On May 2, 2012, we appointed Mr. Milby as Chief Operating Officer pursuant to a three-month consulting agreement with MW Bridges LLC, of which Mr. Milby is Managing Partner. MW Bridges LLC received a consulting fee of $6,400 per month for Mr. Milby's services. Additionally, MW Bridges LLC was granted stock options to purchase 50,000 shares of our common stock at an exercise price of $0.29 per share. Such stock options vested upon CE Mark approval for Neutrolin in July 2013. On October 31, 2012, we and MW Bridges LLC entered into an amendment to the consulting agreement, which, among other things, (i) extended the then-current term for an additional three months, and (ii) increased Mr. Milby's monthly retainer to $12,000, effective October 1, 2012. On December 24, 2012, we again amended the consulting agreement to extend its term to June 24, 2013 and Mr. Milby was appointed our Chief Executive Officer, effective January 1, 2013. On April 1, 2013, Mr. Milby became an employee of the Company and the consulting agreement was terminated.

Outstanding Equity Awards at Fiscal Year-End

The following table presents information regarding unexercised options for each named executive officer as of the end of the fiscal year ended December 31, 2013:

	Number of Shares Underlying Unexercised Options (#) – Exercisable	Number of Shares Underlying Unexercised Options (#) - Unexercisable	Option Exercise Price ($)	Option Expiration Date
Randy Milby	50,000	-	0.29	5/14/2022
	100,000	-	0.68	12/05/2022
	250,000	250,000(1)	0.90	3/20/2023
Richard M. Cohen	20,000	-	3.125	8/15/2015
	30,000	-	2.10	8/15/2015
	70,000	-	0.68	8/15/2015
	40,000	-	0.90	8/15/2015
Steven W. Lefkowitz	30,000	-	1.10	8/11/2021
	30,000	-	0.29	1/06/2022
	150,000	-	0.68	12/5/2022
	45,000	75,000(2)	0.90	3/20/2023
Antony E. Pfaffle	20,000	-	3.125	3/30/2020
	30,000	-	2.10	1/14/2022
	30,000	-	0.29	1/06/2022
	250,000	-	0.68	12/05/2022
	50,000	160,000(3)	0.90	3/20/2023

(1) On March 20, 2013, we granted Mr. Milby 500,000 ten-year non-qualified stock options under the 2013 Plan, with an exercise price of $0.90 per share. These options vest upon specified milestones running through December 31, 2014.
(2) On March 20, 2013, we granted Mr. Lefkowitz 120,000 ten-year non-qualified stock options under the 2013 Plan, with an exercise price of $0.90 per share. These options vest quarterly over two years.
(3) On March 20, 2013, we granted Dr. Pfaffle 210,000 ten-year non-qualified stock options under the 2013 Plan, with an exercise price of $0.90 per share. These options vest upon specified milestones running through December 31, 2014.

Director Compensation

The following table sets forth information with respect to compensation earned by or awarded to each of our non-executive directors who served on the Board during the fiscal year ended December 31, 2013:

Name	Fees Earned ($)	Option Awards (1) (2) ($)	Total ($)
Richard M. Cohen(3)	-	-	-
Gary A. Gelbfish, M.D.	41,250	36,850	78,100

Antony E. Pfaffle, M.D.(4)	-	-	-
Steven Lefkowitz(5)	-	-	-
Matthew P. Duffy	40,850	73,700	114,550

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

(2) As of December 31, 2013, the number of shares underlying options held by each non-employee director was as follows: 200,000 shares for Dr. Gelbfish; and 285,000 shares for Mr. Duffy. For information on options held by Dr. Pfaffle and Mr. Lefkowitz, see the "Outstanding Equity Awards at Fiscal Year End" table above.

(3) On September 30, 2011, Richard Cohen was appointed our Interim Chief Executive Officer and Executive Chairman in a non-employee capacity, and as such, no longer received Board fees and stock options grants from the date thereof. Mr. Cohen's compensation is set forth in the "Summary Compensation Table" above. Mr. Cohen resigned all positions on August 15, 2013.

(4) On January 1, 2013, Antony Pfaffle was appointed our Acting Chief Scientific Officer. All compensation paid to Dr. Pfaffle as an officer and a director is set forth in the "Summary Compensation Table" above.

(5) On August 15, 2013, Steven Lefkowitz was appointed our Interim Chief Financial Officer. All compensation paid to Mr. Lefkowitz as an officer and a director is set forth in the "Summary Compensation Table" above.

The Compensation Committee has adopted the following director cash compensation policy. Employee directors do not receive any compensation for their services on the Board. Non-employee directors are entitled to receive the following cash compensation: (i) a $20,000 annual retainer, except that the Chairman of the Board receives $30,000, (ii) $5,000 annually for service on the Audit Committee, except that the Chairman of the Audit Committee receives $12,000, (iii) $4,000 annually for service on the Nominating and Corporate Governance Committee, except that the Chairman of the Nominating and Corporate Governance Committee receives $5,000, (iv) $4,000 annually for service on the Compensation Committee, except that the Chairman of the Compensation Committee receives $5,000, (v) $1,000 for each in-person meeting of the Board attended, and (vi) $500 for each telephonic meeting of the Board attended.

In addition, the Board has adopted the following equity compensation plan for our non-employee directors: (i) an annual grant to each non-employee director at the first Board meeting of the calendar year of an option to purchase 30,000 shares of our common stock at an exercise price equal to the closing price of the common stock on the grant date, which option vests on the first anniversary of the grant date; and (ii) a one-time grant to each new non-employee director in connection with his or her initial election to the Board of an option to purchase 30,000 shares of our common stock at an exercise price equal to the closing price of the common stock on the grant date, which option vests in equal installments on each of the grant date, the first anniversary of the grant date and the second anniversary of the grant date.

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

The following table sets forth information regarding the number of shares of our common stock beneficially owned at March 14, 2014:

each person known by us to own beneficially more than 5% of the outstanding shares of our common stock;

each directors and nominee for director;

each of our executive officers named in the Summary Compensation Table above (the "Named Executive Officers"); and

all of our directors and executive officers as a group.

This table is based upon the information supplied by our Named Executive Officers, directors and principal stockholders and from Schedules 13D and 13G filed with the SEC. Except as indicated in footnotes to this table, the persons named in this table have sole voting and investment power with respect to all shares of common stock shown, and their address is c/o CorMedix Inc., 745 Route 202-206, Suite 303, Bridgewater, New Jersey 08807. As of March 14, 2014, we had 21,963,384 shares of common stock outstanding. Beneficial ownership in each case also includes shares issuable upon exercise of outstanding options that can be exercised within 60 days after March 14, 2014 for purposes of computing the percentage of common stock owned by the person named. Options owned by a person are not included for purposes of computing the percentage owned by any other person.

Name and Address of Beneficial Owner	Common Stock Beneficially Owned (1)	
	Shares	%
5% or Greater Stockholders:		
Kingsbrook Partners LP (2)	2,324,672	9.9
Elliott Associates, L.P. (3)	2,832,184	9.9
Directors and Named Executive Officers:		
Randy Milby (4)	1,133,743	5.0
Matthew P. Duffy (5)	453,223	2.0
Gary A. Gelbfish, M.D. (6)	1,979,799	8.5
Steve Lefkowitz (7)	965,738	4.3
Antony E. Pfaffle, M.D. (8)	496,725	2.2
Michael W. George	0	na
All executive officers and directors as a group (6 persons) (9)	4,458,021	18.3

(1) Based upon 21,963,384 shares of our common stock outstanding on March 14, 2014 and, with respect to each individual holder, rights to acquire our common stock exercisable within 60 days of March 14, 2014.

(2) Due to the Ownership Limitation (as defined below), Kingsbrook Partners LP (“Kingsbrook”) may be deemed the beneficial owner of 2,324,672 shares of our common stock through securities held by it and by Kingsbrook Opportunities Master Fund LP (the “Fund”), for which Kingsbrook serves as the investment manager. Notwithstanding the above, Kingsbrook beneficially holds: (i) 1,480,000 shares of our common stock held by the Fund, (ii) May 2013 warrants held by the Fund exercisable for 500,000 shares of our common stock, (iii) October 2013 warrants held by the Fund exercisable for 750,000 shares of our common stock, and (iv) 1,667 shares of our Series E non-voting convertible preferred stock held by the Fund convertible into 33,340 shares of our common stock (the May 2013 warrants, the October 2013 warrants and the Series E preferred stock shall collectively be referred to herein as the “Convertible Securities”). However, in accordance with Rule 13d-4 under the Exchange Act, the number of shares of our common stock into which the Convertible Securities are convertible or exercisable, as applicable, are limited pursuant to the terms of the Convertible Securities to that number of shares of our common stock which would result in Kingsbrook having aggregate beneficial ownership of, with respect to the May 2013 warrants, the October 2013 warrants and the Series E preferred stock, 9.99% of the total issued and outstanding shares of our common stock (the "Ownership Limitation"). Kingsbrook disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Convertible Securities if such conversion or exercise would cause Kingsbrook’s aggregate beneficial ownership to exceed or remain above the applicable Ownership Limitation (as is currently the case). Therefore, Kingsbrook disclaims beneficial ownership of any of our common stock other than 438,668 shares, issuable upon any conversion or exercise of the May 2013 warrants, the October 2013 warrants and the Series E preferred stock. The business address of Kingsbrook is 689 Fifth Avenue, 12th Floor, New York, New York 10022. Based solely on information contained in a Schedule 13G filed with the SEC on March 25, 2014 by Kingsbrook Partners and other information known to us.

(3) Due to the Ownership Limitation (as defined below), Elliott Associates, L.P. (“Elliott Associates”) may be deemed the beneficial owner of 2,832,184 shares of our common stock through securities held by it and by Manchester Securities Corp., a wholly-owned subsidiary of Elliott Associates (“Manchester”), and Elliott International, L.P., a wholly-owned subsidiary of Elliott Associates (“Elliott International”). Notwithstanding the above, Elliott Associates beneficially holds: (i) 781,440 shares of our common stock held by Manchester, (ii) 2010 warrants held by Manchester exercisable for 390,720 shares of our common stock, (iii) 2012 warrants exercisable for 1,000,000 shares of our common stock, (iv) May 2013 warrants exercisable for 500,000 shares of our common stock, (v) 52,500 shares of our Series C-2 non-voting convertible preferred stock convertible into 525,000 shares of our common stock, (vi) October 2013 warrants exercisable for 262,500 shares of our common stock, (vii) 97,500 shares of our Series C-2 non-voting convertible preferred stock held by Elliott International convertible into 975,000 shares of our common stock, (viii) October 2013 warrants held by Elliott International exercisable for 487,500 shares of our common stock, (ix) 57,400 shares of our Series D non-voting convertible preferred stock held by Manchester convertible into 1,148,000 shares of our common stock, and (x) 53,537 shares of our Series E non-voting convertible preferred stock held by Manchester convertible into 1,070,740 shares of our common stock (the 2012 warrants, the May 2013 warrants and the October 2013 warrants shall collectively be referred to herein as the “Convertible Securities”). However, in accordance with Rule 13d-4 under the Exchange Act, the number of shares of our common stock into which the Convertible Securities are convertible or exercisable, as applicable, are limited pursuant to the terms of the Convertible Securities to that number of shares of our common stock which would result in Elliott Associates having aggregate beneficial ownership of (a) with respect to the 2012 warrants, 4.999% of the total issued and outstanding shares of our common stock, and (b) with respect to the May 2013 warrants, the October 2013 warrants, the Series C-2 preferred stock, the Series D preferred stock and the Series E preferred stock, 9.99% of the total issued and outstanding shares of our common stock (the "Ownership Limitation"). Elliott Associates disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Convertible Securities if such conversion or exercise would cause Elliott Associates’ aggregate beneficial ownership to exceed or remain above the applicable Ownership Limitation (as is currently the case). Therefore, Elliott Associates disclaims beneficial ownership of any of our common stock issuable upon any conversion or exercise of the 2012 warrants, and any shares of our common stock, other than 4,308,616 shares, issuable upon any conversion or exercise of the May 2013 warrants, the October 2013 warrants, the Series C-2 preferred stock, the Series D preferred stock and the Series E preferred stock. The business address of Elliott Associates is 40 West 57th Street, 30th Floor, New York, New York 10019. Based solely on information contained in a Schedule 13G filed with the SEC on April 9, 2010 by Elliott Associates and other information known to us.

