CorMedix Inc.
Form 10-K
March 27, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended: **December 31, 2012**

OR

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

For the transition period from _____ to _____

Commission file number: 001-34673

CORMEDIX INC.

(Exact name of Registrant as Specified in Its Charter)

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

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 ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ¨ No x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulations S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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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 ¨ Accelerated filer ¨

Non-accelerated filer ¨ Smaller reporting company x

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

Yes ¨ No x

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 $2.3 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 11,882,379 as of March 25, 2013.

DOCUMENTS INCORPORATED BY REFERENCE

None

CORMEDIX INC.

PART IV

Neutrolin® is our registered trademark. All other trade names, trademarks and service marks appearing in this prospectus 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 Annual Report, appear with the trade name, trademark or service mark notice and then throughout the remainder of this Annual 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K 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,” “sh “would,” and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below in the section titled “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

CorMedix Inc.(referred to herein as “we,” “us,” “our” and the “Company”), is a development stage pharmaceutical and medical device company that seeks to in-license, develop and commercialize therapeutic products for the treatment of cardiac and renal dysfunction, specifically in the dialysis and non-dialysis areas.

We have the worldwide rights to develop and commercialize our product candidates, CRMD003 (Neutrolin®) and CRMD004, that 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 candidate in development is CRMD003 (Neutrolin®) for the prevention of catheter related infections in the 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. 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. 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 this 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. We also have successfully completed our stage 2 audit with TÜV SÜD which resulted in our receipt of the ISO 13485:2003 certification from TÜV SÜD on October 10, 2012. 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.

We anticipate receiving a CE mark approval in the second quarter of 2013. If we obtain CE Mark approval in Europe, we intend to launch Neutrolin for the prevention of Catheter Related Bloodstream Infections, or CRBI and maintenance of catheter patency in hemodialysis patients in Europe during 2013. However, we cannot be assured of CE Mark approval of Neutrolin on that timeline or at all.

We are currently exploring the various methods of launching Neutrolin in Europe, whether through a distributorship or partnership arrangement, or otherwise, and plan to initially launch in Germany. To that end, on January 10, 2013, we entered into an Agreement for Work on Pharmaceutical Advertising with MKM Co-Pharma GmbH, or MKM, regarding Neutrolin, for which we anticipate receiving a CE Mark approval in Europe in the second quarter of 2013. Pursuant to the agreement, MKM hired a national sales manager, Joachim Petrak, 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 will visit hemodialysis centers and doctors to, among other things, provide them information and promotional materials. The sales manager will also produce a market review of our product, conduct test sales of Neutrolin in Germany, negotiate wholesaler relationships for initial orders of our product and determine sales projections for launching Neutrolin. In the second phase, from April to May 2013, assuming receipt of CE Mark approval, the sales manager will launch Neutrolin, generating sales on a best efforts basis, and supervise sales representatives. After that time, the sales manager will be responsible for growing Neutrolin sales and expanding the advertising plan. Additionally, to lead the commercialization of Neutrolin in the European Union, we have formed a European subsidiary, CorMedix Europe GmbH. Assuming the receipt of a CE Mark and the launch of Neutrolin, we intend to meet with the FDA to determine the pathway for U.S. approval of Neutrolin, which we expect will entail a Phase 3 trial.

Our other product candidate is CRMD004, which is the gel formulation of Neutrolin that we intend to develop for the 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. CRMD004 is in the pre-clinical stage. However, at this time, we intend to defer the development of CRMD004 until after we receive the CE Mark for Neutrolin in the European Union and have commenced the FDA regulatory approval process for Neutrolin.

During 2011, we completed a phase II study of CRMD001 (deferiprone) an oral formulation of the drug deferiprone which we in-licensed from Shiva Biomedical in 2006. The phase II study was designed for the prevention of Contrast-Induced Nephropathy, or CIN, which is a common and potentially serious complication arising from the use of iodinated contrast media used in X-ray procedures to identify the status of blood vessels in the heart. A total of 61 patients (32 deferiprone, 29 placebo) were enrolled in the study. A variety of biomarkers of kidney injury and function were measured. Clinical events and safety parameters, including Serious Adverse Events or SAEs were followed through day 90. Top-line results were reviewed and interpreted internally, by the principal investigator and by three external academic biomarker experts. In the placebo group, most of the kidney injury biomarkers increased after contrast administration, as expected. Deferiprone tended to reduce acute elevations of the injury biomarkers, particularly in the first 8 hours. Measures of glomerular filtration (serum cystatin C, serum creatinine and Estimated Glomerular Filtration Rate, or EGFR) unexpectedly trended in the opposite direction over the first 8 days, as there was little change in the placebo group and small decreases in renal function in the deferiprone group. Analysis of SAEs indicated no safety signal. Based upon these top-line results, along with the extensive review of our CIN intellectual

property position, the review of biomarker expert opinions, and among other factors such as our current cash position, we decided against pursuing further development of CRMD001. On December 1, 2011 we issued a notice of termination to the Shiva Biomedical license agreement.

In March 2010, we completed our initial public offering, or the IPO, whereby we sold 1,925,000 units, each unit consisting of two shares of our common stock and a warrant to purchase one share of common stock, at $6.50 per unit resulting in gross proceeds of $12,512,500 and net proceeds to us of $10,457,270 after deducting underwriting discounts and commissions and offering expenses payable by us. All of our convertible notes and accrued interest thereon and all of our outstanding shares of Non-Voting Subordinated Class A Common Stock automatically converted into units or common stock upon the completion of the IPO. We effected a 1 for 7.836 reverse stock split of our common stock on February 24, 2010 in connection with the IPO. All shares and per share amounts, except as noted, have been retroactively adjusted to give effect to the reverse stock split.

In September and November of 2012, we conducted a private placement in which we sold an aggregate of 1,324 units for aggregate gross proceeds of $1,324,000. Each unit consisted of (i) a one-year $1,000 principal amount 9% senior convertible note, convertible into shares of our common stock at a conversion price of $0.35 per note, and (ii) a five-year redeemable Warrant, to purchase 2,500 shares of our common stock at a purchase price of $0.40 per share. The total net proceeds (net of placement agent and legal fees) of the private placement to us were $1,095,600. We issued to the investors warrants to purchase an aggregate of 3,310,000 shares of our common stock. We 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. The placement agent warrants have the same terms as those issued to the investors.

On February 19, 2013, we sold to an existing institutional investor 761,429 shares of our newly created 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. 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 is convertible into one share of our common stock at any time at the holder's option. However, the holder will 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 our 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 our common stock then issued and outstanding. On February 22, 2013, an aggregate of 474,105 shares of this Series A non-voting convertible preferred stock was converted into 474,105 shares of our common stock.

We believe that existing cash and the net proceeds from the February 2013 Series A preferred stock financing will be sufficient to fund our projected operating requirements into the second quarter of 2013.

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.

Over the past three years we have made progress toward the development of Neutrolin (CRMD003). On March 5, 2013, TÜV SÜD informed us that the Medicinal Evaluation Board of the Netherlands, or MEB, gave us a positive response on the clinical aspect of our application. The MEB 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. We are now working on the final packaging for Neutrolin with internationally recognized consultants and a leading packaging systems company to meet TÜV SÜD requirements. As a result, we anticipate final approval for the CE Mark certification for Neutrolin during the second quarter of 2013.

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.	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 commenced the application process for CE Mark approval in Europe during the fourth quarter 2010. In the U.S., Neutrolin® is considered to be a drug product, requiring submission and approval of an Investigational New Drug ("IND") application.	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 CRBIs and the inflammatory complications associated with them. Assuming an average of 2 episodes of CRBIs per year, there would be 162,000 episodes per year. Further stated in the American Journal of Kidney Diseases, the total annual cost in the United States of treating all CRBI episodes and their complications would amount to approximately $777 million. 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 catheter-related blood stream infections and inflammatory complications requires decontamination of the internal surface of the catheter to prevent the systemic dissemination of organisms contained within the biofilm and 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 – 5,000 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 for the prevention of CRBIs in central venous catheters.

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.

CRMD003, or 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 March 5, 2013, TÜV SÜD informed us that the Medicinal Evaluation Board of the Netherlands, or MEB, gave us a positive response on the clinical aspect of our application. The MEB 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. We are now working on the final packaging for Neutrolin with internationally recognized consultants and a leading packaging systems company to meet TÜV SÜD requirements. As a result, we anticipate final approval for the CE Mark certification for Neutrolin during the second quarter of 2013.

In the U.S., we plan to resume dialogue with the FDA after we receive our CE Mark in the EU. We anticipate this will be during the second half of 2013. Based upon FDA guidance, we plan to approach the Center for Drug Evaluation and Research, or CDER, anti-infective division and submit our recommended 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 would be for one pivotal Phase III 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 first half of 2014 and be completed in 2015 with NDA submission and potential approval in 2016.

Sales and Marketing Strategy

If we obtain CE Mark approval, we intend to be in a position to launch Neutrolin for the prevention of CRBI and maintenance of catheter patency in hemodialysis patients in Europe during 2013. However, we cannot be assured of CE Mark approval of Neutrolin on that timeline or at all, or, if CE Mark approval is received, we cannot be assured we can effectively launch Neutrolin in 2013. We are currently exploring the various methods of launching Neutrolin in Europe, whether through a distributorship or partnership arrangement or otherwise, and plan to initially launch in Germany. To that end, on January 10, 2013, we entered into an Agreement for Work on Pharmaceutical Advertising with MKM Co-Pharma GmbH regarding Neutrolin, for which we anticipate receiving a CE Mark approval in Europe in the second quarter of 2013. Pursuant to the agreement, MKM hired a national sales manager, Joachim Petrak, 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 will visit hemodialysis centers and doctors to, among other things, provide them information and promotional materials. The sales manager will also produce a market review of our product, conduct test sales of Neutrolin in Germany, negotiate wholesaler relationships for initial orders of our product and determine sales projections for launching Neutrolin. In the second phase, from April to May 2013, assuming receipt of CE Mark approval, the sales manager will launch Neutrolin, generating sales on a best efforts basis, and supervise sales representatives. After that time, the sales manager will be responsible for growing Neutrolin sales and expanding the advertising plan. Additionally, to lead the commercialization of Neutrolin in the European Union, we have formed a European subsidiary, CorMedix Europe GmbH.

Assuming the successful launch of Neutrolin in Europe, 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 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 the 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.

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 in clinical trials. We intend to continue this practice for any future clinical trials and commercialization of our products.

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 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, 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 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 marketing application to the FDA, and approval of the application by the FDA.