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

(5) Consists of (i) 38,339 shares of our common stock, (ii) 385,000 shares of our common stock issuable upon exercise of stock options, (iii) 25,000 shares of our common stock issuable upon exercise of 2012 warrants, and (iv) 4,884 shares of our common stock issuable upon conversion of 2010 warrants. The warrants identified in clause (iii) above prohibit conversion or exercise if after such conversion or exercise Mr. Duffy and his affiliates would beneficially own more than 4.9% of our outstanding common stock.

(6) Consists of (i) 522,559 shares of our common stock held by Dr. Gelbfish individually, (ii) 94,496 shares of our common stock held jointly by Dr. Gelbfish and his wife, (iii) 70,872 shares of our common stock held by Dr. Gelbfish as custodian for certain of his children, (iv) 70,872 shares of our common stock held by Landmark Foundation, of which Dr. Gelbfish and his wife are trustees, (v) 375,000 shares of our common stock issuable upon exercise of stock options held by Dr. Gelbfish individually, (vi) 500,000 shares of our common stock issuable upon conversion of 50,000 shares of our Series C-3 convertible preferred stock, (vii) 250,000 shares of our common stock issuable upon exercise of 2014 warrants held by Dr. Gelbfish individually, (viii) 38,400 shares of our common stock issuable upon exercise of 2009 warrants held jointly by Dr. Gelbfish and his wife, (ix) 28,800 shares of common stock issuable upon exercise of 2009 warrants held by Dr. Gelbfish as custodian for certain of his children, and (x) 28,800 shares of common stock issuable upon exercise of 2009 warrants held by Landmark Foundation. However, in accordance with Rule 13d-4 under the Exchange Act, the number of shares of our common stock into which the 2012 warrants are convertible or exercisable, as applicable, are limited pursuant to their terms to that number of shares of our common stock which would result in Dr. Gelbfish having aggregate beneficial ownership of 4.99% of the total issued and outstanding shares of our common stock, and the number of shares of our common stock into which the Series C-3 preferred stock and 2014 warrants are convertible or exercisable, as applicable, are limited pursuant to their terms to that number of shares of our common stock which would result in Dr. Gelbfish having aggregate beneficial ownership of 9.99% of the total issued and outstanding shares of our common stock (together with the limitation imposed upon the conversion of the 2012 warrants, the "Gelbfish Ownership Limitation"). In accordance with Rule 13d-4 under the Exchange Act, Dr. Gelbfish disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Gelbfish Convertible Securities if such conversion or exercise would cause Dr. Gelbfish's aggregate beneficial ownership to exceed or remain above the Gelbfish Ownership Limitation.

7) Consists of (i) 173,961 shares of our common stock held by Mr. Lefkowitz individually, (ii) 10,000 shares of our common stock held by Mr. Lefkowitz's spouse, (iii) 174,741 shares of our common stock held by Wade Capital Corporation, an entity for which Mr. Lefkowitz has voting and investment control, (iv) 470,000 shares of our common stock issuable upon exercise of stock options, (v) 45,000 shares of our common stock issuable upon conversion of 4,500 shares of our Series C-3 convertible preferred stock held by Mr. Lefkowitz individually, (vi) 30,000 shares of our common stock issuable upon conversion of 3,000 shares of our Series C-3 convertible preferred stock held by Wade Capital Corporation, (vii) 22,500 shares of our common stock issuable upon exercise of 2014 warrants held by Mr. Lefkowitz individually, (viii) 15,000 shares of our common stock issuable upon exercise of 2014 warrants held by Wade Capital Corporation, and (ix) 24,536 shares of our common stock issuable upon exercise of 2009 warrants held by Mr. Lefkowitz individually. The 2012 warrants identified in clauses (vii) and (viii) above prohibit conversion or exercise if after such conversion or exercise Mr. Lefkowitz and his affiliates would beneficially own more than 4.99% of our outstanding common stock, and the number of shares of our common stock into which the Series C-3 preferred stock and 2014 warrants are convertible or exercisable, as applicable, are limited pursuant to their terms to that number of shares of our common stock which would result in Mr. Lefkowitz having aggregate beneficial ownership of 9.99% of the total issued and outstanding shares of our common stock (together with the limitation imposed upon the conversion of the 2012 warrants, the "Lefkowitz Ownership Limitation"). In accordance with Rule 13d-4 under the Exchange Act, Mr. Lefkowitz disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Lefkowitz Convertible Securities if such conversion or exercise would cause Mr. Lefkowitz's aggregate beneficial ownership to exceed or remain above the Lefkowitz Ownership Limitation.

(8) Consists of (i) 16,725 shares of our common stock, and (ii) 480,000 shares of our common stock issuable upon exercise of stock options.

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

Item 13. Certain Relationships and Related Transactions and Director Independence

Director Independence

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

Related Party Transactions

Paramount BioCapital, Inc. and Lindsay A. Rosenwald, M.D.

Dr. Rosenwald is the Chairman, Chief Executive Officer and sole stockholder of Paramount BioCapital, Inc. ("Paramount"). Prior to December 31, 2012, Dr. Rosenwald beneficially owned in excess of 5.0% of our voting capital stock.

On September 20, 2012, Dr. Rosenwald purchased, in a private placement, $50,000 of (i) 9% senior convertible notes, convertible into shares of our common stock, at a conversion price of $0.35 per share; and (ii) a five year redeemable warrant to purchase common stock at an exercise price of $0.40 per share, all on the same terms as other investors in the private placement.

Gary A. Gelbfish, M.D.

On September 20, 2012, Dr. Gelbfish purchased, in a private placement, $100,000 of (i) 9% senior convertible notes, convertible into shares of our common stock, at a conversion price of $0.35 per share; and (ii) a five-year redeemable warrant to purchase common stock at an exercise price of $0.40 per share, all on the same terms as other investors in the private placement.

Steven W. Lefkowitz

On September 20, 2012 and November 13, 2013, Mr. Lefkowitz purchased, indirectly through Wade Capital Corporation Money Purchase Plan (an entity for which he has voting and investment control) and individually, in a private placement, $35,000 and $15,000, respectively (i) 9% senior convertible notes, convertible into shares of our common stock, at a conversion price of $0.35 per share; and (ii) a five-year redeemable warrant to purchase common stock at an exercise price of $0.40 per share, all on the same terms as other investors in the private placement.

Randy Milby

On September 20, 2012, Mr. Milby purchased, indirectly through MW Bridges LLC (an entity for which he is Managing Partner, and has voting and investment control), in a private placement, $50,000 of (i) 9% senior convertible notes, convertible into shares of our common stock, at a conversion price of $0.35 per share; and (ii) a five-year redeemable warrant to purchase common stock at an exercise price of $0.40 per share, all on the same terms as other investors in the private placement.

Elliott Associates, L.P.

As of October 8, 2012, Manchester Securities Corp., a wholly-owned subsidiary of Elliott Associates, L.P., beneficially owned approximately 23.8% of our voting capital stock. In addition, on September 20, 2012, Elliott Associates, L.P. purchased, indirectly through Manchester Securities Corp., in a private placement, $400,000 of (i) 9% senior convertible notes, convertible into shares of our common stock, at a conversion price of $0.35 per share; and (ii) a five-year redeemable warrant to purchase common stock at an exercise price of $0.40 per share, all on the same terms as other investors in the private placement.

Matthew Duffy

On November 13, 2012, Mr. Duffy purchased, in a private placement, $10,000 of (i) 9% senior convertible notes, convertible into shares of our common stock, at a conversion price of $0.35 per share; and (ii) a five-year redeemable warrant to purchase common stock at an exercise price of $0.40 per share, all on the same terms as other investors in the private placement.

Procedures for Review and Approval of Transactions with Related Persons

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

Item 14. Principal Accountant Fees and Services

The following table sets forth fees billed to us by CohnReznick LLP, our independent registered public accounting firm, during the years ended December 31, 2013 and 2012 for: services relating to auditing our annual financial statements, reviewing our financial statements included in our quarterly reports on Form 10-Q, reviewing registration statements in connection with a Form S-3 filed during 2012 and Forms S-3 and S-8 filed during 2013 and services rendered in connection with tax compliance, tax advice and tax planning, and all other fees for services rendered.

	2013	2012
Audit Fees	$ 190,445	$ 91,031
Audit Related Fees	-	-
Tax Fees	7,850	19,675
All Other Fees	-	-
Totals	$198,295	$110,706

Audit Committee Pre-Approval Policies and Procedures

Pursuant to its charter, the Audit Committee is responsible for reviewing and approving in advance any audit and any permissible non-audit engagement or relationship between us and our independent registered public accounting firm. The Audit Committee may delegate to one or more designated members of the Audit Committee the authority to grant pre-approvals, provided such approvals are presented to the Audit Committee at a subsequent meeting. If the Audit Committee elects to establish pre-approval policies and procedures regarding non-audit services, the Audit Committee must be informed of each non-audit service provided by our independent registered public accounting firm. Audit Committee pre-approval of audit and non-audit services will not be required if the engagement for the services is entered into pursuant to pre-approval policies and procedures, provided the policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service provided and such policies and procedures do not include delegation of the Audit Committee's responsibilities under the Exchange Act to our management. Audit Committee pre-approval of non-audit services (other than review and attestation services) also will not be required if such services fall within available exceptions established by the SEC. All services performed by our independent registered public accounting firm during 2013 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

1. Financial Statements:

The financial statements of the Company and the related report of the Company's independent registered public accounting firm 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.				
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 212013.	8-K	10/23/2013	3.5	
3.7	Certificate of Amendment to Certificate of Designation of Series C-1 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.10	
3.8	Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.6	

3.9	Certificate of Amendment to Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.11
3.10	Certificate of Designation of Series C-3 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.9
3.11	Certificate of Designation of Series D Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 4, 2013.	8-K	10/23/2013	3.7
3.12	Certificate of Amendment to Certificate of Designation of Series D Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 21, 2014.	8-K	1/09/2014	3.12
3.13	Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.8

3.14	Certificate of Amendment to Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.13
4.1	Specimen of Common Stock Certificate.	S-1/A	3/19/2010	4.1
4.2	Specimen Unit certificate.	S-1/A	3/19/2010	4.2
4.3	Specimen warrant certificate.	S-1/A	3/19/2010	4.3
4.4	Form of warrant agreement.	S-1/A	3/19/2010	4.4
4.5	Common Stock Exchange and Stockholder Agreement, dated as of October 6, 2009, by and between CorMedix Inc. and Shiva Biomedical, LLC.	S-1	11/25/2009	4.6
4.6	Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC.	S-1	11/25/2009	4.7
4.7	Form of Third Bridge Warrant.	S-1/A	1/20/2010	4.18
4.8	Form of 9% Senior Convertible Note due 2013.	10-Q	11/13/2012	4.1
4.9	Form of Purchaser Warrant.	10-Q	11/13/2012	4.2
4.10	Form of Placement Agent Warrant.	10-Q	11/13/2012	4.3
4.11	Form of Subscription Agreement.	10-Q	11/13/2012	4.4
4.12	Form of Registration Rights Agreement.	10-Q	11/13/2012	4.5
4.13	Form of Senior Secured Convertible Note.	8-K	5/24/2013	4.19
4.14	Form of Warrant issued on May 30, 2013.	8-K	5/24/2013	4.20
4.15	Form of Warrant issued on July 30, 2013.	8-K	5/24/2013	4.21
4.16	Form of Warrant issued on October 22, 2013.	8-K	1/09/2014	4.23
4.17	Form of Warrant issued on January 8, 2014.			
10.1*	Contribution Agreement, dated as of July 28, 2006, by and between Shiva Biomedical, LLC, Picton Pharmaceuticals, Inc., Picton Holding Company, Inc., and the stockholders of Picton Pharmaceuticals, Inc.	S-1/A	12/31/2009	10.1
10.2*	Amendment to Contribution Agreement, dated as of October 6, 2009, by and between Shiva Biomedical, LLC and CorMedix, Inc.	S-1/A	12/31/2009	10.2
10.3	Amendment No. 2 to Contribution Agreement, dated as of February 22, 2010, by and between the Company and Shiva Biomedical, LLC.	S-1/A	3/01/2010	10.15
10.4*	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
10.5	Escrow Agreement, dated as of January 30, 2008, among the Company, ND Partners LLC and the Secretary of the Company, as Escrow Agent.	S-1	11/25/2009	10.6
10.6*		S-1/A	3/01/2010	10.7