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 Investigational New Drug 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 I studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease. Phase I 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 II, 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 III, 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 II studies. These studies are often referred to as “phase I/II” studies. However, even if patients participate in initial human testing and a phase I/II study is carried out, the sponsor is still responsible for obtaining all the data usually obtained in both phase I and phase II studies.

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

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

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

Following the completion of a clinical trial, the data are analyzed to determine whether the trial successfully demonstrated safety and effectiveness and whether a product approval application may be submitted. In the United States, if the product is regulated as a drug, a New Drug Application must be submitted and approved before commercial marketing may begin. The New Drug Application 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 CorMedix may decide to use, must be listed in the New Drug Application 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 cGMP requirements.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing a New Drug Application, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. For fiscal year 2012, the New Drug Application review fee alone is $1,841,500, although certain limited deferral, waivers, and reductions may be available.

Each New Drug Application 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 New Drug Application, thereby triggering substantive review of the application. The FDA can refuse to file any New Drug Application 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 a New Drug Application. 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 its products to reach a point at which a New Drug Application 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, CorMedix is 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 CorMedix or its 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, 2012. 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. As of December 31, 2012, no milestone payments have been earned by or paid to NDP.

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. 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 $90,000. 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, 2012, Dr. Polaschegg has received an aggregate of approximately $471,000 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, 2013, we had no employees, but instead we have engaged various consultants primarily serving in executive management, including our Chief Executive Officer and Chief Financial Officer and Chief Scientific Officer, project management and research and development, manufacturing and regulatory development, marketing, financing 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 Rt. 202-206, Suite 303, Bridgewater, NJ 08807. Our telephone number is (908) 517-9500.

The Company maintains a website at www.cormedix.com; however, the information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. This Annual Report on Form 10-K and all of the Company's 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

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

In their report accompanying our audited financial statements, our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern. A "going concern" opinion could impair our ability to finance our operations through the sale of debt or equity securities or through bank financing. We believe our recent decision to focus the majority of our resources, including our research and development efforts, primarily on the CE Mark approval and commercialization of Neutrolin® in Europe will result in our currently available capital resources being sufficient to meet our operating needs only into the second quarter of 2013, after giving effect to our receipt of approximately $1,324,000 in aggregate gross proceeds from the sale of our Senior Convertible Notes in September and November 2012 and the gross proceeds of $533,000 received from the private placement of our Series A non-voting convertible preferred stock during the first quarter of 2013. Our ability to continue as a going concern will depend, on our ability to obtain additional financing. Thereafter, our ability to generate positive cash flow from operations will depend on our ability to receive a CE Mark for and launch Neutrolin® in Europe. None of these undertakings are certain. Additional capital may not be available on reasonable terms, or at all. If adequate financing is not available, we would be required to terminate or significantly curtail our operations, or enter into arrangements with collaborative partners or others that may require us to relinquish rights to certain aspects of our technologies, or potential markets that we would not otherwise relinquish. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

We have a limited operating history and a history of escalating operating losses, and expect to incur significant additional operating losses.

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 net losses of approximately $6.7 million and $3.4 million for the years ended December 31, 2011 and 2012, respectively. As of December 31, 2012, we had an accumulated deficit of approximately $46.4 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trial and commercialization activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products unless and until we receive a CE Mark for and launch Neutrolin® in Europe, and might never generate revenues from the sale of products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following: successful completion of the development of our product candidates, particularly Neutrolin®; obtaining necessary regulatory approvals for Neutrolin® from the applicable European agencies, other foreign agencies and the FDA and from the FDA and international regulatory agencies for any other products; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. Even if we succeed in developing and commercializing Neutrolin® or other product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue to undertake development 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 for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability would negatively impact the value of our securities.

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

We have no approved product on the market and have generated no product revenues. Unless and until we receive applicable regulatory approval for Neutrolin® and any other product candidates, we cannot sell our products and will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants.

We believe that existing cash will be sufficient to enable us to fund our projected operating requirements only into the second quarter of 2013, based upon our recent decision to focus the majority of our resources, including our research and development efforts, primarily on the CE Marking approval and commercialization of Neutrolin® in Europe. 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 product candidates are still in development.

We are a development stage pharmaceutical and medical device company with product candidates 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 have elected to delay our other product candidates' development until we have obtained CE Marking approval in Europe for Neutrolin®. Our product candidates are currently at the following stages:

- CRMD003 (Neutrolin®) - submitted a CE Mark application for approval in Europe; 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. Our product candidates will require significant additional development, clinical trials, regulatory clearances and/or investment by us or our collaborators before they can be commercialized. Specifically, if we receive a CE Mark for Neutrolin®, we will need to commercially launch it in Europe either on our own or through a third party, which will take time and capital.

Successful development of our products is uncertain.

Our development 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, 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 may 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 current Good Manufacturing Practices requirements, referred to herein as cGMP, for use in clinical trials;
- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of patients;
- modification of clinical trial protocols;

- changes in regulatory requirements for clinical trials;
- lack of effectiveness during clinical trials;
- emergence of unforeseen safety issues;
- delays, suspension, or termination of clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and
- government or regulatory delays or "clinical holds" requiring suspension or termination of the trials.

The results from early pre-clinical and clinical trials are not necessarily predictive of results to be obtained in later clinical trials. Accordingly, even if we obtain positive results from early pre-clinical or clinical trials, we may not achieve the same success in later clinical trials.

Our clinical trials may be conducted in patients with serious or life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product is expected to be used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. We cannot ensure that safety issues will not arise with respect to our products in clinical development.

Clinical trials may not demonstrate statistically significant safety and effectiveness to obtain the requisite regulatory approvals for product candidates. As an example in late 2011, we terminated development of CRMD001 due to disappointing data from our phase II study. The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of our product candidates. Such a failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay the filing of any New Drug Application, or 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, 30 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 have contracted with TÜV SÜD, a European Union notified body, to handle the CE Marking process for Neutrolin®. In October 2012, TÜV SÜD awarded the ISO 13485:2003 certification for Neutrolin®, an important step in the CE Marking process. However, certain individual countries within the European Union require further approval by their national regulatory agencies. Failure to receive or maintain the right to affix the CE Mark or other requisite approvals could prohibit us from marketing and selling Neutrolin® in the European Economic Area or elsewhere.

We do not have, and may never obtain, the regulatory approvals we need to market our product candidates.

We have filed a design dossier submission with TÜV SÜD, the European Union notified body, as part of the regulatory CE Marking approval process in Europe for Neutrolin® and have received ISO 13485:2003 certification. However, there cannot be any assurance that Neutrolin® will receive a CE Mark that would allow it to be sold in 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 a NDA or PMA to the FDA for any product.

It is possible that none of our product candidates will be approved for marketing. Failure to obtain regulatory approvals, or delays in obtaining regulatory approvals, especially for Neutrolin® in Europe, would adversely affect the successful commercialization of it or any other drugs or biologics 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.

Physicians and patients may not accept and use our products.

Even if we receive FDA or foreign regulatory approval for one or more of our product candidates, physicians and patients may not accept and use it. 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 our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products 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 therewith 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 does not include the sale of commercial products. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any 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 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 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, Richard Cohen (our former Interim Chief Executive Officer, former Interim Chief Financial Officer and, effective January 1, 2013, our Chief Financial Officer), Randy Milby (our former Chief Operating Officer and, effective January 1, 2013,

our Chief Executive Officer) and Dr. Antony Pfaffle, our director and, effective January 1, 2013, our Acting Chief Scientific Officer. While we have a consulting agreement, as amended, with MW Bridges LLC, of which Randy Milby is Managing Partner, consulting and employment agreements cannot ensure our retention of the persons covered by such agreements. 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 director Richard Cohen to serve as our Interim Chief Executive Officer and Interim Chief Financial Officer. 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 Mr. Cohen as our Chief Financial Officer and one of our directors, Dr. Antony Pfaffle, as our 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 over financial reporting), lack of accuracy and timeliness of financial reporting as a result of the resignation of our former Chief Financial Officer and Chief Operating Officer.

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.

If we receive CE Mark approval for Neutrolin®, our success will depend upon the expansion of our operations to commercialize Neutrolin® and the effective management of our 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. 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 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. 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); and
- 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).

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 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, 2013, 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 believe we will receive the Appeals Board final written decision sometime in the first half of 2013. We intend to continue to vigorously defend the patent. 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 Our Dependence on Third Parties

If we are not able to develop 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 pharmaceutical products; for other products we may also rely on such marketing collaborations or out-licensing or our product candidates. Specifically, for Neutrolin®, assuming we receive applicable regulatory approval, we plan to enter into distribution agreements with one or more third parties for the sale of Neutrolin® in various European 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, will be successful, or that we will be successful in gaining market acceptance for our products. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third-parties.

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

no assurance that we will be able to establish internal marketing, sales, or distribution capabilities. If we are unable to, or choose not to establish these capabilities, or if the capabilities we establish are not sufficient to meet our needs, we will be required to establish collaborative marketing, sales, or distribution relationships with third parties, which we might not be able to do on acceptable terms or at all.

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

Completion of our clinical trials and commercialization of 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 qualities 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, 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

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 27, 2013, 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 CE Mark approval 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 February 28, 2013, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

- 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 and 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;
- 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 2,135,630 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 $1.26 per share;
- outstanding Senior Convertible Notes issued in our 2012 private placement with an aggregate face value of $1,324,000, convertible into an aggregate of 3,782,857 shares of our common stock;
- warrants issued to investors in our 2012 private placement to purchase an aggregate of 3,310,000 shares of our common stock with an exercise price of $0.40 per share;
- warrants issued to the placement agent for our 2012 private placement to purchase an aggregate of 331,000 shares of our common stock with an exercise price of $0.40 per share;
- 287,324 shares of our common stock issuable upon the conversion of 287,324 shares of our Series A Non-Voting Convertible preferred stock issued on February 19, 2013; and
- 400,000 shares of our common stock issuable upon the exercise of a warrant issued on February 19, 2013.

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.

In addition, we have agreed to register the shares issuable upon the conversion of the Senior Convertible Notes and the exercise of the warrants issued in our 2012 private placement under the Securities Act of 1933, or the Securities Act. If those shares are issued, registration of those shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

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.

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

In the preparation of this Annual Report, we identified a material weakness in our internal control over financial reporting process with respect to lack of accounting expertise related to non-routine, complex accounting matters. This material weakness did not have any impact on our financial statements for the year ended December 31, 2012 but did result in a restatement of the financial statements in our September 30, 2012 Quarterly Report on Form 10-Q.

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.

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 February 28, 2013, options to purchase 2,135,630 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of $1.26 per share, were outstanding. In addition, at February 28, 2013, there were outstanding warrants to purchase an aggregate of 8,610,665 shares of our common stock at prices ranging from $0.40 to $10.66, an aggregate of 287,324 shares of Series A preferred stock convertible into an aggregate of 287,324 shares of our common stock, and convertible notes convertible into an aggregate of 3,782,857 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 options issued under our 2006 Stock Plan are exercised, or any warrants are exercised, or Series A non-voting convertible preferred shares or convertible notes 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, as was done in February 2013 when we issued shares of Series A non-voting convertible preferred stock;
- 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.

We received notice from the NYSE MKT that we fail to comply with certain of its continued listing standards, which 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. On April 20, 2012, the NYSE MKT notified us that we were not in compliance with certain listing standards relating to our financial condition and we had to submit a plan to regain compliance with the listing standards by August 22, 2012, which we submitted on May 17, 2012. On June 27, 2012, the NYSE MKT notified us that it had accepted our plan to regain compliance with the continued listing standards of NYSE MKT by August 22, 2012. On August 20, 2012, we requested an extension of the plan period. On September 21, 2012, NYSE MKT notified us that it was granting us an extension until January 31, 2013 to regain compliance with the continued listing standards of the NYSE MKT. On February 1, 2013, the NYSE MKT notified us that it was granting us an extension until April 15, 2013 to regain compliance with the continued listing standards of the NYSE MKT. The NYSE MKT determined that in accordance with Section 109 of the Company Guide, we made reasonable demonstration of our ability to regain compliance with Section 1003(a)(iv) of the Company Guide by the end of the extended plan period. We will be subject to periodic review by the NYSE MKT during the extended plan period. Although we believe that, to date, we are making progress with the plan and that we will be in compliance with the continued listing standards, unless we can raise capital through various potential sources, such as equity, debt financing, strategic relationships, out-licensing or distribution arrangements of our products, we may receive further notice from the NYSE MKT informing us that we are not in compliance with the listing standards. If we are not in compliance with the listing standards at the end of the extended plan period, or if we do not make progress consistent with the plan during the extended plan period, the NYSE MKT staff may initiate delisting proceedings. We may appeal a staff determination to initiate delisting proceedings in accordance with Section 1010 and Part 12 of the NYSE MKT Company Guide.

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 is low, 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 is low, 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 regulation 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 the subscription agreements executed with the investors in our 2012 convertible note private placement, we agreed not to declare or pay any dividends or make any distributions on any of our shares or other equity securities as long as any of the convertible notes remain unpaid or unconverted and 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 $187,000 as of December 31, 2012.

Item 3. Legal Proceedings

On April 19, 2012, CorMedix was served with a lawsuit by the Superior Court of New Jersey regarding non-payment of services to Xerimis, a vendor of the Company. The Company settled the outstanding balance in May 2012 in the amount of $80,986.93.

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, 2013, 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 believe we will receive the Appeals Board final written decision sometime in the first half of 2013. We intend to continue to vigorously defend the patent. 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

From March 30, 2010 to May 13, 2010, the units issued in connection with the IPO were traded on NYSE MKT under the symbol “CRMD.U”, each unit consisting of two shares of our common stock and a warrant to purchase one share of our common stock at an exercise price of $3.4375. These units separated and ceased to be traded independently on May 13, 2010, on which date the common stock and the warrants comprising the units commenced trading on NYSE MKT under the symbols “CRMD” and “CRMD.WS”, respectively. Based upon information furnished by our transfer agent, at March 25, 2013, we had approximately 94 holders of record of our common stock. 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 2012	High	Low
First Quarter	$0.62	$0.24
Second Quarter	$0.50	$0.15
Third Quarter	$0.35	$0.16
Fourth Quarter	$1.25	$0.24

Fiscal Year 2011	High	Low
First Quarter	$2.50	$1.44
Second Quarter	$2.04	$1.33
Third Quarter	$1.50	$0.82
Fourth Quarter	$0.90	$0.21

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 the subscription agreements executed with the investors in our 2012 convertible note private placement, we agreed not to declare or pay any dividends or make any distributions on any of our shares or other equity securities as long as any of the convertible notes remain unpaid or unconverted and outstanding; a portion of those notes is due on September 20, 2013 and the remaining portion is due on November 13, 2013. 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, 2012 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]	2,135,630	$ 1.26	164,370
Equity compensation plans not approved by security holders [2]	371,931	1.30	—
Total	2,507,561	$ 1.27	164,370

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

(2) Consists of 17,869 shares of common stock issuable pursuant to a warrant issued to various consultants in 2008 (with an exercise price of $10.66 per share) which expired on January 30, 2013, 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 331,000 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 pharmaceutical and medical device company that seeks to in-license, develop and commercialize therapeutic products for the treatment of cardiac and renal dysfunction, specifically in the dialysis and non-dialysis areas.

We have the worldwide rights to develop and commercialize our product candidates CRMD003 (Neutrolin®) and CRMD004. CRMD003 is a liquid designed to prevent central venous Catheter Related Bloodstream infections, or CRBI, and maintenance of catheter patency in central venous catheters (initially in hemodialysis catheters).

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. Since our inception, we have had no revenue from product sales. Our operations have been primarily limited to organizing and staffing, licensing product candidates, developing clinical trials for our product candidates, establishing manufacturing for our product candidates and maintaining and improving our patent portfolio. We have generated significant losses since our inception and we expect to continue to generate losses as we progress towards the commercialization of our lead product candidate CRMD003 (Neutrolin®). As of December 31, 2012, we had a deficit accumulated during the development stage of $46,373,234. Because we do not generate revenue from any of our product candidates, our losses will continue as we continue development of our product candidates. As a result, our operating losses are likely to be substantial until at least the planned launching of Neutrolin® in Europe and thereafter, if not successful. We are unable to predict the extent of any future losses or when we will become profitable, if at all. These matters raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On February 19, 2013, we sold 761,429 shares of our newly created 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. An aggregate of 474,105 shares of this Series A non-voting convertible preferred stock was converted to 474,105 shares of our

common stock on February 22, 2013.

During the year ended December 31, 2012, we completed two series of private placements for an aggregate 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 3,310,000 shares of common stock, to certain accredited investors pursuant to a Subscription Agreement dated September 20, 2012 and November 13, 2012 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 these private placements. The Notes issued have maturity dates of September 20, 2013 as to the 850 Units and November 13, 2013 as to the 474 Units. We 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. The placement agent warrants have the same terms as those issued to the investors. *(See Notes to the Financial Statements – Note 6.)*

In March 2010, we completed our IPO, whereby we sold 1,925,000 units, each unit consisting of two shares of our common stock and a warrant to purchase one share of common stock, at $6.50 per unit resulting in gross proceeds of $12,512,500 and net proceeds to us of $10,457,270 after deducting underwriting discounts and commissions and offering expenses payable by us. All of our convertible notes and accrued interest thereon and all of our outstanding shares of Non-Voting Subordinated Class A Common Stock automatically converted into units or common stock upon the completion of the IPO. We effected a 1 for 7.836 reverse stock split of our common stock on February 24, 2010 in connection with the IPO. All shares and per share amounts, except as noted, have been retroactively adjusted to give effect to the reverse stock split.

We believe that as a result of our decision in late 2011 to focus the majority of our resources, including our research and development efforts primarily on CE Mark approval and the commercialization of Neutrolin® (CRMD003) in Europe, the net proceeds from the IPO, the net proceeds from our 2012 convertible note private placement financing and the gross proceeds from the private placement of our Series A non-voting convertible preferred stock in February 2013, our existing cash will be sufficient to fund our projected operating requirements into the second quarter of 2013. We intend to raise additional funds through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of our products, however, we can provide no assurances that such financing will be available on acceptable terms, or at all.

Financial Operations Overview

Revenue

We have not generated any revenue since our inception. As of December 31, 2012, we have funded our operations primarily through debt 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, 2012, we incurred $23,343,305 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 CRMD003 and our earlier-stage R&D projects.

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, 2012
	2012	2011	
CRMD001	6 %	32 %	49 %
CRMD002	0 %	0 %	0 %
CRMD003	88 %	66 %	48 %
CRMD004	6 %	2 %	3 %

The process of conducting pre-clinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties 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 this 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. We also have successfully completed our stage 2 audit with TÜV SÜD which resulted in our receipt of the ISO 13485:2003 certification from TÜV SÜD on October 10, 2012. 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.

We anticipate receiving a CE Mark approval by the end of the second quarter of 2013. If we obtain CE Mark approval in Europe, we intend to launch Neutrolin® for the prevention of Catheter Related Bloodstream Infections, or CRBI and maintenance of catheter patency in hemodialysis patients in Europe during 2013. However, we cannot be assured of CE Mark approval of Neutrolin® or the planned commercialization timeline. We are currently exploring the various methods of launching Neutrolin® in Europe, whether through a distributorship or partnership arrangement, or otherwise, and plan to initially launch in Germany. Assuming the receipt of a CE Mark and the launch of Neutrolin®, we intend to meet with the FDA to determine the pathway for U.S. approval of Neutrolin®, which we expect to entail a Phase 3 trial.

General and Administrative Expense

General and Administrative, or G&A, expense consists primarily of salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, finance and accounting functions. Other G&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 G&A expenses will increase if we add personnel and as a result of the reporting obligations applicable to public companies. From our inception on July 28, 2006 through December 31, 2012, we incurred $12,776,034 of G&A expense.

Other Income

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, 2012, we received $420,987 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, 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, 2012, we received $126,307 of interest income through interest bearing savings accounts and incurred $11,575,964 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, 2012 and December 31, 2011

R&D Expense. R&D expense was $1,187,631 for the year ended December 31, 2012, a decrease of $2,910,594, from $4,098,225 for the year ended December 31, 2011. The decrease was attributable to our strategic change of direction during September 2011, which is to focus primarily on CE Mark approval for Neutrolin® in Europe. During the fourth quarter of 2011, we also discontinued the development of CRMD001, deferiprone and returned the product candidate to the licensor in December 2011. Our strategic change of direction also resulted in lower clinical research organization, manufacturing and regulatory expenses related to the development of CRMD003 during the second quarter of 2012 and lower personnel costs as a result of our Chief Medical Officer ("CMO") transitioning to a part-time status and a 50% reduction of salary effective March 2012.