	Exclusive License and Consulting Agreement, dated as of January 30, 2008, between the Company and Hans-Dietrich Polaschegg.			
10.7	Amended and Restated Consulting Agreement, dated as of January 10, 2008, between the Company and Sudhir V. Shah, M.D.	S-1	11/25/2009	10.11
10.8	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl.	S-1	11/25/2009	10.12
10.9*	Supply Agreement, dated as of December 7, 2009, between the Company and Navinta, LLC.	S-1/A	3/01/2010	10.13
10.10*	Manufacture and Development Agreement, dated as of March 5, 2007, by and between the Company and Emcure Pharmaceuticals USA, Inc.	S-1/A	12/31/2009	10.14
10.11	Amended and Restated 2006 Stock Incentive Plan.	S-1/A	3/01/2010	10.8
10.12	Form of Indemnification Agreement between the Company and each of its directors and executive officers.	S-1/A	3/01/2010	10.17
10.13*	Amendment No. 3 to Contribution Agreement, effective as of August 31, 2011, by and between the Company and Shiva Biomedical, LLC.	10-Q	11/10/2011	10.2
10.14	Subscription Agreement by and between the Company and certain accredited investors (with attached schedule of parties thereto).	8-K	11/15/2012	10.1

10.15	Amended and Restated Investment Banking Agreement, dated August 20, 2012, between the Company and John Carris Investments, LLC.	8-K	11/15/2012	10.2	
10.16	Agreement for Work on Pharmaceutical Advertising dated January 10, 2013 by and between MKM Co-Pharma GmbH and CorMedix Inc.	8-K	1/16/2013	10.22	
10.17	Form of Securities Purchase Agreement, dated February 18, 2013, between CorMedix Inc. and the investor named therein.	8-K	2/19/2013	10.23	
10.18	Consulting Agreement, as amended December 24, 2012, between the Company and MW Bridges LLC.	10-K	3/27/2013	10.26	
10.19	2013 Stock Incentive Plan	10-K	3/27/2013	10.27	
10.20	Form of Securities Purchase Agreement, dated May 23, 2013, between CorMedix Inc. and the investor named therein.	8-K	5/24/2013	10.29	
10.21	Form of Securities Purchase Agreement, dated July 25, 2013, between CorMedix Inc. and the investor named therein.	8-K	7/26/2013	10.30	
10.22	Form of Securities Purchase Agreement, dated October 17, 2013, between CorMedix Inc. and the investor named therein.	8-K	10/18/2013	10.32	
10.23	Form of Securities Purchase Agreement, dated October 17, 2013, between CorMedix Inc. and the investor named therein.	8-K	10/18/2013	10.33	
10.24	Form of Securities Purchase Agreement, dated January 7, 2014, between CorMedix Inc. and the investors named therein.	8-K	1/09/2014	10.36	
21.1	List of Subsidiaries	10-K	3/27/2013	21.1	
23.1	Consent of Independent Registered Public Accounting Firm.				X
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following materials from CorMedix Inc. Form 10-K for the year ended December 31, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) Balance				X

Sheets at December 31, 2013 and December 31, 2012, (ii) Statements of Operations for the years ended December 31, 2013 and 2012 and for the Cumulative Period from July 28, 2006 (inception) through December 31, 2013, (iii) Statements of Changes in Stockholders' Equity for the year ended December 31, 2013, (iv) Statements of Cash Flows for the years ended December 31, 2013 and 2012 and for the Cumulative Period from July 28, 2006 (inception) through December 31, 2013 and (v) Notes to the Financial Statements.**

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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.

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 31, 2014 By: /s/ Randy Milby
Randy Milby
Chief Executive Officer
(Principal Executive Officer)

March 31, 2014 By: /s/ Steven Lefkowitz
Steven Lefkowitz
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ Randy Milby Randy Milby	Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2014
/s/ Steven Lefkowtiz Steven Lefkowitz	Interim Chief Financial Officer and Director (Principal Financial and Accounting Officer)	March 31, 2014
/s/ Matthew Duffy Matthew Duffy	Director	March 31, 2014
/s/ Gary A. Gelbfish Gary A. Gelbfish	Chairman of the Board	March 31, 2014
/s/ Michael George Michael George	Director	March 31, 2014
/s/ Antony E. Pfaffle Antony E. Pfaffle	Acting Chief Scientific Officer and Director	March 31, 2014

CORMEDIX INC.

(A Development Stage Company)
FINANCIAL STATEMENTS

Financial Statements Index

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
CorMedix Inc.

We have audited the accompanying consolidated balance sheets of CorMedix Inc. and Subsidiary (A Development Stage Company) as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficiency) and cash flows for the years then ended and for the period from July 28, 2006 (Inception) to December 31, 2013. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our 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 CorMedix Inc. and Subsidiary (A Development Stage Company) as of December 31, 2013 and 2012, and the results of their operations and their cash flows for the years then ended and for the period from July 28, 2006 (Inception) to December 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

/s/ CohnReznick LLP

Roseland, New Jersey
March 31, 2014

CORMEDIX INC.
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2013	December 31, 2012
ASSETS		
Current assets		
Cash	$2,373,893	$835,471
Restricted cash	220,586	-
Trade receivables	2,339	-
Inventories	80,021	-
Prepaid research and development expenses	6,205	11,221
Other prepaid expenses and current assets	232,987	30,677
Total current assets	2,916,031	877,369
Property and equipment, net	36,061	4,668
Deferred financing costs	2,366	257,886
Security deposit	13,342	13,342
TOTAL ASSETS	$2,967,800	$1,153,265
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities		
Accounts payable	$939,785	$928,553
Accrued expenses	713,179	261,983
Accrued interest, related parties	-	16,175
Senior convertible notes, net of debt discount of $647,939 in 2012	-	16,061
Senior convertible notes – related parties, net of debt discount of $406,316 in 2012	-	253,684
Dividend payable	21,117	-
Total current liabilities	1,674,081	1,476,456
Derivative liability	5,308,804	-
Deferred rent	7,258	12,185
TOTAL LIABILITIES	6,990,143	1,488,641
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIENCY		
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 857,160 and 0 shares issued and outstanding at December 31, 2013 and 2012, respectively	857	-
Common stock - $0.001 par value: 80,000,000 shares authorized; 16,606,695 and 11,408,274 shares issued and outstanding at December 31, 2013 and 2012, respectively	16,606	11,408
Deferred stock issuances	(146)	(146)
Accumulated other comprehensive loss	(9,323)	-
Additional paid-in capital	51,720,302	45,886,596
Deficit accumulated during the development stage	(55,750,639)	(46,233,234)
TOTAL STOCKHOLDERS' DEFICIENCY	(4,022,343)	(335,376)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	$2,967,800	$1,153,265

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

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CORMEDIX INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31, 2013	Year Ended December 31, 2012	Cumulative Period from July 28, 2006 (Inception) Through December 31, 2013
SALES			
Net sales	$ 2,001	$ -	$ 2,001
Cost of sales	(201,605)	-	(201,605)
Gross loss	(199,604)	-	(199,604)
OPERATING EXPENSES			
Research and development	1,226,874	1,142,631	24,430,179
Selling, general and administrative	3,488,917	1,857,080	16,264,951
Total operating expenses	4,715,791	2,999,711	40,695,130
LOSS FROM OPERATIONS	(4,915,395)	(2,999,711)	(40,894,734)
OTHER INCOME (EXPENSE)			
Other income (expense)	(4,513)	-	416,474
Interest income	668	1,965	126,975
Loss on issuance of convertible notes and warrants	(945,892)	-	(945,892)
Change in fair value of convertible notes and warrants	(363,919)	-	(363,919)
Loss on extinguishment of convertible notes	(1,459,661)	-	(1,459,661)
Interest expense, including amortization and write-off of deferred financing costs and debt discounts	(1,444,386)	(382,936)	(13,020,350)
LOSS BEFORE INCOME TAXES	(9,133,098)	(3,380,682)	(56,141,107)
State income tax benefit	-	-	774,775
NET LOSS	(9,133,098)	(3,380,682)	(55,366,332)
OTHER COMPREHENSIVE LOSS			
Foreign currency translation loss	(9,323)	-	(9,323)
COMPREHENSIVE LOSS	$ (9,142,421)	$ (3,380,682)	$ (55,375,655)
NET LOSS	$ (9,133,098)	$ (3,380,682)	$ (55,366,332)
Dividends, including beneficial conversion feature	(384,307)	-	(384,307)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (9,517,405)	$ (3,380,682)	$ (55,750,639)
N NET LOSS PER COMMON SHARE – BASIC AND DILUTED	$ (0.69)	$ (0.30)	
WWEIGHTED AVERAGE COMMON SHARES OUTSTANDING – BASIC AND DILUTED	13,823,130	11,408,274	

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

CORMEDIX INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Period from July 28, 2006 (Inception) to December 31, 2013

	Common Stock		Non-Voting Common Stock – Class A		Common Stock – Series B - F		Deferred Stock Issuances	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount				
Common stock issued to founders at $0.008 per share in July 2006	510,503	$510						$3,490		$4,000
Common stock issued and held in escrow to licensor at $0.008 per share in August 2006					1,000,000	$1,000	$(1,000)			-
Common stock issued to employee at $0.008 per share in November 2006	53,743	54						367		421
Stock-based compensation								4,726		4,726
Net loss									$(975,317)	(975,317)
Balance at December 31, 2006	564,246	564			1,000,000	1,000	(1,000)	8,583	(975,317)	(966,170)
Common stock issued to employees at $0.008 per share in January and March 2007	27,056	27						185		212
Common stock issued to			193,936	$194						194

technology finders at $0.008 per share in March 2007										
Warrants issued in connection with senior convertible notes								748,495		748,495
Debt discount on senior convertible notes								2,993,981		2,993,981
Stock-based compensation								64,875		64,875
Net loss									(7,237,526)	(7,237,526)
Balance at December 31, 2007	591,302	591	193,936	194	1,000,000	1,000	(1,000)	3,816,119	(8,212,843)	(4,395,939)
Common stock issued to licensor at $8.23 per share in January 2008	39,980	40						328,908		328,948
Common stock issued to licensor and held in escrow in January 2008	15,992	16					(125)	109		-
Common stock issued to consultant at $8.23 per share in May 2008	939	1						7,720		7,721
Debt discount on senior convertible notes								747,215		747,215
Stock-based compensation								281,652		281,652
Net loss									(8,996,745)	(8,996,745)
Balance at December 31, 2008	648,213	$648	193,936	$194	1,000,000	$1,000	$(1,125)	$5,181,723	$(17,209,588)	$(12,027,148)

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

CORMEDIX INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Period from July 28, 2006 (Inception) to December 31, 2013

	Common Stock		Non-Voting Common Stock – Class A		Common Stock – Series B - F		Deferred Stock Issuances	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	St
	Shares	Amount	Shares	Amount	Shares	Amount				(D
Balance at December 31, 2008 (carried forward)	648,213	$648	193,936	$194	1,000,000	$1,000	$(1,125)	$5,181,723	$(17,209,588)	$(
Common stock issued to consultant at $32.05 per share in July 2009	639	1						20,449		2
Common stock issued to licensor at $32.05 per share in exchange for Series B-F common stock in October 2009	98,739	99			(1,000,000)	(1,000)	1,186	3,164,217		3
Common stock issued to licensor at $32.05 per share in October 2009	28,156	28						902,316		9
Common stock issued to licensor and held in escrow in October 2009	11,263	11					(88)	77		-
Debt discount on senior convertible notes								1,238,265		1
								114,143		1

Stock-based compensation										
Net loss									(8,096,455)	(8
Balance at December 31, 2009	787,010	787	193,936	194	-	-	(27)	10,621,190	(25,306,043)	(
Common stock issued to consultant at $32.05 per share in February 2010	4,059	4						130,087		1
Common stock issued upon conversion of Class A Non-Voting Common Stock at a 1 for 7.836 conversion rate in February 2010	24,750	25	(193,936)	(194)				169		-
Common stock issued from debt conversion to noteholders in March 2010	5,914,431	5,914						18,891,253		1
Common stock issued to licensors at $3.125 per share in March 2010	828,024	828					(119)	2,217,215		2
Common stock issued in initial public offering at $3.125 per share in March 2010, net of issuance costs	3,850,000	3,850						10,453,420		1
Stock-based compensation								1,167,081		1
Net loss									(10,875,236)	(
Balance at December 31, 2010	11,408,274	$11,408	-	$-	-	$-	$(146)	$43,480,415	$(36,181,279)	$7

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

CORMEDIX INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

Period from July 28, 2006 (Inception) to December 31, 2013

	Common Stock Shares	Common Stock Amount	Non Voting Preferred Stock – Series A, Series B, Series C-1, Series C-2, Series D and Series E Shares	Non Voting Preferred Stock – Series A, Series B, Series C-1, Series C-2, Series D and Series E Amount	Non-Voting Common Stock – Class A Shares	Non-Voting Common Stock – Class A Amount	Non-Voting Common Stock – Series B - F Shares	Non-Voting Common Stock – Series B - F Amount	Deferred Stock Issuances	Accumulated Other Comprehen-sive Income	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Sto (De
Balance at December 31, 2010 (carried forward)	11,408,274	$11,408	-	$-	-	$-	-	$-	$(146)	$-	$43,480,415	$ (36,181,279)	$ 7
Stock-based compensation											692,403		6
Net loss											-	(6,671,273)	(
Balance at December 31, 2011	11,408,274	11,408	-	-	-	-	-	-	(146)		44,172,818	(42,852,552)	1
Stock-based compensation											274,358	-	2
Debt discount											1,333,307	-	1
Warrants issued to placement agent in connection with financing											106,113	-	1
Net loss											-	(3,380,682)	(
Balance at December 31, 2012	11,408,274	11,408	-	-	-	-	-	-	(146)		45,886,596	(46,233,234)	(
Series A non-voting preferred stock issued in February 2013 private placement at $0.70 per share, net			761,429	761							506,372		5
Conversion of Series A non-voting preferred stock to common stock	761,429	761	(761,429)	(761)							-	-	-
Deemed dividend related to beneficial conversion feature of Series A non-voting preferred stock											309,944	(309,944)	-
Series B non-voting preferred stock issued in July 2013 private			454,546	455							480,007		4

placement at $1.10 per share, net			
Deemed dividend related to beneficial conversion feature of Series B non-voting preferred stock	53,246	(53,246)	-
Repurchase of outstanding warrants	(33,000)		(
Stock-based compensation	1,345,136		1
Dividends related to Series D and Series E preferred stock		(21,117)	(

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

CORMEDIX INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

Period from July 28, 2006 (Inception) to December 31, 2013

	Common Stock		Non Voting Preferred Stock – Series A, Series B, Series C-1, Series C-2, Series D and Series E		Non-Voting Common Stock – Class A		Common Stock – Series B - F		Deferred Stock Issuances	Accumulated Other Comprehen-sive Income (Loss)	Additio Paid-Capit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Warrants issued in connection with license agreement											76,574
Stock issued in connection with 9% senior convertible note at $0.35 per share	2,640,000	2,640									921,36
Stock issued in connection with 8% senior convertible note and interest conversion, fair value	1,009,238	1,009									866,55
Stock issued in connection with warrants exercised	677,754	678									59,322
Stock issued in connection with stock options exercised	10,000	10									2,390
Series C-1 and Series C-2 non voting preferred stock issued in October 2013 financing at $10 per share, net, fair value			300,000	300							57,555
Conversion of Series C-1 non-voting preferred stock	100,000	100	(10,000)	(10)							69,015

to common stock, fair value										
Stock issued in connection with the exchange of 8% senior convertible notes and interest into Series D non-voting preferred stock, net, fair value			57,400	57						500,16
Stock issued in connection with the exchange of 8%senior convertible notes and interest into Series E non-voting preferred stock, net, fair value			55,214	55						619,05
Other comprehensive loss									(9,323)	
Net loss										-
Balance at December 31, 2013	16,606,695	$16,606	857,160	$857	-$	-	-$	-$	(146)	$(9,323) $51,720

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

CORMEDIX INC.

(A Development Stage Company)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2013	Year Ended December 31, 2012	Period from July 28, 2006 (Inception) To December 31, 2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(9,133,098)	$(3,380,682)	$(55,366,332)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	1,345,136	274,358	3,944,374
Stock issued in connection with license agreements	-	-	6,613,718
Stock issued in connection with consulting agreement	-	-	158,262
Warrants issued in connection with license agreements	76,574	-	76,574
Amortization of deferred financing costs	282,886	76,632	2,407,399
Amortization of debt discount	1,054,255	279,052	6,312,768
Loss on issuance of convertible notes and warrants	945,892	-	945,892
Loss on extinguishment of convertible notes	1,459,661	-	1,459,661
Non-cash charge for beneficial conversion feature	-	-	1,137,762
Non-cash interest expense	41,113	-	3,048,131
Revaluation of convertible notes and warrants	363,919	-	363,919
Expenses paid on behalf of the Company satisfied through the issuance of notes	-	-	51,253
Depreciation	5,161	7,022	62,203
Changes in operating assets and liabilities:			
Restricted cash	(220,586)	-	(220,586)
Trade receivables	(2,279)	-	(2,279)
Inventory	(80,021)	-	(80,021)
Prepaid expenses and other current assets	(193,350)	503,742	(237,248)
Security deposits	-	-	(13,342)
Accounts payable	10,560	(15,743)	908,310
Accrued expenses and accrued interest	448,747	(18,354)	726,905
Accrued interest, related party	(16,175)	-	(16,175)
Deferred rent	(4,927)	(2,287)	7,258
Net cash used in operating activities	(3,618,532)	(2,276,260)	(27,711,594)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of equipment	(35,683)	-	(97,392)
Net cash used in investing activities	(35,683)	-	(97,392)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from notes payable to related parties, net	-	597,735	3,063,484
Proceeds from senior convertible notes, net	686,250	598,865	14,650,088
Proceeds from senior convertible notes, related party, net	686,250	-	686,250
Proceeds from Series C-1 preferred stock, net	1,463,439	-	1,463,439
Proceeds from Series C-2 preferred stock, related party, net	1,463,439	-	1,463,439
Proceeds from exercise of warrants	60,000	-	60,000
Proceeds from exercise of stock options	2,400	-	2,400
Proceeds from Galenica, Ltd. promissory note	-	-	1,000,000
Payment of deferred financing costs	(157,696)	(70, 203)	(1, 675,299)
Repayment of amounts loaned under related party notes	-	-	(1,981,574)

Proceeds from sale of equity securities	1,033,000	-	11,490,270
Repurchase of outstanding warrants	(33,000)	-	(33,000)
Proceeds from receipt of stock subscriptions and issuances of common stock	-	-	4,827
Net cash provided by financing activities	5,204,082	1,126,397	30,194,324
Foreign exchange effect on cash	(11,445)	-	(11,445)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,538,422	(1,149,863)	2,373,893
CASH AND CASH EQUIVALENTS – BEGINNING OF YEAR	835,471	1,985,334	-
CASH AND CASH EQUIVALENTS – END OF YEAR	$2,373,893	$835,471	$2,373,893
Cash paid for interest	$118,064	$-	$136,489
Supplemental Disclosure of Non Cash Financing Activities:			
Conversion of notes payable and accrued interest to common stock, fair value	$1,768,722	$-	$20,665,889
Exchange of convertible notes to preferred stock	$1,119,340	$-	$1,119,340
Conversion of preferred stock to common stock	$602,105	$-	$602,105
Reclassification of deferred financing fees to additional paid-in capital	$-	$-	$148,015
Stock issued to technology finders and licensors	$-	$-	$155
Warrants issued to placement agent	$-	$106,113	$854,608
Debt discount on senior convertible notes	$-	$1,333,307	$6,312,768
Dividend, including beneficial conversion feature	$384,307	$-	$384,307
Accrued deferred financing costs	$2,366	$30,803	$33,169

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business:

CorMedix Inc. and Subsidiary ("CorMedix" or the "Company") was incorporated in the State of Delaware on July 28, 2006. CorMedix is a development-stage pharmaceutical and medical device company that seeks to in-license, develop and commercialize therapeutic products for the treatment of cardiorenal and infectious diseases, including the dialysis and non-dialysis areas. As of the date of this report, we have in-licensed all of the product candidates in our pipeline.

Basis of Presentation:

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

To date, the Company has not generated significant revenues and, accordingly, the Company is considered to be in the development stage. The Company is in the process of transitioning from a development stage to a commercial pharmaceutical and medical device company. For the year ended December 31, 2013 and the period from July 28, 2006 (inception) to December 31, 2013, the Company incurred net losses of $9,133,098 and $55,366,332, respectively. The Company has a stockholders' deficiency as of December 31, 2013 of $4,022,343. Management believes that the Company's existing cash, after giving effect to the Company's aggregate net proceeds of $8,600,000 from the Company's private placement of Series C-3 non-voting preferred stock in January 2014 and the registered direct public offering of common stock and warrants in March 2014 (see Note 11), will be sufficient to meet the Company's operating needs to fund its research and development, as well as its operations in general into 2015. The Company's continued operations will depend on whether it is able to generate substantial revenue from the sale of Neutrolin and on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products, until it achieves profitability, if ever. However, the Company can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. The Company expects to incur increases in its cash used in operations as it continues to commercialize Neutrolin in Europe and other foreign markets and seeks FDA approval of Neutrolin in the U.S.

Note 2 — 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.

Foreign Currency:

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

Geographic Information:

For the first time since its inception in 2006, the Company reported revenues of $2,001, all of which was attributable to its European operations, which are based in Germany. Of the Company's $36,061 of net property and equipment at December 31, 2013, $2,497 was located in the United States, with the remainder located in Germany.

Restricted Cash:

As of December 31, 2013, the Company invested in a twelve-month 0.14% certificate of deposit held by the bank as collateral for a letter of credit in connection with the Company's purchase of raw materials due to be delivered in the next twelve months. The certificate of deposit will terminate without penalties once the transaction covered by the letter of credit is completed. The certificate of deposit is recorded on the consolidated balance sheet as restricted cash.

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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:

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.

Property and Equipment:

Property and equipment consist primarily of furnishings, fixtures, leasehold improvements, office equipment and computer equipment which are recorded at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation of property and equipment is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. Property and equipment, net as of December 31, 2013 and 2012 were $36,061 and $4,668, respectively, net of accumulated depreciation of $62,283, and $57,042, respectively.

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:

	2013	2012
Licensing fee	$500,000	$-
Royalty fee	-	45,000
Accrued payroll and payroll taxes	197,969	-
Professional fees	12,000	108,532
Accrued interest	-	10,763
Other	3,210	97,688
Total	$713,179	$261,983

Stock-Based Compensation:

The Company accounts for stock options granted to employees according to the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) No. 718 (“ASC 718”), “Compensation — Stock

Compensation". Under ASC 718, share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis.

The Company accounts for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing method in accordance with ASC 718. The initial noncash charge to operations for non-employee options with service vesting are revalued at the end of each reporting period based upon the change in the fair value of the options and amortized to expense over the related vesting period. For stock options granted to non-employees with vesting contingent upon various performance metrics, the Company used the guidelines in accordance with FASB ASC No. 505-50 ("ASC 505"), "Equity-Based Payments to Non-Employees", of which if the performance condition is outside of the control of the non-employee, the cost to be recognized is the lowest aggregate fair value prior to the achievement of the performance condition, even if the Company believes it is probable that the performance condition will be achieved. During the year ended December 31, 2013, certain of the performance conditions were achieved and the Company recorded total expense of $503,294. During the year ended December 31, 2012, the performance conditions of such stock options were not achieved; therefore, no non-employee stock options vested and no expense was recorded during the year ended December 31, 2012.