G&A Expense. G&A expense was $1,857,080 for the year ended December 31, 2012, a decrease of $1,291,679 from $3,148,759 for the year ended December 31, 2011. The decrease was primarily attributable to lower compensation and stock-based compensation expense as a result of the separation of our former President and Chief Executive Officer in September 2011 and the resignation of our Chief Financial Officer/Chief Operating Officer in April 2012 and lower expenses related to investor relations.

Other Income. Other income during 2011 in the amount of $29,819 represented a research and development funding reimbursement from the State of New York research and development tax refund program. No other income was recognized for the year ended December 31, 2012.

Interest Income. Interest income was $1,965 for the year ended December 31, 2012, a decrease of $10,072, from $12,037 for the year ended December 31, 2011. The decrease was attributable to having lower interest-bearing cash balances during the year ended December 31, 2012 compared to the year ended December 31, 2011.

Interest Expense. Interest expense was $382,936 for the year ended December 31, 2012. No interest expense was recognized for the year ended December 31, 2011. The interest expense charges consisted primarily of a beneficial conversion feature charge of $279,052 related to the senior convertible notes and warrants we issued in September and November 2012 in the aggregate principal amount of $1,324,000, amortization of deferred financing fees of $76,632 and accrued interest of $26,938 related to the one-year 9% senior convertible notes.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant R&D expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in July 2006. Prior to the IPO, 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 series of private placements for an aggregate 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 3,310,000 shares of common stock, to certain accredited investors pursuant to a Subscription Agreement dated September 20, 2012 and November 13, 2012 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 these private placements. The Notes issued have maturity dates of September 20, 2013 as to the 850 Units and November 13, 2013 as to the 474 Units.

On February 19, 2013, we sold 761,429 shares of our newly created 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.

Net Cash Used in Operating Activities

Net cash used in operating activities was $2,276,260 for the year ended December 31, 2012. The net loss of $3,425,682 for the year ended December 31, 2012 was higher than cash used in operating activities by $1,149,422. The primary reasons for the difference are amortization of debt discount of $279,052, noncash stock-based compensation charges of $274,358 and amortization of deferred financing costs of $76,633, primarily due to the beneficial conversion feature of the convertible notes and warrants we issued, and an increase in accrued expenses of $26,646, offset by decreases in prepaid expenses and other current assets of $503,742, relating primarily to the collection of other receivables related to 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 accounts payable of $15,743. Net cash used in operating activities was $6,296,725 for the year ended December 31, 2011. The net loss of $6,711,273 for the year ended December 31, 2011 was higher than cash used in operating activities by $414,548. The primary reasons for the difference are non-cash stock-based compensation charges of $692,403, offset by decreases in accounts payable and accrued expenses of $130,783 and $139,855, respectively, relating primarily to clinical research organization costs, clinical site costs, manufacturing costs, patent fees and accrued legal fees.

Net Cash Used in Investing Activities

Net cash used in investing activities was $0 for the year ended December 31, 2012 a decrease of $1,625 for the same period last year due to a purchase of office equipment during the year ended December 31, 2011.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $1,126,397 for the year ended December 31, 2012 as compared to $0 for the same period last year. The increase was attributable to the gross proceeds from senior convertible notes of $1,324,000 offset by deferred financing costs of $197,603.

Funding Requirements

Our total cash on hand as of December 31, 2012 was $835,471, compared to $1,985,334 at December 31, 2011. Because our business does not generate positive operating cash flow, we will need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development, as well as to fund operations generally. Our continued operations will depend on whether we are able to 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, 2012, all of our financing has been through the issuance of convertible notes in September and November 2012, 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.

We do not anticipate that we will generate significant product sales revenue for 2013, if any. In the absence of additional funding, we expect our continuing operating losses to result in increases in our cash used in operations over the next several quarters.

Based on our cash resources at December 31, 2012, the private placement of our Series A non-voting convertible preferred stock in February 2013, and our current plan of expenditure on continuing development of Neutrolin®, we believe that we have sufficient capital to fund our operations into the second quarter of 2013, and will need additional financing 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. These matters raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 1,380,000 shares of common stock to our employees, non-employees and directors and officers during the year ended December 31, 2012. For the purpose of valuing options and warrants granted to our employees, directors and officers during the year ended December 31, 2012, 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, 2012, 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, 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 period ended December 31, 2012. 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

ASUs not effective until after December 31, 2012 are not expected to have a significant effect on our financial position or results 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

In the preparation of this Annual Report, we identified a material weakness in our internal control over financial reporting with respect to a lack of accounting expertise related to non-routine, complex accounting matters. This material weakness did not have any impact on our financial statements for the year ended December 31, 2012 but did result in a restatement of the financial statements in our September 30, 2012 Quarterly Report on Form 10-Q. In the first quarter of 2013, we initiated appropriate measures to remediate this weakness by forming an accounting oversight committee ("Oversight Committee"), comprised of members of our senior management, which intends to engage a third party GAAP advisor, charged with the task of discussing and reviewing all significant transactions that have financial recognition issues, either to be recorded or disclosed. The Oversight Committee will consult with outside corporate counsel, and retain a third party GAAP advisor to assist as well as advise the CFO and the Audit Committee on a timely basis, including quarter-end and year-end reviews of proposed accounting for and disclosure of significant financial transactions and changes in GAAP.

Evaluation of Disclosure Controls and Procedures

Disclosure control and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) 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, 2012 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, 2012. 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. 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, 2012.

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 year ended December 31, 2012, 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

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended (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 an initial filing on Form 3 by Randy Milby, that was due on May 24, 2012 and was filed on September 24, 2012.

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 1, 2013.

Name	Age	Position
Randy Milby	59	Chief Executive Officer
Richard M. Cohen	61	Executive Chairman, Director and Chief Financial Officer
Gary A. Gelbfish, M.D. (2), (3)	54	Director
Antony E. Pfaffle, M.D. (1), (3)	49	Director and Chief Scientific Officer
Steven Lefkowitz (1), (2)	57	Director
Matthew Duffy (1), (3),	50	Director

(1) Member of the Compensation Committee.
(2) Member of the Audit Committee.
(3) Member of the Nominating and Corporate Governance 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. Mr. Milby brings extensive commercial operational experience to the Company.

Richard M. Cohen has been a director of CorMedix since December 2009, was appointed our Chief Financial Officer effective January 1, 2013, was Executive Chairman in September 2011, our Interim Chief Executive Officer in November 2011 and Interim Chief Financial Officer in May 2012. Since 2002, Mr. Cohen has served as a Managing Director of Encore/Novation, a company that purchases and securitizes settlement assets. He also served as Chief Financial Officer of Dune Energy, an oil and gas exploration and production company, from 2003 to 2005. Since 2006, Mr. Cohen has been a member of the Board of Directors and Chairman of the Audit Committee of Helix Biomedix. From 2007 to 2012, he was a member of the Board of Directors and the Audit Committee of Rodman & Renshaw, a public investment bank. Mr. Cohen holds a C.P.A. from the State of New York, received his M.B.A. from Stanford University, and received his B.S. from the Wharton School of the University of Pennsylvania. Mr. Cohen shares with the Board his expertise in financial and investment matters and significant experience in accounting matters as a certified public accountant.

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. Mr. Duffy shares with the Board his commercial and marketing expertise with development stage biotechnology companies.

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. Dr. Gelbfish shares with the Board his in-depth knowledge of the practice of medicine and understanding of the science behind our product candidates.

Steven W. Lefkowitz has been a director of CorMedix, chairman of the Audit Committee 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 shares with the Board his financial expertise with development stage biotechnology companies. Mr. Lefkowitz received his A.B. from Dartmouth College in 1977 and his M.B.A. from Columbia University in 1985.

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. Dr. Pfaffle shares with the Board his financial expertise, knowledge of the investment community, medical science background and experience with development stage biopharmaceutical companies.

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. Lefkowitz (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. Lefkowitz qualifies as an “audit committee financial expert” as that term is defined in the rules and regulations of the SEC. The designation of Mr. Lefkowitz 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, and has established such procedures upon the effectiveness of the registration statement filed with the SEC in connection with the IPO. 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 and Mr. Lefkowitz, each of whom satisfies the independence requirements of NYSE MKT and SEC 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 have not used the services of any compensation consultant in matters affecting the compensation of named executive officers or Directors during 2012. 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, each of whom satisfies the independence requirements of NYSE Amex and SEC rules and regulations. Dr. Gelbfish serves as chairman of the Nominating and Corporate Governance Committee.

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

Code of Ethics

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

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

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, 2012 and 2011:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Richard M. Cohen[(2)]						
Executive Chairman and Interim	2012	86,250	-	39,200	-	125,450
Chief Executive Officer and	2011	22,500	-	50,900	31,500	104,900

Interim Chief Financial Officer						
Randy Milby[3]	2012	58,800	-	67,750	-	126,550
Chief Operating Officer						
Mark A. Klausner, M.D.[4]	2012	180,833	-	-	7,556	188,389
Chief Medical Officer	2011	258,333	-	453,000[11]	-	711,333
Brian Lenz [5]						
Former Chief Operating Officer and						
Chief Financial Officer, Treasurer	2012	93,750	-	71,200	17,966	182,916
and Secretary	2011	250,000	-	-	-	250,000

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

(2) Mr. Cohen has been a director of CorMedix since December 2009, was appointed Executive Chairman in September 2011, our Interim Chief Executive Officer in November 2011 and our Interim Chief Financial Officer in May 2012. As compensation for serving as a director of CorMedix in 2011, Mr. Cohen received $31,500 in director fees, which is reflected in the "All Other Compensation" column in the table above, and was granted options to purchase 30,000 shares of our common stock, which is reflected in the "Option Awards" column in the table above. Effective upon his appointment as our Interim Chief Executive Officer, Mr. Cohen no longer received Board fees and Board stock options grants from the date thereof. On December 5, 2012, we granted Mr. Cohen options to purchase 70,000 shares of our common stock under our 2006 Stock Plan, which options vest (i) 50% on the date of issuance of a CE mark approval in Europe for Neutrolin® if the approval is received on or before June 30, 2013, and (ii) 50% on December 31, 2013. Effective January 1, 2013, the Board appointed Mr. Cohen as our Chief Financial Officer.

(3) Mr. Milby became our Chief Operating Officer in May 2012, pursuant to a consulting agreement described below under "Employment Agreements and Arrangements." On May 14, 2012, we granted Mr. Milby options to purchase 50,000 shares of our common stock under our 2006 Stock Plan, which options vest on the date of issuance of a CE mark approval in Europe for Neutrolin®. On December 5, 2012, we granted Mr. Milby options to purchase 100,000 shares of our common stock under our 2006 Stock Plan, which options vest (i) 50% on the date of issuance of a CE mark approval in Europe for Neutrolin® if the approval is received on or before June 30, 2013, and (ii) 50% on December 31, 2013. Effective January 1, 2013, the Board appointed Mr. Milby our Chief Executive Officer.