For the purpose of valuing options and warrants granted during the year ended December 31, 2013, the Company used the Black-Scholes option pricing model. The Company estimated the expected term of the stock options granted to officers, directors and employees based on anticipated exercises in future periods. The expected term of the stock options granted to consultants is based upon the contractual terms established within agreements with the Company. Given the Company's short period of publicly-traded stock history, management's estimate of expected volatility is based on the average volatilities of a sampling of five companies with similar attributes to the Company, including: industry, stage of life cycle, size and financial leverage. The Company will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. The expected dividend yield of 0.0% reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

	2013	2012
Risk-free interest rate	0.34% - 2.88%	0.27% – 1.6%
Expected volatility	86% - 131%	98% – 127%
Expected life of options in years	2 - 10 years	5
Expected dividend yield	0.0%	0.0%

Research and Development:

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

Income Taxes:

Under ASC 740, “Income Taxes” (“ASC 740”), deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some or all of the deferred tax assets will not be realized.

Loss Per Common Share:

Basic loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity. Since the Company has only incurred losses, basic and diluted loss per share are the same. Additionally, there were 145,543 shares of common stock being held in escrow at December 31, 2013 and 2012, pending the achievement of certain regulatory and sales-based milestones as part of the license agreement with ND Partners LLC. The following potentially dilutive shares have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive.

	December 31,	
	2013	2012

Convertible notes	-	3,782,857
Series B non-voting preferred stock	454,546	-
Series C non-voting preferred stock (see Note 7)	2,900,000	-
Series D non-voting preferred stock (see Note 7)	1,148,000	-
Series E non-voting preferred stock (see Note 7)	1,104,280	-
Shares underlying outstanding warrants	10,422,525	8,448,534
Shares underlying outstanding stock options	3,453,630	2,135,630
Total	19,482,981	14,367,021

Fair Value Option:

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

Accounting Standards Updates:

There were no recent accounting pronouncements that are expected to have a material effect on the Company's consolidated financial position or consolidated results of operations.

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Note 3 — Related Party Transactions (also see Note 5):

Consulting Services:

During the year ended December 31, 2012, the Company engaged Chord Advisors, LLC, a financial services outsourcing company, to provide accounting services to the Company for aggregate consideration of $10,000 through March 2013. The Company's then Chief Financial Officer, Richard M. Cohen (who resigned in August 2013), is also the Chairman as well as Co-Founder of Chord Advisors, LLC. The Company's Audit Committee reviewed and approved this engagement.

Notes Payable:

On September 20, 2012, Gary A. Gelbfish and Stephen W. Lefkowitz, both members of the Company's board of directors, and Randy Milby, the Company's Chief Operating Officer, participated in the Company's private placement pursuant to the Subscription Agreement referred to in Note 6. Dr. Gelbfish purchased 100 Units, Mr. Lefkowitz purchased 35 Units, indirectly through Wade Capital Corporation Money Purchase Plan (an entity for which he has voting and investment control) and Mr. Milby purchased 50 Units, indirectly through MW Bridges LLC (an entity for which he is Managing Partner, and has voting and investment control). Also, beneficial owners of more than 5% of the Company's voting securities, including Dr. Lindsay Rosenwald and Elliott Associates, indirectly through Manchester Securities Corp., purchased 50 Units and 400 Units, respectively.

On November 13, 2012, Matthew Duffy and Stephen W. Lefkowitz, both members of the Company's board of directors, participated in the Company's private placement pursuant to the Subscription Agreement referred to in Note 6. Mr. Duffy purchased 10 Units and Mr. Lefkowitz purchased 15 Units, respectively.

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

Note 4 — Income Taxes:

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

	December 31,	
	2013	2012
United States	$(8,745,624)	$(3,380,682)
Foreign	(387,474)	-
Total	$(9,133,098)	$(3,380,682)

The Company had no state income benefit for the year ended December 31, 2013 or 2012, related to the sale of its state net operating losses. There was no current or deferred income tax provision for the year ended December 31, 2013 or 2012.

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

	December 31, 2013	2012
Net operating loss carryforwards – Federal	$ 10,957,000	$ 9,561,000
Net operating loss carryforwards – state	1,331,000	1,099,000
Net operating loss carryforwards – foreign	116,000	-
Capitalized licensing fees	2,361,000	2,541,000
Convertible debt and warrants	1,106,000	142,000
Stock-based compensation	690,000	110,000
Other	3,000	80,000
Totals	16,564,000	13,533,000
Less valuation allowance	(16,564,000)	(13,533,000)
Deferred tax assets	$ -	$ -

At December 31, 2013, the Company had potentially utilizable Federal, state and foreign net operating loss tax carryforwards of approximately $32,225,000, $22,411,000 and $387,000, respectively. The net operating loss tax carryforwards will start to expire in 2026 for Federal purposes and 2014 for state purposes. The foreign net operating loss tax carryforwards do not expire.

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

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

	December 31,			
	2013		2012	
Statutory Federal tax rate	(34.0	)%	(34.0	)%
State income tax rate (net of Federal)	(4.6	)%	(6.0	)%
Effect of foreign operations	0.2	%	0.0	%
Other permanent differences	(0.6	)%	0.0	%
Effect of valuation allowance	39.0	%	40.0	%
Effective tax rate	0.0	%	0.0	%

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The net change in the total valuation allowance for the years ended December 31, 2013 and 2012 and for the period from July 28, 2006 (inception) to December 31, 2013 was $3,031,000, $1,369,000 and $16,564,000, respectively. The tax benefit assumed the Federal statutory tax rate of 34% and a state tax rate (net of federal) of 6% and has been fully offset by the aforementioned valuation allowance.

In July 2006, the Company adopted guidance under ASC Topic 740-10 which clarifies the accounting and disclosure for uncertainty in income taxes. The adoption of this interpretation did not have a material impact on the Company's financial statements.

Management believes that the Company does not have any tax positions that will result in a material impact on the Company's financial statements because of the adoption of ASC 740-10. However management's conclusion may be subject to adjustment at a later date based on ongoing analyses of tax laws, regulations and related Interpretations. The Company will report any tax-related interest and penalties related to uncertain tax positions as a component of income tax expense. The Company's tax returns from 2010 to 2013 remain open.

Note 5 — Commitments and Contingencies:

Operating Leases:

On March 18, 2010, the Company entered into a lease agreement with UA Bridgewater Holdings, LLC for office space located in Bridgewater, New Jersey, for an initial term of 60 months, with a commencement date of April 1, 2010, an expiration date of March 31, 2015, and lease payments beginning on July 1, 2010. In accordance with the lease agreement, the Company has deposited $13,342 with the landlord, the equivalent of two months' rent. The Company has been granted the option to extend the lease term for one additional period of three years, commencing the day following the then-current expiration date of the term, March 31, 2015, provided the Company delivers notice to the landlord no later than nine months prior to March 31, 2015. The total 60-month lease obligation is approximately $389,000. The Company's total remaining lease obligation is $104,470 as of December 31, 2013, as set forth below:

Years Ending December 31,	Amount
2014	$ 83,576

2015	20,894
Total	$ 104,470

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 €442. The total 36 month lease obligation is approximately €15,900 and the remaining lease obligation was approximately €14,100 as of December 31, 2013. Additionally, its subsidiary leases its copier pursuant to a lease agreement dated October 10, 2013 with Frima Buromaschinen Schafer GmbH & Co. KG. The lease has a term of 48 months which commenced on November 1, 2013 for a monthly payment of €59. The total 48 month lease obligation is approximately €2,800. Our total remaining obligation was approximately €2,700 as of December 31, 2013.

Consulting:

On May 14, 2012, the Company entered into a Consulting Agreement (the "Consulting Agreement") with MW Bridges LLC, of which Randy Milby is Managing Partner. Pursuant to the Consulting Agreement, Mr. Milby initially served as the Company's Chief Operating Officer for a monthly retainer of $6,400. In addition, the Company granted Mr. Milby stock options to purchase 50,000 shares of the Company's common stock, which option vests upon the Company's receipt of CE Mark approval for CRMD003, Neutrolin®. Further, the Company agreed to reimburse Mr. Milby for all reasonable and necessary expenses incurred while performing services in connection with the Consulting Agreement. The initial term (the "Term") of the Consulting Agreement was for three months. Pursuant to its terms, the Consulting Agreement was renewed upon mutual written agreement of the parties upon the same terms. On October 31, 2012, the Company and MW Bridges LLC entered into an Amendment to the Consulting Agreement (the "Amendment"), which, among other things, (i) extended the then-current Term for an additional three months, and (ii) increased Mr. Milby's monthly retainer to $12,000, effective October 1, 2012. In addition, either party may terminate the Consulting Agreement, as amended, upon 30 days' prior written notice. Mr. Milby was named Chief Executive Officer of the Company effective January 1, 2013. In April 2013, Mr. Milby became an employee of the Company with an annual salary of $250,000 and the consulting agreement was terminated. As of December 31, 2013, Mr. Milby had no employment agreement with the Company.

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Other:

The Company has entered into various contracts with third parties in connection with the development of the licensed technology described in Note 9.

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland, or Geistlich, filed an opposition against the Sodemann patent covering our Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to the Company pursuant to the License and Assignment Agreement between the Company and ND Partners LLC. The opposition against the Sodemann patent that was filed at the head office of the European Patent Office in Munich, Germany, was for lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions described in the Lehner patent. In June 2008 the opposition division at the European Patent Office held oral proceedings and rejected the opposition by Geistlich and maintained the patent as granted. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. The Company filed a response to the appeal of Geistlich on March 25, 2009 where it requested a dismissal of the appeal and to maintain the patent as granted. On October 10, 2012, the Company became aware that the Board of Appeals of the European Patent Office issued, on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeal of the European Patent Office held oral proceedings and verbally upheld the Sodemann patent covering Neutrolin®, but remanded the proceeding to the opposition division as the lower court to consider restricting certain of the Sodemann patent claims. The Company received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. In a letter dated September 30, 2013, the Company was notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils the requirements of Clarity, Novelty, and Inventive Step, and invited the parties to provide their comments and/or requests by February 10, 2014. The Company filed its response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division has granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. The Company intends to continue to vigorously defend the patent in a restricted form. However, the Company can provide no assurances regarding the outcome of this matter.

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company’s request in such capacities. The Company’s maximum exposure under these arrangements is unknown as of December 31, 2013. The Company does not anticipate recognizing any significant losses relating to these arrangements.

Note 6 — Convertible Notes:

On July 5, 2013, the Company received from existing institutional investors net proceeds of $1,372,500 upon approval of a CE Mark certification. The Company had entered into an agreement with existing stockholders in May 2013 for an aggregate principal amount of $1,500,000 of senior secured convertible notes and warrants to purchase up to an aggregate of 1,000,000 shares of its common stock. The receipt of net proceeds of $1,372,500 was dependent upon receipt of a CE Mark certification, which occurred on July 5, 2013. The notes bear interest at the rate of 8.0% per

annum and will be subject to a "make-whole" upon any conversion of the notes into common stock, as if the notes being converted were outstanding to April 1, 2014. Interest was first payable on September 3, 2013 and is payable on the first trading day of each month thereafter. The notes mature on April 1, 2016 unless redeemed prior to that date, subject to amortization, discussed below. A noteholder may elect to have any interest due prior to April 1, 2014 added to the principal amount of a note; thereafter, interest will be paid in cash only. The warrants are exercisable one year after issuance, have an exercise price of $1.10 per share, subject to anti-dilution adjustment, and a term of five years from the date they are first exercisable. The holders of the notes and warrants will be prohibited from converting the notes into or exercising the warrants for shares of common stock if, as a result of such conversion or exercise, the holder, together with its affiliates, would own more than 4.99% or 9.99%, respectively, at the initial holder's election, of the total number of shares of the Company's common stock then issued and outstanding.

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

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

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

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

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

A summary of the key assumptions used by the Company in the Monte Carlo simulation model to value the hybrid instrument at each of the relevant measurement dates during the year is as follows:

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

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

Volatility – Given that the Company recently received CE Mark approval for Neutrolin, the volatility used in the analysis was a weighted average of 1) the Company's historical volatility, 2) the Company's volatility after the receipt of CE approval and 3) the volatilities of comparable companies following the receipt of product approval. The resulting volatility used in the analysis was 75%.