(4) Dr. Klausner became our Chief Medical Officer in March 2011. On March 1, 2011, we granted Dr. Klausner options to purchase 356,000 shares of our common stock under our 2006 Stock Plan with an exercise price of $1.61 per share. On February 29, 2012, we and Dr. Klausner amended his employment agreement effective March 1, 2012 which provided for a 50% reduction in both Dr. Klausner's services to our company and his compensation. The amount reflected in the "All Other Compensation" column represents life, long-term and short-term disability and health insurance premiums. Dr. Klausner's employment agreement expired on February 28, 2013 at which time his employment ceased.

(5) Mr. Lenz became our Chief Financial Officer and Treasurer in February 2010, our Secretary in January 2011 and our Chief Operating Officer in January 2012. On March 20, 2012, we granted Mr. Lenz options to purchase 180,000 shares of our common stock under our 2006 Stock Plan with an exercise price of $0.49 per share. The amount reflected in the "All Other Compensation" column represents life, dental, long-term and short-term disability and health insurance premiums. In April 2012, Mr. Lenz resigned all positions. In connection with his resignation, Mr. Lenz and we entered into a Memorandum of Understanding in May 2012, as described below under "Employment Agreements and Arrangements".

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 CorMedix; 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 employed by us as of December 31 and determine their compensation, based on initial recommendations from the Chief Executive Officer. Our Interim 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 2012.

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 2011 or 2012. 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 CorMedix's 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 2012 is set forth in the table above. As a result of our financial condition, the Interim Chief Executive Officer and the Compensation Committee recommended to the Board that no merit increases be granted to our named executive officers for 2012 or for 2013 due to changes in our management effective January 1, 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 was established to provide our employees, including our named executive officers, with incentives to help align employees' interests with the interests of our stockholders. 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 effective July 28, 2006. 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.

Stock Options. Our 2006 Stock Plan authorizes us to grant options to purchase shares of common stock to our employees, directors and consultants. The Compensation Committee generally oversees the administration of our 2006 Stock Plan.

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 members of management, such as Richard M. Cohen, our Executive Chairman and former Interim Chief Executive Officer, and Randy Milby, our current Chief Executive Officer.

Stock options granted have an exercise price equal to the fair market value of our common stock on the day of grant, typically vest annually over a three-year period 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, as amended.

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, such as options granted in December 2012, 50% of which vest if we receive a CE Mark for Neutrolin® by June 30, 2013.
- 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 2006 Stock Plan authorizes us to grant restricted stock. No restricted stock grants were awarded during 2011 or 2012. 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

Mark A. Klausner

On February 25, 2011, we entered into an employment agreement with Mark A. Klausner, M.D., our Chief Medical Officer. Pursuant to his employment agreement, on March 1, 2011, we granted Dr. Klausner options to purchase 356,000 shares of our common stock under our 2006 Stock Plan with an exercise price of $1.61 per share. These options vest in equal installments on each of the first three anniversaries of the grant date.

On February 29, 2012, we and Dr. Klausner agreed to amend Dr. Klausner's employment agreement in order to reduce our overhead expenditures and help achieve our strategic focus of achieving CE Mark approval for Neutrolin®. The amendment to the employment agreement, effective as of March 1, 2012, provided for a 50% reduction in both Dr. Klausner's services to our company and his compensation. Pursuant to the amendment, we paid Dr. Klausner an annual base salary equal to $155,000 and, at the sole discretion of the Board, we could pay Dr. Klausner a cash bonus each calendar year in an amount equal to up to 35% of the aggregate base salary. Dr. Klausner's employment agreement expired on February 28, 2013 at which time his employment ceased.

Brian Lenz

On March 20, 2012, the Compensation Committee awarded Brian Lenz, our former Chief Operating Officer and Chief Financial Officer, a cash bonus in the amount of $25,000. Payment of the bonus was contingent upon (i) the closing of a financing by us on or before December 31, 2012 with gross proceeds to us equal to or in excess $1.5 million, including the issuance by us of equity, debt or any combination thereof; and (ii) Mr. Lenz's continued employment. On April 30, 2012, Mr. Lenz resigned as our Chief Operating Officer and Chief Financial Officer. As such, no bonus was paid to Mr. Lenz.

On May 2, 2012, in connection with Mr. Lenz's resignation as our Chief Operating Officer, Treasurer, Secretary and Chief Financial Officer effective April 30, 2012, we and Mr. Lenz entered into a Memorandum of Understanding, or MOU, whereby Mr. Lenz provided certain transition services to us through May 31, 2012, and remained reasonably available to us from and after May 31, 2012. In exchange for providing such services to us, we agreed to compensate Mr. Lenz in the amount of $10,417, less applicable taxes and withholdings. Additionally, in consideration of Mr. Lenz's execution of the MOU and performance of the undertakings contained therein, on May 1, 2012, the Compensation Committee approved an extension of Mr. Lenz's right to exercise 45,000 of his vested stock options through and including May 31, 2014, which options had been granted to Mr. Lenz on March 20, 2012 and have an exercise price of $0.49. Mr. Lenz had 90 days from April 30, 2012 to exercise any other remaining vested options, all of which have expired. All unvested options were forfeited and cancelled on April 30, 2012.

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. As our Chief Operating Officer, in 2012 Mr. Milby rendered services to us as directed by Richard Cohen, our Executive Chairman, Interim Chief Executive Officer and Interim Chief Financial Officer. MW Bridges LLC receives 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 will vest upon CE Mark approval for Neutrolin®. 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. In addition, either party may terminate the consulting agreement, as amended, upon 30 days' prior written notice.

Effective January 1, 2013, Mr. Milby was appointed our Chief Executive Officer.

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, 2012:

	Option Awards			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Richard M. Cohen [1]	20,000	-	3.125	3/30/2020
	30,000	-	2.10	1/14/2021
	-	70,000	0.68	12/05/2022
Randy Milby [2]	-	50,000	0.29	5/14/2022
	-	100,000	0.68	12/05/2022
Brian Lenz [3]	45,000	-	0.49	5/13/2014
Mark A. Klausner, M.D. [4]	118,665	237,335	1.61	3/1/2021

(1) On December 5, 2012, we granted Mr. Cohen options to purchase 70,000 shares of our common stock under our 2006 Stock Plan, which options vest (i) 50% on the date of issuance of a CE mark approval in Europe for Neutrolin® if the approval is received on or before June 30, 2013, and (ii) 50% on December 31, 2013.

(2) On May 14, 2012, we granted Mr. Milby options to purchase 50,000 shares of our common stock under our 2006 Stock Plan, which options vest on the date of issuance of a CE mark approval in Europe for Neutrolin®. On December 5, 2012, we granted Mr. Milby options to purchase 100,000 shares of our common stock under our 2006 Stock Plan, which options vest (i) 50% on the date of issuance of a CE mark approval in Europe for Neutrolin® if the approval is received on or before June 30, 2013, and (ii) 50% on December 31, 2013.

(3) On March 20, 2012, we granted Mr. Lenz options to purchase shares of our common stock under our 2006 Stock Plan, of which options only 45,000 had vested.

(4) On March 1, 2011, we granted Dr. Klausner options to purchase 356,000 shares of our common stock under our 2006 Stock Plan, which options vest in equal installments on each of the first three anniversaries of the grant date.

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, 2012:

Name	Fees Earned ($)	**Option Awards[1] [2] [3] ($)**	Total ($)
Richard M. Cohen[4]	-	-	-
Gary A. Gelbfish, M.D.	48,500	39,200	87,700
Antony E. Pfaffle, M.D.	48,500	146,900	195,400
Steven Lefkowitz	56,083	90,900	146,983
Matthew P. Duffy	30,667	76,900	107,567
Timothy M. Hofer[5]	46,083	24,596	70,679

(1) On January 10, 2012, each of our non-executive directors was granted an option to purchase 30,000 shares of our common stock.

(2) The amounts included in this column are the dollar amounts representing the full grant date fair value and, in the case of Mr. Hofer, the incremental fair value of modifications to his outstanding options in November 2012, 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.

(3) As of December 31, 2012, the number of shares underlying options held by each non-employee director was as follows: 150,000 shares for Dr. Gelbfish; 330,000 shares for Dr. Pfaffle; 210,000 shares for Mr. Lefkowitz; 185,000 shares for Mr. Duffy; and 80,000 shares for Mr. Hofer.

(4) 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.

(5) Mr. Hofer's term as a director ended on November 30, 2012.

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.

As an equity incentive, upon the consummation of our initial public offering in March 2010, we granted to each of our non-employee directors an option to purchase 20,000 shares of our common stock under our 2006 Stock Plan with an exercise price of $3.125 per share. These options vest in equal installments on each of the grant date and the first two anniversaries of the grant date.

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 February 28, 2013:

- each person, or group of affiliated persons, known to us to beneficially own 5% or more of our outstanding common stock;
- each of our directors and named executive officers; and
- all of our directors and executive officers as a group.

For purposes of the table below, we treat shares of our common stock subject to options or warrants that are currently exercisable or exercisable within 60 days after February 28, 2013 to be outstanding and to be beneficially owned by the person holding the options or warrants for the purpose of computing the percentage ownership of the person, but we do not treat the shares as outstanding for the purpose of computing the percentage ownership of any other stockholder. Except as otherwise set forth below, the address of each of the persons listed below is c/o CorMedix Inc., 745 Rt. 202-206, Suite 303, Bridgewater, NJ 08807.

Name and Address of Beneficial Owner	**Common Stock Beneficially Owned** [1]	
	Shares	%
5% or Greater Stockholders:		
PharmaBio Development Inc. [2]	1,173,344	9.6
Elliott Associates, L.P. [3]	3,315,017	23.0
Lindsay A. Rosenwald, M.D. [4]	845,011	6.9
Directors and Named Executive Officers:		
Randy Milby [5]	367,857	3.0
Richard M. Cohen [6]	85,000	*
Matthew P. Duffy [7]	180,723	1.5
Gary A. Gelbfish, M.D. [8]	982,954	7.8
Steve Lefkowitz [9]	477,665	3.9
Antony E. Pfaffle, M.D. [10]	221,850	1.8
All executive officers and directors as a group (6 persons) [11]	2,316,049	16.7

* Represents holdings of less than 1% of shares outstanding.

(1) Based upon 11,882,379 shares of our common stock outstanding on February 28, 2013 and, with respect to each individual holder, rights to acquire our common stock exercisable within 60 days of February 28, 2013.

(2) Includes (i) 778,563 shares of our common stock and (ii) 394,781 shares of our common stock issuable upon exercise of warrants. The business address of PharmaBio Development Inc. is 4208 Six Forks Road, Suite 920, Raleigh, North Carolina 27609. Based solely on information contained in a Schedule 13G and Form 4 filed with the SEC on March 23, 2011 and April 13, 2012, respectively by PharmaBio Development Inc.

(3) Includes (i) 781,440 shares of our common stock held by Manchester Securities Corp. (“Manchester”), a wholly-owned subsidiary of Elliott Associates, L.P. (“Elliott Associates”), (ii) 1,142,857 shares of our common stock issuable upon conversion of senior convertible notes, held by Manchester, and (iii) 1,390,720 shares of our common stock issuable upon exercise of warrants held by Manchester. The business address of Elliott Associates is 712 Fifth Avenue, 36th 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 the Company.

(4) Includes (i) 82,257 shares of our common stock held directly by Dr. Rosenwald, (ii) 228,400 shares of our common stock issuable upon exercise of warrants held directly by Dr. Rosenwald, (iii) 142,857 shares of our common stock

issuable upon conversion of senior convertible notes, held directly by Dr. Rosenwald, (iv) 60,998 shares of our common stock held by PBS, of which Dr. Rosenwald is sole member, and (v) 30,499 shares of our common stock issuable upon exercise of warrants held by PBS. The business address of Dr. Rosenwald is c/o Paramount BioSciences, LLC, 787 Seventh Avenue, 48th Floor, New York, New York 10036. Based solely on information contained in a Schedule 13G filed with the SEC on December 9, 2010 by Dr. Rosenwald and other information known to the Company.

(5) Consists of (i) 100,000 shares of our common stock issuable upon exercise of stock options, (ii) 142,857 shares of our common stock issuable upon conversion of senior convertible notes, held by MW Bridges LLC, of which Mr. Milby is Managing Partner, and (iii) 125,000 shares of our common stock issuable upon exercise of warrants held by MW Bridges LLC.

(6) Consists of 85,000 shares of our common stock issuable upon exercise of stock options.

(7) Consists of (i) 9,768 shares of our common stock, (ii) 112,500 shares of our common stock issuable upon exercise of stock options (iii) 29,884 shares of our common stock issuable upon exercise of warrants and (iv) 28,571 shares of our common stock issuable upon conversion of senior convertible notes.

(8) Consists of (i) 115,000 shares of our common stock issuable upon exercise of stock options 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) 285,714 shares of our common stock issuable upon conversion of senior convertible notes, held by Dr. Gelbfish individually, (vi) 250,000 shares of our common stock issuable upon exercise of warrants held by Dr. Gelbfish individually, (vii) 38,400 shares of our common stock issuable upon exercise of warrants held jointly by Dr. Gelbfish and his wife, (viii) 28,800 shares of common stock issuable upon exercise of warrants held by Dr. Gelbfish as custodian for certain of his children, and (ix) 28,800 shares of common stock issuable upon exercise of warrants held by Landmark Foundation.

(9) Consists of (i) 55,272 shares of our common stock, (ii) 10,000 shares of our common stock held by Mr. Lefkowitz's spouse, (iii) 125,000 shares of our common stock issuable upon exercise of stock options, (iv) 100,000 shares of our common stock issuable upon conversion of senior convertible notes, held by Wade Capital Corporation Money Purchase Plan, an entity for which Mr. Lefkowitz has voting and investment control, (v) 42,857 shares of our common stock issuable upon conversion of senior convertible notes, held by Mr. Lefkowitz individually, (vi) 57,036 shares of our common stock issuable upon exercise of warrants, and (vii) 87,500 shares of our common stock issuable upon exercise of warrants held by Wade Capital Corporation Money Purchase Plan.

(10) Consists of (i) 16,850 shares of our common stock, and (ii) 205,000 shares of our common stock issuable upon exercise of stock options.

(11) Consists of (i) 328,130 shares of our common stock, (ii) 742,500 shares of our common stock issuable upon exercise of stock options, (iii) 599,999 shares of our common stock issuable upon conversion of senior convertible notes, and (iv) 645,420 shares of our common stock issuable upon exercise of warrants.

Item 13. Certain Relationships and Related Transactions and Director Independence

Director Independence

The Board has determined that each of our directors, with the exception of Mr. Cohen, qualifies as "independent" under the listing standards of NYSE Amex, federal securities laws and SEC rules with respect to members of boards of directors and members of all board committees on which he or she serves.

Related Party Transactions

Chord Advisors, LLC

During the year ended December 31, 2012, we engaged Chord Advisors, LLC, a financial services outsourcing company, to provide accounting services to us for aggregate consideration of $10,000 through March 2013. Our Chief Financial Officer, Richard M. Cohen, is also the Chairman as well as Co-Founder of Chord Advisors, LLC. Our Audit Committee has reviewed and approved this engagement.

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"). As of February 28, 2013, Dr. Rosenwald beneficially owned approximately 7.2% of our voting capital stock. In addition, as of February 28, 2013, certain trusts established for the benefit of Dr. Rosenwald's children (the "Family Trusts") beneficially owned less than 1% of our voting capital stock. In addition, as of February 28, 2013, certain other trusts established for the benefit of Dr. Rosenwald and his family beneficially owned less than 1% 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, 2012 and 2011 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 the Form S-3 filed during 2012 and services rendered in connection with tax compliance, tax advice and tax planning; and all other fees for services rendered.

	2012	2011
Audit Fees	$91,031	$91,187
Audit Related Fees	-	-
Tax Fees	19,675	12,000
All Other Fees	-	-
Totals	$110,706	$103,187

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 2012 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 No.	Description
3.1	Form of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
3.2	Form of Amended and Restated By-laws (incorporated by reference to Exhibit 3.4 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
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 (incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K, filed on February 19, 2013).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.2	

	Specimen Unit certificate (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.3	Specimen warrant certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.4	Form of warrant agreement (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.5	Common Stock Exchange and Stockholder Agreement, dated as of October 6, 2009, by and between CorMedix Inc. and Shiva Biomedical, LLC (incorporated by reference to Exhibit 4.6 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.6	Stockholder Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC (incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.11	Form of Third Bridge Warrant (incorporated by reference to Exhibit 4.18 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on January 20, 2010).
4.12	Form of 9% Senior Convertible Note due 2013 (incorporated by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q, filed on November 13, 2012).
4.13	Form of Purchaser Warrant (incorporated by reference to Exhibit 4.2 to the Quarterly Report on Form 10-Q, filed on November 13, 2012).
4.14	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Quarterly Report on Form 10-Q, filed on November 13, 2012).
4.15	Form of Subscription Agreement (incorporated by reference to Exhibit 4.4 to the Quarterly Report on Form 10-Q, filed on November 13, 2012).
4.16	Form of Registration Rights Agreement (incorporated by reference to Exhibit 4.5 to the Quarterly Report on Form 10-Q, filed on November 13, 2012).
4.17	Form of Registered Direct Warrant (incorporated by reference to Exhibit 4.13 to the Current Report on Form 8-K, filed on February 19, 2013).

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. (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.2	Amendment to Contribution Agreement, dated as of October 6, 2009, by and between Shiva Biomedical, LLC and CorMedix, Inc. (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.3	Amendment No. 2 to Contribution Agreement, dated as of February 22, 2010, by and between the Company and Shiva Biomedical, LLC (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.4	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC. (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
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 (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.6	Exclusive License and Consulting Agreement, dated as of January 30, 2008, between the Company and Hans-Dietrich Polaschegg (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).‡
10.7	Amended and Restated Consulting Agreement, dated as of January 10, 2008, between the Company and Sudhir V. Shah, M.D. (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.8	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.9	Supply Agreement, dated as of December 7, 2009, between the Company and Navinta, LLC (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).‡
10.10	Manufacture and Development Agreement, dated as of March 5, 2007, by and between the Company and Emcure Pharmaceuticals USA, Inc. (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.13	Employment Agreement, dated as of February 4, 2010, between the Company and Brian Lenz (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010.
10.14	Amendment to Employment Agreement, dated as of January 14, 2011, by and between CorMedix Inc. and Brian Lenz (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed with the SEC on January 19, 2011.
10.15	Employment Agreement, dated as of February 25, 2011, between the Company and Mark A. Klausner M.D. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on March 3, 2011.
10.16	Amended and Restated 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.17	Form of Indemnification Agreement between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.18	Separation and General Release Agreement, effective as of September 30, 2011, by and between the Company and John C. Houghton (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2011).

10.19	Amendment No. 3 to Contribution Agreement, effective as of August 31, 2011, by and between the Company and Shiva Biomedical, LLC (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2011). ‡
10.20	Amendment to Employment Agreement, dated February 29, 2012, by and between CorMedix, Inc. and Mark A. Klausner, M.D. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed on February 27, 2012).
10.21	Amendment to Employment Agreement, dated March 22, 2012, by and between CorMedix Inc. and Brian Lenz (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, filed on May 15, 2012).

10.22	Subscription Agreement by and between the Company and certain accredited investors (with attached schedule of parties thereto) (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed on November 15, 2012).
10.23	Amended and Restated Investment Banking Agreement, dated August 20, 2012, between the Company and John Carris Investments, LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed on November 15, 2012).
10.24	Agreement for Work on Pharmaceutical Advertising dated January 10, 2013 by and between MKM Co-Pharma GmbH and CorMedix Inc. (incorporated by reference to Exhibit 10.22 to the Current Report on Form 8-K, filed on January 16, 2013).
10.25	Form of Securities Purchase Agreement, dated February 18, 2013, between CorMedix Inc. and the investor named therein (incorporated by reference to Exhibit 10.23 to the Current Report on Form 8-K, filed on February 19, 2013).
10.26	Consulting Agreement, as amended December 24, 2012, between the Company and MW Bridges LLC.*
10.27	2013 Stock Incentive Plan.*
21.1	List of Subsidiaries.*
23.1	Consent of Independent Registered Public Accounting Firm.*
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following materials from CorMedix Inc. Form 10-K for the year ended December 31, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2012 and December 31, 2011, (ii) Statements of Operations for the years ended December 31, 2012 and 2011 and for the Cumulative Period from July 28, 2006 (inception) through December 31, 2012, (iii) Statements of Changes in Stockholders' Equity for the year ended December 31, 2012, (iv) Statements of Cash Flows for the years ended December 31, 2012 and 2011 and for the Cumulative Period from July 28, 2006 (inception) through December 31, 2012 and (v) Notes to the Financial Statements.**

* Filed herewith.