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

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

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

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

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

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

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

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

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

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

During the year ended December 31, 2012, the Company completed a private placement of an aggregate of 1,324 Units, each Unit consisting of (i) a one-year $1,000 aggregate principal amount 9% Senior Convertible Note (the "Notes"), convertible into shares (the "Conversion Shares") of common stock, at a conversion price of $0.35 per share, and (ii) a five-year redeemable Warrant (the "Warrants") to purchase 2,500 shares of common stock (the "Warrant Shares"), to certain accredited investors (the "Purchasers") pursuant to Subscription Agreements dated September 20, 2012 and November 13, 2012 (the “Subscription Agreements”). The Company received aggregate gross proceeds of $1,324,000. The total net proceeds (net of placement agent and legal fees) of the private placement to the Company were $1,095,600. The Company paid the placement agent for the private placement a total of $109,900 in fees and issued it warrants to purchase an aggregate of 331,000 shares of its common stock. The placement agent warrants have the same terms as those issued to the investors. The Notes issued have maturity dates of September 20, 2013 and November 13, 2013. During the year ended December 31, 2013, $924,000 of these notes were converted resulting in the issuance of 2,640,000 shares of the Company’s common stock in October 2013. The remaining $400,000 convertible note, including interest, was exchanged into 57,400 shares of Series D preferred stock, which are convertible into 1,148,000 shares of common stock.

The Notes bear interest at 9% per annum payable quarterly in arrears. The Company has the right to prepay, in certain instances, all (but not less than all, subject to certain share ownership limitations) of the then outstanding Notes by paying 120% of the principal and accrued but unpaid interest through and including the date each Note is repaid.

The Purchasers were issued Warrants to purchase the Company's common stock, exercisable for a period of five years at an initial exercise price of $0.40, subject to anti-dilution adjustment. The Warrants provide for customary adjustments to the exercise price in the event of stock splits, stock dividends and other similar corporate events and may be exercised on a cashless basis. The Warrants do not confer any voting rights or any other rights as a shareholder.

The Company, upon thirty-day notice to holders of outstanding Warrants, has the right, subject to certain limitations, to redeem all or any portion of the Warrants then outstanding for consideration of $0.001 per Warrant if (i) either (a) there is an effective registration statement for resale of all of the Conversion Shares, or (b) all of the Conversion Shares may be resold pursuant to Rule 144 without any restrictions or limitations, and (ii) for the ten consecutive trading days prior to the date that the Company notifies such holders of such redemption, (a) the daily volume-weight adjusted market price of the Common Stock is equal to or greater than 140% of the then exercise price, and (b) the average daily value of the trading volume is not less than $100,000.

The Company accounted for the beneficial conversion feature (“BCF”) and warrant in accordance with FASB ASC 470-20, Debt with Conversion and Other Options. The Company recorded a BCF related to the issuance of convertible debt that had conversion features at fixed rates that were “in-the-money” when issued and the fair value of warrants issued in connection with those instruments. The BCF for the convertible instruments is recognized and

measured by allocating a portion of the proceeds to warrants, based on their relative fair value, and as a reduction to the carrying amount of the convertible debt equal to the intrinsic value of the conversion feature. The discount recorded in connection with the BCF and warrant valuation is amortized over the terms of the convertible notes and is recognized as non-cash interest expense. The Company recorded an aggregate of $1,333,307 for the calculated fair value of the warrants and BCF, in conjunction with the convertible notes issued on September 20, 2012 and November 13, 2012.

The Company valued the warrants using the fair value method, at the date the warrants were issued, using the Black-Scholes valuation model and the following assumptions:

	September 20, 2012		November 13, 2012	
Contractual Term	5 years		5 years	
Volatility	117.57	%	119.15	%
Dividend yield	0.0	%	0.0	%
Risk-free interest rate	0.70	%	0.63	%

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Note 7 — Stockholders' Equity (Deficiency):

Common Stock:

During July 2006, the Company issued 510,503 shares of Common Stock to its founders for proceeds of $4,000 or $0.008 per share.

In accordance with the Shiva Contribution Agreement (see Note 9), during August 2006, the Company issued 800,000 shares of Series B Common Stock, 50,000 shares of Series C Common Stock, 50,000 shares of Series D Common Stock, 50,000 shares of Series E Common Stock and 50,000 shares of Series F Common Stock to Shiva Biomedical, LLC at $0.008 per share. These shares of Series B-F Common Stock were subsequently surrendered by Shiva in exchange for Common Stock in October 2009, as described below, and were eliminated from the Company's certificate of incorporation pursuant to an amendment effected in connection with such exchange. During 2006, the Company recorded $1,000 in deferred stock issuances for these shares of Series B-F Common Stock which were issued but were held in escrow until achievement of certain future clinical milestones (see Note 9).

During November 2006, the Company issued 53,743 shares of Common Stock to an employee in connection with an employment agreement for proceeds of $421 or $0.008 per share which vested equally over a three year period. In connection with this stock issuance, the Company recorded compensation expense at $1.72 per share for a total of $92,649. During January and March 2007, the Company issued 27,056 shares of Common Stock to employees in connection with employment agreements for proceeds of $212 or $0.008 per share which vested equally over a three year period. In connection with this stock issuance, the Company recorded compensation expense at $1.72 per share for a total $46,641. During March 2007, the Company issued 193,936 shares of Non-Voting Subordinated Class A Common Stock to technology finders for proceeds of $194 or $0.008 per share which vested equally over a three year period. In connection with this stock issuance, the Company recorded compensation expense at $1.72 per share for a total of $42,666. In accordance with the NDP License Agreement (see Note 9), during January 2008, the Company issued 39,980 shares of Common Stock to ND Partners LLC at $8.23 per share. During 2008, the Company recorded $328,948 in research and development expense in connection with this issuance. In addition, under the NDP License Agreement, the Company issued an additional 15,992 shares of Common Stock which are being held in escrow pending the achievement of certain regulatory and sales-based milestones. During 2008, the Company recorded $125 in deferred stock issuances for this common stock which was issued but is being held in escrow (see Note 9).

During May 2008, the Company issued 939 shares of Common Stock to a consultant in lieu of payment for consulting services at $8.23 per share. During 2008, the Company recorded $7,721 in research and development expense in connection with this issuance.

During July 2009, the Company issued 639 shares of Common Stock to a consultant as partial payment for consulting services at $32.05 per share. During 2009, the Company recorded $20,450 in research and development expense in connection with this issuance.

Pursuant to an amendment to the Shiva Contribution Agreement, dated as of October 6, 2009, and a corresponding common stock exchange and stockholder agreement of the same date (the "Exchange Agreement"), during October 2009, the Company issued 98,739 shares of Common Stock to Shiva Biomedical, LLC at $32.05 per share in exchange for the surrender by Shiva of all rights to the Series B-F Common Stock. During 2009, the Company

recorded $3,164,502 in research and development expense in connection with the issuance (see Note 9).

During October 2009, the Company issued 28,156 shares of Common Stock to ND Partners LLC at $32.05 per share in accordance with the NDP License Agreement as a result of anti-dilution adjustments in connection with the issuance of shares to Shiva Biomedical, LLC under the Exchange Agreement. During 2009, the Company recorded $902,344 in connection with the issuance (see Note 9).

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During October 2009, the Company issued 11,263 shares of Common Stock into escrow for the benefit of ND Partners LLC at $32.05 per share in accordance with the NDP License Agreement as a result of anti-dilution adjustments in connection with the issuance of shares to Shiva Biomedical, LLC under the Exchange Agreement (see Note 9).

During February 2010, the Company issued 4,059 shares of Common Stock to a consultant as payment for consulting services at $32.05 per share. During 2010, the Company recorded $130,091 in general and administrative expense in connection with this issuance.

During February 2010, the Company issued 24,750 shares of Common Stock to technology finders as a result of the conversion of Non-Voting Subordinated Class A Common Stock to Common Stock.

During March 2010, the Company issued a total of 5,914,431 shares of Common Stock to the holders of its convertible notes as a result of the conversion of such notes into Common Stock in conjunction with the IPO.

During March 2010, the Company issued a total of 828,024 shares of Common Stock to Shiva Biomedical, LLC and ND Partners LLC at $3.125 per share, as a result of anti-dilution adjustments pursuant to their respective agreements, of which 145,543 shares are being held in escrow for ND Partners LLC pending the achievement of certain regulatory and sales-based milestones. The anti-dilution provisions under these agreements were terminated upon the completion of the Company’s IPO in March 2010 (see Note 9).

During March 2010, the Company issued 3,850,000 shares of Common Stock in connection with the Company’s IPO at a per share price of $3.125.

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

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

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

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

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

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

Preferred Stock

On October 22, 2013, the Company sold to existing institutional investors 150,000 shares of Series C-1 preferred stock and 150,000 shares of Series C-2 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 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 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 preferred stock and Series C-2 preferred stock have identical rights, privileges and terms and are referred to collectively as the “Series C Stock.” Each share of Series C Stock is convertible into 10 shares of common stock at any time at the holder’s option at a conversion price of $1.00 per share. However, the holder will be prohibited from converting Series C Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company’s common stock then issued and outstanding. In the event of the Company’s liquidation, dissolution, or winding up, holders of the Series C Stock will receive a payment equal to $10.00 per share of Series C Stock, subject to adjustment, before any proceeds are distributed to the holders of common stock. Shares of the Series C Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company’s board of directors.

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

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Each share of Series D 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 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 preferred stock will receive a payment equal to $7.00 per share of Series D preferred stock on parity with the payment of the liquidation preference due the Series E preferred stock, but before any proceeds are distributed to the holders of common stock, Series B preferred stock, the Series C-1 preferred stock and the Series C-2 preferred stock. Shares of Series D preferred stock will receive a dividend of 9% per annum and are entitled to receive dividends on shares of the Series D preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

The issuance of the Series D Preferred stock in exchange for the extinguishment of $400,000 of convertible debt and $1,800 of interest resulted in a loss on extinguishment of $930,708.

Each share of Series E preferred stock is convertible into 20 shares of the Company's common stock (subject to adjustment) at a per share price of $0.82 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series E preferred stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 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 will receive a payment equal to $16.40 per share of Series E preferred stock on parity with the payment of the liquidation preference due the Series D preferred stock, but before any proceeds are distributed to the holders of common stock, Series B preferred stock, the Series C-1 preferred stock and the Series C-2 preferred stock. Shares of Series E preferred stock will receive a dividend of 8% per annum and are entitled to receive dividends on shares of the Series E preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

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

The issuance of the Series E preferred stock in exchange for the extinguishment of convertible debt with a carrying value of $801,231 and $3,000 of accrued interest resulted in a loss on extinguishment of $495,326.

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

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

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

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

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

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

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

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

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

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On July 30, 2013, the Company sold 454,546 shares of its Series B non-voting convertible preferred stock and a warrant to purchase up to 227,273 shares of the Company's common stock, for gross proceeds of $500,000. The Series B shares and the warrant were sold together at a price of $1.10 per share for each share of Series B stock. Each share of Series B stock is convertible into one share of the Company's common stock at any time at the holder's option. However, the holder will be prohibited from converting Series B stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 3.99% of the total number of shares of the Company's common stock then issued and outstanding.

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

Because the Series B non-voting preferred stock is immediately convertible at the option of the holder, we recorded a deemed dividend of $53,246 from the beneficial conversion feature associated with the issuance of the Series B non-voting convertible preferred stock and the warrant during the quarter ended September 30, 2013.

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

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

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

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

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

Common Stock Options:

On March 20, 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. The 2013 Plan was approved by the stockholders on July 30, 2013.

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

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

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

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

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

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

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

During the year ended December 31, 2012, the Company granted 25,000 ten-year stock options to a consultant with an exercise price of $0.68 per share based on the closing price of the Company's common stock on the date of grant. These options vested as to 50% on the date of the issuance of the CE Mark approval in Europe for the Company's Neutrolin® product candidate and 50% vested on December 31, 2013. At December 31, 2013, the Company expensed the full value of these options.