‡ 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 and 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 27, 2013 By: /s/ Randy Milby
Randy Milby
Chief Executive Officer

(Principal Executive 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 (Principal Executive Officer)	March 27, 2013
/s/ Richard M. Cohen Richard M. Cohen	Executive Chairman, Director and Chief Financial Officer (Principal Financial and Accounting Officer)	March 27, 2013
/s/ Matthew Duffy Matthew Duffy	Director	March 27, 2013
/s/ Gary A. Gelbfish Gary A. Gelbfish	Director	March 27, 2013
/s/ Steven W. Lefkowitz Steven W. Lefkowitz	Director	March 27, 2013
/s/ Antony E. Pfaffle Antony E. Pfaffle	Director	March 27, 2013

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 balance sheets of CorMedix Inc. (A Development Stage Company) as of December 31, 2012 and 2011, and the related statements of operations, changes in stockholders' equity (deficiency) and cash flows for the years then ended and the period from July 28, 2006 (Inception) to December 31, 2012. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits 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 financial statements referred to above present fairly, in all material respects, the financial position of CorMedix Inc. (A Development Stage Company) as of December 31, 2012 and 2011, and its results of operations and cash flows for the years then ended and the period from July 28, 2006 (Inception) to December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company incurred a net loss of $3,425,682 for the year ended December 31, 2012 and, as of that date, had a deficit accumulated during the development stage of $46,373,234. These matters, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ CohnReznick LLP

Roseland, New Jersey

March 27, 2013

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CorMedix Inc.
(A Development Stage Company)

BALANCE SHEETS

	December 31, 2012	December 31, 2011
ASSETS		
Current assets		
Cash and cash equivalents	$ 835,471	$ 1,985,334
Prepaid research and development expenses	11,221	19,888
Deferred financing costs	257,886	-
Other receivable	-	493,855
Other prepaid expenses and current assets	30,677	31,897
Total current assets	1,135,255	2,530,974
Property and equipment, net	4,668	11,689
Security deposit	13,342	13,342
TOTAL ASSETS	$ 1,153,265	$ 2,556,005
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities		
Accounts payable	$ 1,023,553	$ 1,008,493
Accrued expenses	306,983	296,512
Accrued interest, related parties	16,175	-
Senior convertible notes, net of debt discount of $647,939	16,061	-
Senior convertible notes – related parties, net of debt discount of $406,316	253,684	-
Total current liabilities	1,616,456	1,305,005
Deferred rent	12,185	14,472
TOTAL LIABILITIES	1,628,641	1,319,477
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIENCY)		
Preferred stock - $0.001 par value: 2,000,000 shares authorized in 2012, none issued and outstanding	-	-
Common stock - $0.001 par value: 80,000,000 and 40,000,000 shares authorized in 2012 and 2011, respectively; 11,408,274 shares issued and outstanding at December 31, 2012 and 2011	11,408	11,408
Deferred stock issuances	(146)	(146)
Additional paid-in capital	45,886,596	44,172,818
Deficit accumulated during the development stage	(46,373,234)	(42,947,552)
TOTAL STOCKHOLDERS' EQUITY (DEFICIENCY)	(475,376)	1,236,528
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)	$ 1,153,265	$ 2,556,005

The accompanying Notes are integral part of these financial statements.

CorMedix Inc.
(A Development Stage Company)

STATEMENTS OF OPERATIONS

	Year Ended December 31, 2012	Year Ended December 31, 2011	Cumulative Period from July 28, 2006 (Inception) Through December 31, 2012
OPERATING EXPENSES			
Research and development	$ 1,187,631	$ 4,098,225	$ 23,343,305
General and administrative	1,857,080	3,148,759	12,776,034
Total operating expenses	3,044,711	7,246,984	36,119,339
LOSS FROM OPERATIONS	(3,044,711)	(7,246,984)	(36,119,339)
OTHER INCOME (EXPENSE)			
Other income	-	29,819	420,987
Interest income	1,965	12,037	126,307
Interest expense, including amortization and write-off of deferred financing costs and debt discounts	(382,936)	-	(11,575,964)
LOSS BEFORE INCOME TAXES	(3,425,682)	(7,205,128)	(47,148,009)
State income tax benefit	-	493,855	774,775
NET LOSS	$ (3,425,682)	$ (6,711,273)	$ (46,373,234)
NET LOSS PER COMMON SHARE – BASIC AND DILUTED	$ (0.30)	$ (0.59)	
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING – BASIC AND DILUTED	11,408,274	11,408,274	

The accompanying Notes are integral part of these financial statements.

CORMEDIX INC.
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Period from July 28, 2006 (Inception) to December 31, 2012

	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,	564,246	564			1,000,000	1,000	(1,000)	8,583	(975,317)	(966,170)

2006										
Common stock issued to employees at $0.008 per share in January and March 2007	27,056	27						185		212
Common stock issued to technology finders at $0.008 per share in March 2007			193,936	$194						194
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)

CORMEDIX INC.
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Period from July 28, 2006 (Inception) to December 31, 2012

	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 Stockholde Equity (Deficiency
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2007 (carried forward)	591,302	$591	193,936	$194	1,000,000	$1,000	$(1,000)	$3,816,119	$(8,212,843)	$(4,395,93
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
								281,652		281,652

Stock-based compensation										
Net loss									(8,996,745)	(8,996,74
Balance at December 31, 2008	648,213	648	193,936	194	1,000,000	1,000	(1,125)	5,181,723	(17,209,588)	(12,027,1
Common stock issued to consultant at $32.05 per share in July 2009	639	1						20,449		20,450
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		3,164,502
Common stock issued to licensor at $32.05 per share in October 2009	28,156	28						902,316		902,344
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		1,238,265
Stock-based compensation								114,143		114,143
Net loss									(8,121,455)	(8,121,45

Balance at December 31, 2009	787,010	787	193,936	194	-	-	(27)	10,621,190	(25,331,043)	(14,708,8

CORMEDIX INC.
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Period from July 28, 2006 (Inception) to December 31, 2012

	Common Stock		Non-Voting Common Stock – Class A		Common Stock – Series B - F		Deferred Stock Issuance	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2009 (carried forward)	787,010	$787	193,936	$194			$(27)	$10,621,190	$(25,331,043)	$(14,708,899)
Common stock issued to consultant at $32.05 per share in February 2010	4,059	4						130,087		130,091
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		18,897,167
Common stock issued to	828,024	828					(119)	2,217,215		2,217,924

licensors at $3.125 per share in March 2010										
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		10,457,270
Stock-based compensation								1,167,081		1,167,081
Net loss									(10,905,236)	(10,905,236)
Balance at December 31, 2010	11,408,274	11,408	-	-	-	-	(146)	43,480,415	(36,236,279)	7,255,398
Stock-based compensation								692,403		692,403
Net loss									(6,711,273)	(6,711,273)
Balance at December 31, 2011	11,408,274	$11,408	-	-	-	-	$(146)	$44,172,818	$(42,947,552)	$1,236,528

CORMEDIX INC.
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Period from July 28, 2006 (Inception) to December 31, 2012

	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				
Balance at December 31, 2011 (carried forward)	11,408,274	$11,408	-	$ -	-	$ -	$ (146)	$44,172,818	$(42,947,552)	$1,236,528
Stock-based compensation	-	-						274,358	-	274,358
Debt discount	-	-	-	-	-	-	-	1,333,307	-	1,333,307
Warrants issued to placement agent in connection with financing	-	-	-	-	-	-	-	106,113	-	106,113
Net loss	-	-	-	-	-	-	-	-	(3,425,682)	(3,425,682)
Balance at December 31, 2012	11,408,274	$11,408	-	$ -	-	$ -	$ (146)	$45,886,596	$(46,373,234)	$(475,376)

The accompanying Notes are integral part of these financial statements.

CorMedix Inc.
(A Development Stage Company)

STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2012	Year Ended December 31, 2011	Period from July 28, 2006 (Inception) To December 31, 2012
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (3,425,682)	$ (6,711,273)	$ (46,373,234)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	274,358	692,403	2,599,238
Stock issued in connection with license agreements	-	-	6,613,718
Stock issued in connection with consulting agreement	-	-	158,262
Amortization of deferred financing costs	76,632	-	2,124,513
Amortization of debt discount	279,052	-	5,258,513
Non-cash charge for beneficial conversion feature	-	-	1,137,762
Non-cash interest expense	-	-	3,007,018
Expenses paid on behalf of the Company satisfied through the issuance of notes	-	-	51,253
Depreciation	7,022	12,246	57,042
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	503,742	(17,176)	(41,898)
Security deposits	-	-	(13,342)
Accounts payable	(15,743)	(130,783)	992,750
Accrued expenses and accrued interest	26,646	(139,855)	323,158
Deferred rent	(2,287)	(2,287)	12,185
Net cash used in operating activities	(2,276,260)	(6,296,725)	(24,093,062)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of equipment	-	(1,625)	(61,709)
Net cash used in investing activities	-	(1,625)	(61,709)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from notes payable to related parties, net	597,735	-	3,063,484
Proceeds from senior convertible notes, net	598,865	-	13,963,838
Proceeds from Galenica, Ltd. promissory note	-	-	1,000,000
Payment of deferred financing costs	(70, 203)	-	(1, 517,603)
Repayment of amounts loaned under related party notes	-	-	(1,981,574)
Proceeds from sale of equity securities, net of issuance costs	-	-	10,457,270
Proceeds from receipt of stock subscriptions and issuances of common stock	-	-	4,827

Net cash provided by financing activities	1,126,397	-	24,990,242
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,149,863)	(6,298,350)	835,471
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	1,985,334	8,283,684	-
CASH AND CASH EQUIVALENTS – END OF PERIOD	$ 835,471	$ 1,985,334	$ 835,471
Cash paid for interest	$ -	$ -	$ 18,425
Supplemental Disclosure of Non Cash Financing Activities:			
Conversion of notes payable and accrued interest to common stock	$ -	$ -	$ 18,897,167
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
Accrued deferred financing costs	$ 30,803	$ -	$ 30,803

The accompanying Notes are integral part of these financial statements.

CORMEDIX INC.