During the year ended December 31, 2012, 200,000 five-year stock options were granted to a consultant of the Company with an exercise price of $0.44 per share based on the closing price of the Company's common stock on the date of grant. 50,000 of these options vested immediately at the date of grant and the remainder to vest upon completion of certain operational and strategic milestones, including, but not limited to, receipt of CE Mark approval for CRMD003, Neutrolin®. The Company recorded the expense related to the 50,000 stock options that vested immediately. At December 31, 2013, 60,000 of these performance options were forfeited due to non-achievement of performance and 90,000 performance options were achieved. The Company recorded the value of the options on the date the performance was achieved. No expense was recognized for the options that were forfeited at December 31, 2013.

During the year ended December 31, 2012, 10,000 five-year stock options were awarded to a consultant of the Company with an exercise price $0.24 per share based on the closing price of the Company's common stock on the date of grant. Vesting is contingent upon the receipt of the Company's Neutrolin® CE Mark which was received during 2013. The Company recorded the value of the options on the date the CE Mark was approved. These options were exercised during the year ended December 31, 2013.

During the year ended December 31, 2012, 50,000 ten-year stock options were awarded to a consultant with an exercise price of $0.29 per share based on the closing price of the Company's common stock on the date of grant. Vesting is contingent upon the receipt of the Company's Neutrolin® CE Mark which was received during

2013. The Company recorded the value of the options on the date the CE Mark was approved.

During the year ended December 31, 2012, 180,000 stock options were granted to the Company's former Chief Operating Officer/Chief Financial Officer ("COO/CFO") with an exercise price of $0.49 per share. As a result of the Company's COO/CFO's resignation in April 2012, all of the options mentioned above except for the 45,000 vested options were forfeited. The vested 45,000 stock options were amended to extend the exercise period up to and through May 31, 2014. The Company re-measured and recorded as an expense the value of the 45,000 stock options and reversed the recorded expense of the forfeited stock options.

The Company recorded $1,345,136, $274,358 and $3,944,374 of stock-based compensation expense during the years ended December 31, 2013 and 2012 and the period from July 28, 2006 (inception) to December 31, 2013, respectively, in accordance with ASC 718 and ASC 505 for stock options issued to employees and non-employees, respectively.

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

	Year Ended December 31, 2013		Year Ended December 31, 2012	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	2,135,630	$1.26	1,236,342	$2.47
Granted	1,814,000	$0.90	1,380,000	$0.56
Exercised	(10,000)	$0.24	-	$-
Cancelled	(118,667)	$1.61	(217,662)	$3.13
Forfeited	(367,333)	$1.28	(263,050)	$1.72
Outstanding at end of year	3,453,630	$1.06	2,135,630	$1.26
Outstanding at end of year expected to vest	587,278	$0.90	961,034	$1.26
Options exercisable	2,490,880	$1.12	758,297	$2.16
Weighted-average fair value of options granted during the year		$0.76		$0.46

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The weighted average remaining contractual life of stock options outstanding at December 31, 2013 is 7.5 years. The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying options and the quoted closing price of the common stock of the Company as of December 31, 2013 for those options that have an exercise price below the quoted closing price. As of December 31, 2013, the aggregate intrinsic value of all stock options exercised and outstanding is $6,100 and $1,404,110, respectively.

The Company has experienced forfeitures of stock options issued to its former officers, a board member and employees. Consistent with its historical forfeiture experience, the Company has applied a forfeiture rate of 39% and 55% to calculate stock option expense for each of the years ended December 31, 2013 and 2012, respectively. The Company will continue to evaluate the estimated forfeiture rate derived from previous forfeitures of officers, directors and employees and may adjust the forfeiture rate based upon actual forfeitures that may occur in the future.

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

Warrants:

The following table is the summary of warrants outstanding at December 31, 2013:

	Number of Warrants	Exercise Price	Expiration Date
Issued to co-placement agents in connection with previous convertible note financings	18,250	$7.84	10/29/2014
Issued in connection with 2009 private placement	503,034	3.4375	10/29/2014
Issued in connection with IPO	4,043,569	3.4375	3/24/2015
Issued to IPO underwriters that, if exercised, would result in the issuance of an additional 4,812 shares of common stock and warrants to purchase an additional 2,406 shares of common stock	4,812	3.90	3/24/2015
Issued in connection with September 20, 2012 private placement of convertible notes	2,125,000	0.40	9/20/2017
Issued to placement agent in connection with September 20, 2012 private placement of convertible notes	15,420	0.40	9/20/2017
Issued in connection with November 13, 2012 private placement of convertible notes	375,000	0.40	11/13/2017
Issued to placement agent in connection with November 13, 2012 private placement of convertible notes	85,167	0.40	11/13/2017
Issued in connection with February 2013 private placement of Series A convertible preferred stock	400,000	1.50	2/19/2018
Issued in connection with license agreement amendment	125,000	1.50	4/11/2018
Issued in connection with July 2013 private placement of Series B convertible preferred stock	227,273	1.50	7/30/2018
Issued in connection with May 2013 private placement	1,000,000	1.00	

of convertible notes, which funded in July 2013			5/30/2019
Issued in connection with October 2013 private placement of Series C-1 and C-2 convertible preferred stock	1,500,000	1.25	10/22/2019
Total warrants outstanding at December 31, 2013	10,422,525		

Note 8 — Fair Value Measurements:

The fair value of the Company's cash, convertible notes, and accounts payable at December 31, 2013 are estimated to approximate their carrying values due to the relative liquidity and/or short-term nature of these instruments. The following table presents the fair value hierarchy, carrying amounts and fair values of the Company's financial instruments measured at fair value on a recurring basis as of December 31, 2013. There were no financial instruments measured at fair value on a recurring basis at December 31, 2012.

	Fair Value Hierarchy	Fair Value
Financial Liabilities Measured at Fair Value on a Recurring Basis:		
Series C non-voting preferred stock	3	$2,027,330
Series D non-voting preferred stock	3	901,625
Series E non-voting preferred stock	3	735,619
Warrants issued in connection with convertible debt	3	660,869
Warrants issued in connection with Series C non-voting preferred stock	3	983,361
Total		$5,308,804

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Note 9 — License and Other Agreements:

On July 28, 2006, the Company entered into a contribution agreement (as amended on October 6, 2009 and on February 22, 2010) (the "Shiva Contribution Agreement") with Shiva Biomedical, LLC, a New Jersey limited liability company ("Shiva"), and certain other parties. Pursuant to the Shiva Contribution Agreement, Shiva contributed to the Company its kidney products business and granted the Company an exclusive, worldwide license agreement for a patent estate covering proprietary formulations of the first "iron chelator" for kidney diseases, specifically deferiprone (the "Compound"), and a biomarker diagnostic test for measuring levels of labile iron (the "Test"). Specifically, the Company licensed treatment, formulation and dosing regimens and methods of using the Compound and the Test, for the treatment and diagnosis of diseases and disorders, and the corresponding United States and foreign patents and applications in all fields of use (collectively, the "Shiva Technology"). As consideration in part for the rights to the Shiva Technology, the Company paid Shiva an initial licensing fee of $500,000 and granted Shiva up to a 20% equity interest in the Company consisting of shares of the Company's Series B, C, D, E and F Common Stock which were placed in escrow to be released upon the achievement of certain clinical milestones. Pursuant to the October 2009 amendment and corresponding Exchange Agreement, Shiva surrendered all rights to such shares in exchange for 7.0% of the outstanding shares of Common Stock as of the date of exchange, or 98,739 shares (see Note 7). The Company was also obligated to issue additional shares of Common Stock to Shiva sufficient to maintain its ownership percentage at 7.0% of the outstanding Common Stock on a fully diluted basis, and the Company issued an additional 412,338 shares to Shiva at a price of $3.125 per share as a result of this obligation in connection with the Company's IPO; however, such anti-dilution obligation terminated upon the completion of the IPO. In addition, the Company was required to make substantial payments to Shiva upon the achievement of certain clinical and regulatory based milestones. The maximum aggregate amount of such milestone payments, assuming achievement of all milestones, was $10,000,000. Events that trigger milestone payments included, but were not limited to, the reaching of various stages of clinical trials and regulatory approval processes. In the event that the Shiva Technology was commercialized, the Company was obligated to pay to Shiva annual royalties based upon net sales of the product. In the event that the Company sublicensed the Shiva Technology to a third party, the Company was obligated to pay to Shiva a portion of the royalties, fees or other lump-sum payments it receives from the sublicense, subject to certain deductions. Through December 31, 2011, no milestone payments or royalty payments had been earned by or paid to Shiva. The Company had the right to terminate the Shiva Contribution Agreement for any reason upon 30 days prior written notice. On December 1, 2011, the Company issued Shiva a notice of termination letter of the license agreement and, as such, had no further financial obligation to Shiva. The Company reassigned to Shiva all of the Company's intellectual property rights with respect to the Shiva Technology.

On February 22, 2010, the Company and Shiva entered into an amendment to the Shiva Contribution Agreement, pursuant to which the Company's deadline for meeting a certain development progress requirement was extended from April 30, 2010 to June 30, 2010 and the Company paid $25,000 to Shiva following completion of the Company's IPO, as partial reimbursement for Shiva's expenses in connection with such amendment and prior amendments to the Shiva Contribution Agreement.

On August 29, 2011, the Company and Shiva entered into an amendment to the Shiva Contribution Agreement, pursuant to certain changes with respect to the development and milestone payments of the licensed products.

During the year ended December 31, 2011 and the period from July 28, 2006 (Inception) to December 31, 2012, the Company expensed $100,000 and $4,920,310, respectively, in connection with the Shiva Contribution Agreement.

In connection with the Shiva Contribution Agreement, on July 28, 2006, the Company entered into a Consulting Agreement with Dr. Sudhir Shah, which was amended and restated on April 1, 2010 as a Scientific Advisory Board Agreement (the "Shah Consulting Agreement") and was further amended and restated on August 29, 2011. Pursuant to the Shah Consulting Agreement, as amended, for a period of one year commencing on April 1, 2010, Dr. Shah provided the Company with consulting services involving areas mutually agreed to by Dr. Shah and the Company and beginning on August 29, 2011 provided consulting services for up to 17.5 hours per month and served on one of the Company's Scientific Advisory Boards. During the year ended December 31, 2011 and the period from July 28, 2006 (Inception) to December 31, 2012, the Company expensed $29,000 and $196,000, respectively, in connection with the Shah Consulting Agreement.

On January 30, 2008, the Company entered into a License and Assignment Agreement (the "NDP License Agreement") with ND Partners LLC, a Delaware limited liability company ("NDP"). Pursuant to the NDP License Agreement, NDP granted the Company exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the "NDP Technology"). The Company acquired such licenses and patents through our assignment and assumption of NDP's rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann and Dr. Johannes Reinmueller. NDP also granted the Company exclusive licenses, with the right to grant sublicenses, to use and display certain trademarks in connection with the NDP Technology. As consideration in part for the rights to the NDP Technology, the Company paid NDP an initial licensing fee of $325,000 and granted NDP a 5% equity interest in the Company, consisting of 39,980 shares of the Company's Common Stock. In connection with this stock issuance, the Company recorded $328,948 of research and development expense in 2008. In addition, the Company is required to make payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The Company was also obligated to issue additional shares of common stock to NDP sufficient to maintain its ownership percentage at 5.0% of the outstanding common stock (7.0%, including the escrow shares) on a fully diluted basis, until such time that the Company has raised $25 million through the sale of its equity securities or until an initial public offering, reverse merger or a sale of the Company. As a result of this obligation, in October 2009, the Company issued an additional 28,156 shares to NDP and an additional 11,263 shares into the escrow, at a price of $32.05 per share, in connection with the issuance of shares to Shiva under the Exchange Agreement as described above, and in March 2010 the Company issued an additional 297,398 shares to NDP and an additional 118,288 shares into the escrow, at a price of $3.125 per share, in connection with the Company's IPO; however, such anti-dilution obligation terminated upon the completion of the IPO. The maximum aggregate number of shares issuable upon achievement of milestones and the number of shares held in escrow as of December 31, 2011 is 145,543 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. Through December 31, 2013, no milestone payments have been earned by or paid to NDP.

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On April 11, 2013, the Company entered into an amendment to the NDP License Agreement. Under Article 6 of the NDP License Agreement, the Company was obligated to make a milestone payment of $500,000 to ND Partners upon the first issuance of a CE Marking for a licensed product, which payment was payable to ND Partners within 30 days after such issuance. Pursuant to the terms of the amendment, the Company and ND Partners agreed to delay such milestone payment to a time, to be chosen by the Company, anytime within 12 months after the achievement of such issuance. As consideration for the amendment, the Company issued ND Partners a warrant to purchase 125,000 shares of the Company's common stock at an exercise price of $1.50 per share. The warrant is exercisable immediately upon issuance and has a term of five years. The warrant contains a cashless exercise feature and standard adjustment features in the event of a stock split, stock dividend, recapitalization or similar events. In January 2014, the Company settled this milestone payment which resulted in the issuance of 50,000 shares of the Company's Series C-3 non-voting convertible preferred and 250,000 shares issuable upon exercise of warrants at an exercise price of $1.25 per share (see Note 11 – Subsequent Events).

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.

During the period from July 28, 2006 (Inception) to December 31, 2013, the Company expensed $3,092,356 in connection with the NDP License Agreement.

On January 30, 2008, the Company also entered into an Exclusive License and Consulting Agreement with Dr. Polaschegg (the "Polaschegg License Agreement"). The Polaschegg License Agreement replaced the original license agreement between NDP and Dr. Polaschegg that the Company was assigned and the Company assumed under the NDP License Agreement. Pursuant to the Polaschegg License Agreement, Dr. Polaschegg granted the Company an exclusive, worldwide license for a certain antimicrobial solution and certain taurolidine treatments and the corresponding United States patent applications (the "Polaschegg Technology"), and agreed to provide the Company with certain consulting services. As consideration for the rights to the Polaschegg Technology, the Company paid Dr. Polaschegg an initial payment of $5,000 and agreed to pay Dr. Polaschegg certain royalty payments ranging from 1% to 3% of the net sales of the Polaschegg Technology. The Polaschegg License Agreement also sets forth certain minimum royalty payments (on an annual basis) to be made to Dr. Polaschegg in connection with the Polaschegg Technology, which payments range from $10,000 to $45,000. As compensation for Dr. Polaschegg's consulting services to be provided under the Polaschegg License Agreement, Dr. Polaschegg is being paid €200 per hour for services consisting of scientific work and €250 per hour for services consisting of legal work.

The Company may terminate the Polaschegg License Agreement with respect to any piece of the Polaschegg Technology upon 60 days notice. If the Polaschegg License Agreement is terminated with respect to any piece of the Polaschegg Technology by either party, all rights with respect to such portion of the Polaschegg Technology will revert to Dr. Polaschegg.

During the years ended December 31, 2013 and 2012 and the period from July 28, 2006 (Inception) to December 31, 2013, the Company expensed approximately $45,000, $45,000 and $230,000, respectively, in connection with the Polaschegg License Agreement.

Navinta LLC, a U.S.-based Active Pharmaceutical Ingredient ("API") developer, provides API manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for CRMD003, pursuant to a supply

agreement dated December 7, 2009 (the "Navinta Agreement"). The Navinta Agreement provides that Navinta supply taurolidine (the API for CRMD003) to the Company on an exclusive worldwide basis in the field of the prevention and treatment of human infection and/or dialysis so long as the Company purchased a minimum of $350,000 of product from Navinta by December 30, 2010, which the Company achieved, and following the Company's first commercial sale of a product incorporating taurolidine, purchase a minimum of $2,250,000 of product on an annual basis for five years. The Company is also required to make certain cash payments to Navinta upon the achievement of certain sales-based milestones. The maximum aggregate amount of such payments, assuming achievement of all milestones, is $1,975,000. The Navinta Agreement has a term of five years, but may be terminated by either party upon 30 days written notice.

Note 10 — Retirement Plan:

On May 1, 2010, the Company adopted a 401(k) savings plan (the "401(k) Plan") for the benefit of its employees. Under the safe harbor provisions of the 401(k) Plan, the Company is required to make contributions equal to 3% of eligible compensation for each eligible employee whether or not the employee contributes to the 401(k) Plan. During the year ended December 31, 2013, the 401(k) Plan was terminated. For the year ended December 31, 2012 and from July 28, 2006 (inception) through December 31, 2012, the Company recorded $11,370 and $44,390, respectively, of required contributions in accordance with the Safe Harbor provision of the 401(k) Plan.

Note 11 — Subsequent Events:

On January 8, 2014, the Company sold an aggregate of 200,000 shares of its Series C-3 non-voting convertible preferred stock and warrants to purchase up to an aggregate of 1,000,000 shares of common stock for gross proceeds of $2,000,000. The Series C-3 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 preferred stock has rights, privileges and terms that are identical to the Company's Series C-1 and C-2 non-voting convertible preferred 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 at a conversion price of $1.00 per share. However, the holder is prohibited from converting Series C-3 preferred stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding. The warrants are exercisable one year after issuance, have an exercise price of $1.25 per share, subject to adjustment, and a term of five years from the date they are first exercisable. However, a holder is prohibited from exercising a warrant if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% or 9.99%, at the holder's election, of the total number of shares of the Company's common stock then issued and outstanding. Included in this financing is the settlement of an aggregate amount of $645,500 in accruals and payables owed to ND Partners, the Company's CEO for his 2013 salary, and a consultant.

On March 10, 2014, the Company sold an aggregate of 2,960,000 units in a registered direct offering. 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. The purchase price was $2.50 per unit. The warrants have an exercise price of $3.10 per share, are exercisable commencing six months from the date of issuance, and have a term of five years from the date of exercisability. However, a holder is prohibited from exercising a warrant if, as a result of such exercise, the holder, together with its affiliates, would own more than 3.99% or 4.99%, at the holder's election, of the total number of shares of the Company's common stock then issued and outstanding.

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.				
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 212013.	8-K	10/23/2013	3.5	
3.7	Certificate of Amendment to Certificate of Designation of Series C-1 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.10	
3.8	Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.6	
3.9	Certificate of Amendment to Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.11	
3.10	Certificate of Designation of Series C-3 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.9	
3.11	Certificate of Designation of Series D Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 4, 2013.	8-K	10/23/2013	3.7	
3.12	Certificate of Amendment to Certificate of Designation of Series D Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 21, 2014.	8-K	1/09/2014	3.12	
3.13	Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.8	
3.14	Certificate of Amendment to Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.13	
4.1	Specimen of Common Stock Certificate.	S-1/A	3/19/2010	4.1	
4.2	Specimen Unit certificate.	S-1/A	3/19/2010	4.2	
4.3	Specimen warrant certificate.	S-1/A	3/19/2010	4.3	

4.4	Form of warrant agreement.	S-1/A	3/19/2010	4.4
4.5	Common Stock Exchange and Stockholder Agreement, dated as of October 6, 2009, by and between CorMedix Inc. and Shiva Biomedical, LLC.	S-1	11/25/2009	4.6
4.6	Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC.	S-1	11/25/2009	4.7
4.7	Form of Third Bridge Warrant.	S-1/A	1/20/2010	4.18
4.8	Form of 9% Senior Convertible Note due 2013.	10-Q	11/13/2012	4.1
4.9	Form of Purchaser Warrant.	10-Q	11/13/2012	4.2
4.10	Form of Placement Agent Warrant.	10-Q	11/13/2012	4.3
4.11	Form of Subscription Agreement.	10-Q	11/13/2012	4.4
4.12	Form of Registration Rights Agreement.	10-Q	11/13/2012	4.5
4.13	Form of Senior Secured Convertible Note.	8-K	5/24/2013	4.19
4.14	Form of Warrant issued on May 30, 2013.	8-K	5/24/2013	4.20
4.15	Form of Warrant issued on July 30, 2013.	8-K	5/24/2013	4.21
4.16	Form of Warrant issued on October 22, 2013.	8-K	1/09/2014	4.23
4.17	Form of Warrant issued on January 8, 2014.			

10.1	*	Contribution Agreement, dated as of July 28, 2006, by and between Shiva Biomedical, LLC, Picton Pharmaceuticals, Inc., Picton Holding Company, Inc., and the stockholders of Picton Pharmaceuticals, Inc.	S-1/A	12/31/2009	10.1	
10.2	*	Amendment to Contribution Agreement, dated as of October 6, 2009, by and between Shiva Biomedical, LLC and CorMedix, Inc.	S-1/A	12/31/2009	10.2	
10.3		Amendment No. 2 to Contribution Agreement, dated as of February 22, 2010, by and between the Company and Shiva Biomedical, LLC.	S-1/A	3/01/2010	10.15	
10.4	*	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	
10.5		Escrow Agreement, dated as of January 30, 2008, among the Company, ND Partners LLC and the Secretary of the Company, as Escrow Agent.	S-1	11/25/2009	10.6	
10.6	*	Exclusive License and Consulting Agreement, dated as of January 30, 2008, between the Company and Hans-Dietrich Polaschegg.	S-1/A	3/01/2010	10.7	
10.7		Amended and Restated Consulting Agreement, dated as of January 10, 2008, between the Company and Sudhir V. Shah, M.D.	S-1	11/25/2009	10.11	
10.8		Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl.	S-1	11/25/2009	10.12	
10.9	*	Supply Agreement, dated as of December 7, 2009, between the Company and Navinta, LLC.	S-1/A	3/01/2010	10.13	
10.10	*	Manufacture and Development Agreement, dated as of March 5, 2007, by and between the Company and Emcure Pharmaceuticals USA, Inc.	S-1/A	12/31/2009	10.14	
10.11		Amended and Restated 2006 Stock Incentive Plan.	S-1/A	3/01/2010	10.8	
10.12		Form of Indemnification Agreement between the Company and each of its directors and executive officers.	S-1/A	3/01/2010	10.17	
10.13	*	Amendment No. 3 to Contribution Agreement, effective as of August 31, 2011, by and between the Company and Shiva Biomedical, LLC.	10-Q	11/10/2011	10.2	
10.14		Subscription Agreement by and between the Company and certain accredited investors (with attached schedule of parties thereto).	8-K	11/15/2012	10.1	
10.15		Amended and Restated Investment Banking Agreement, dated August 20, 2012, between the Company and John Carris Investments, LLC.	8-K	11/15/2012	10.2	
10.16		Agreement for Work on Pharmaceutical Advertising dated January 10, 2013 by and between MKM Co-Pharma GmbH and CorMedix Inc.	8-K	1/16/2013	10.22	
10.17		Form of Securities Purchase Agreement, dated February 18, 2013, between CorMedix Inc. and the investor named therein.	8-K	2/19/2013	10.23	
10.18		Consulting Agreement, as amended December 24, 2012, between the Company and MW Bridges LLC.	10-K	3/27/2013	10.26	
10.19		2013 Stock Incentive Plan	10-K	3/27/2013	10.27	
10.20		Form of Securities Purchase Agreement, dated May 23, 2013, between CorMedix Inc. and the investor named therein.	8-K	5/24/2013	10.29	
10.21		Form of Securities Purchase Agreement, dated July 25, 2013, between CorMedix Inc. and the investor named therein.	8-K	7/26/2013	10.30	
10.22		Form of Securities Purchase Agreement, dated October 17, 2013, between CorMedix Inc. and the investor named therein.	8-K	10/18/2013	10.32	
10.23		Form of Securities Purchase Agreement, dated October 17, 2013, between CorMedix Inc. and the investor named therein.	8-K	10/18/2013	10.33	
10.24		Form of Securities Purchase Agreement, dated January 7, 2014, between CorMedix Inc. and the investors named therein.	8-K	1/09/2014	10.36	
21.1		List of Subsidiaries	10-K	3/27/2013	21.1	
23.1		Consent of Independent Registered Public Accounting Firm.				X

31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
101	The following materials from CorMedix Inc. Form 10-K for the year ended December 31, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2013 and December 31, 2012, (ii) Statements of Operations for the years ended December 31, 2013 and 2012 and for the Cumulative Period from July 28, 2006 (inception) through December 31, 2013, (iii) Statements of Changes in Stockholders' Equity for the year ended December 31, 2013, (iv) Statements of Cash Flows for the years ended December 31, 2013 and 2012 and for the Cumulative Period from July 28, 2006 (inception) through December 31, 2013 and (v) Notes to the Financial Statements.**	X

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

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