(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business:

CorMedix Inc. (f/k/a Picton Holding Company, Inc.) ("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 fulfill selected, significant medical needs in the preventive areas of catheter related infections in dialysis and non-dialysis catheters. On January 18, 2007, the Company changed its name from Picton Holding Company, Inc. to CorMedix Inc.

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 and raising funds through the issuance of debt and equity securities. The Company has not generated any revenues and, accordingly, the Company is considered to be in the development stage.

The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments through the normal course of business. For the year ended December 31, 2012 and the period from July 28, 2006 (inception) to December 31, 2012, the Company incurred net losses of $3,425,682 and $46,373,234, respectively. The Company has stockholders' deficit as of December 31, 2012 of $475,376. Management believes that the Company will continue to incur losses for the foreseeable future and will need additional equity or debt financing or will need to generate revenue from the licensing or distribution of its products or by entering into strategic alliances to be able to sustain its operations until it can achieve profitability and positive cash flows, if ever. Management believes that the Company's decision to focus the majority of the Company's resources, including the Company's research and development efforts, primarily on the CE Marking approval and commercialization of Neutrolin® (CRMD003) in Europe will result in the currently available capital resources of the

Company being sufficient to meet the Company's operating needs into the second quarter of 2013, after giving effect to the Company's gross receipt of $1,324,000 from the Company's convertible note financing during the year ended December 31, 2012 and the gross proceeds of $533,000 from the private placement of Series A non-voting convertible preferred stock in February 2013 (see Note 11). The Company intends to raise additional funds through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products, however, the Company can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. If adequate financing or a strategic relationship is not available, the Company may be required to terminate or significantly curtail or cease its operations, or enter into arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, or potential markets that the Company would not otherwise relinquish. If the Company is unable to achieve these goals, its business would be jeopardized and it may not be able to continue operations.

These matters, among others, raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On February 24, 2010, the Company effected a 1 for 7.836 reverse stock split of its common stock. All share and per-share information in these financial statements have been adjusted to give effect to the reverse stock split.

Note 2 — Summary of Significant Accounting Policies:

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.

CORMEDIX INC.

(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

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.

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.

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, 2012 and 2011 were $4,668 and $11,689, respectively, net of accumulated depreciation of $57,042, and $50,020, respectively.

Description	Estimated Useful Life
Office equipment and furniture	5 years

Leasehold improvements	5 years
Computer equipment	5 years
Computer software	3 years

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. As of 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 performance based options granted to a non-employee during the year ended December 31, 2011, the Company used the standard Monte Carlo stock price simulation method. To estimate the number of stock options expected to vest, the Company used the Monte Carlo stock price simulation method. The Monte Carlo analysis uses several random simulations along with performance vesting metrics, an initial stock price of $1.72, expected volatility of 100% for the one-year period of the vesting contingency and a one-year risk-free rate of 0.25%. The Company then used the results of the Monte Carlo analysis together with the Black-Scholes option pricing model to estimate the fair value of the options issued. 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 our awards. The Company estimated the expected term of the options granted based on anticipated exercises in future periods assuming the success of the Company's business model as currently forecasted.

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For the purpose of valuing options and warrants granted during the year ended December 31, 2012, the Company used the Black-Scholes option pricing model. The Company estimated the expected term of the stock options granted based on anticipated exercises in future periods assuming the success of its business model as currently forecasted for employees, officers and directors. The expected dividend yield of 0.0% reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The expected stock price volatility for the stock options was calculated by examining historical volatilities for publicly traded industry peers, since the Company does not have a significant trading history for its common stock. The Company will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for its common stock becomes available. The Company has experienced forfeitures of stock options issued to its former employees, officers, directors and board members. Since the stock options currently outstanding are primarily held by the Company's senior management and directors, the Company will continue to evaluate the effects of such future potential forfeitures, as they may arise, to ascertain an estimated forfeiture rate.

	2012	2011
Risk-free interest rate	0.27% – 1.6%	0.9% – 2.1%
Expected volatility	98% – 127%	109% – 115%
Expected life of options in years	5	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 earnings (loss) per common share excludes dilution and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per common share reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity. Since the Company has only incurred losses, basic and diluted loss per share are the same. The amount of potentially dilutive securities excluded from the calculation was 14,367,021 and 6,043,876 shares of common stock underlying warrants, convertible notes and options at December 31, 2012 and 2011, respectively. Additionally, there were 145,543 shares of common stock being held in escrow at December 31, 2012 and 2011, pending the achievement of certain regulatory and sales-based milestones as part of the license agreement with ND Partners LLC.

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Accounting Standards Updates:

ASUs not effective until after December 31, 2012 are not expected to have a significant effect on the Company's financial position or results of operations.

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 Chief Financial Officer, Richard M. Cohen, is also the Chairman as well as Co-Founder of Chord Advisors, LLC. The Company's Audit Committee has 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 has no state income benefit for the year ended December 31, 2012 and recorded $493,855 for the year ended December 31, 2011, 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, 2012 and $493,855 for the year ended December 31, 2011.

The Company's deferred tax assets as of December 31, 2012 and 2011 consist of the following:

	2012	2011
Net operating loss carryforwards – Federal	$9,561,000	$8,612,000
Net operating loss carryforwards – state	1,099,000	931,000
Common stock issued to licensors	2,541,000	2,541,000
Amortization of debt discount	142,000	-
Stock-based compensation	110,000	-
Other	80,000	80,000
Totals	13,533,000	12,164,000
Less valuation allowance	(13,533,000)	(12,164,000)
Deferred tax assets	$-	$-

At December 31, 2012, the Company had potentially utilizable Federal and state net operating loss tax carryforwards of approximately $28,123,000 and $18,309,000, respectively. The net operating loss tax carryforwards will start to expire in 2026 for Federal purposes and 2013 for state purposes.

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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.

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

	December 31,	
	2012	2011
Statutory Federal tax rate	(34.0)%	(34.0)%
State income tax rate (net of Federal)	(6.0)%	(6.0)%
Other permanent differences	0.0 %	3.9 %
Sale of State of New Jersey net operating losses (net of Federal)	0.0 %	(6.9)%
Effect of valuation allowance	40.0 %	36.1 %
Effective tax rate	0.0 %	(6.9)%

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, 2012 and 2011 and for the period from July 28, 2006 (inception) to December 31, 2012 was $1,369,000, $3,891,000, and $13,533,000, respectively. The tax benefit assumed the Federal statutory tax rate of 34% and a state tax rate 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 2009 to 2012 remain open.

Note 5 — Commitments and Contingencies:

Operating Lease:

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 $187,167 as of December 31, 2012, as set forth below:

Schedule of Future Minimum Lease Payments	
Years Ending December 31,	Amount
2013	$82,697
2014	83,576
2015	20,894
Total	$187,167

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Employment Agreements:

On January 14, 2011, the Company entered into an amendment to the employment agreement, effective January 1, 2011, with its Chief Financial Officer, Brian Lenz (the “Lenz Amendment”). The Lenz Amendment amended that certain Employment Agreement, dated as of February 4, 2010, by and between the Company and Mr. Lenz to (i) increase Mr. Lenz’s annual base salary to $250,000 and (ii) eliminate Mr. Lenz’s annual guaranteed bonus.

On April 27, 2012, in connection with Brian Lenz's resignation as the Company’s Chief Operating Officer and Chief Financial Officer effective April 30, 2012, the Company and Mr. Lenz entered into a Memorandum of Understanding (the "MOU") on May 2, 2012 whereby Mr. Lenz provided certain transition services to the Company through May 31, 2012, and remained reasonably available to the Company, as requested from time to time by the Company from and after May 31, 2012. In exchange for providing such services to the Company, the Company agreed to compensate Mr. Lenz in the amount of $10,417, less applicable taxes and withholdings, in accordance with the regular payroll processing of the Company. Additionally, in consideration of Mr. Lenz's execution of the MOU and performance of the undertakings contained therein, on May 1, 2012, the Compensation Committee of the Board of Directors of the Company approved an extension of Mr. Lenz's right to exercise his 45,000 vested stock options through and including May 31, 2014, in accordance with the terms of the Company's Plan. The options granted to Mr. Lenz on March 20, 2012 have an exercise price of $0.49 per share. Mr. Lenz’s unvested options were forfeited effective April 30, 2012.

On February 25, 2011, the Company entered into an employment agreement with Mark A. Klausner, M.D. to serve as the Company’s Chief Medical Officer which was amended on February 29, 2012 to provide for a 50% reduction in both Dr. Klausner’s services to the Company and his compensation. Pursuant to the amendment, the Company paid Dr. Klausner an annual base salary equal to $155,000 and, at the sole discretion of the Company’s Board of Directors, the Company could pay Dr. Klausner an additional cash bonus each calendar year during the term in an amount equal to up to 35% of the aggregate base salary. The term of the Employment Agreement commenced on March 1, 2011 and continued for two years. On February 28, 2013, Dr. Klausner’s employment agreement, as amended, was not renewed and Dr. Klausner’s employment terminated.

On March 1, 2011, in connection with the Klausner Employment Agreement, the Company issued to Dr. Klausner an option to purchase 356,000 shares of the Company’s common stock at an exercise price of $1.61 per share. Such option vested in equal installments on each of the first three anniversaries of the grant date. The stock option had an

approximate fair value of approximately $453,100 at the date of grant based on the Black-Scholes option-pricing model.

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®, in accordance with the terms of the Company's Amended and Restated 2006 Stock Incentive Plan. 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, which expired on or about August 14, 2012. 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. The terms and conditions of the Consulting Agreement remained the same.

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On November 9, 2012, the Company entered into a Consulting Agreement (the "Consulting Agreement") with Oliver Buck, pursuant to which Mr. Buck provides services and support to the Company in the field of strategic and corporate development and will specifically include direct general support to the Company's executive management team with regard to strategic planning, corporate development and implementation of mutually agreed to tasks and projects. Mr. Buck received a monthly retainer of $5,400. Any additional work performed by Mr. Buck will be pre-approved by the Company on a case-by-case basis, and Mr. Buck was compensated for such additional work at a rate of $1,800 per day. In addition, the Company granted to Mr. Buck stock options to purchase 200,000 shares of the Company's common stock in accordance with the terms of the Company's Amended and Restated 2006 Stock Incentive Plan. The Options have an exercise price of $0.44, the closing sale price of the Company's common stock, as reported on the NYSE-MKT on November 9, 2012. 50,000 shares of common stock underlying the option vested immediately upon grant with 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®. Further, the Company will reimburse Mr. Buck for all reasonable documented and necessary expenses incurred in connection with services provided pursuant to the Consulting Agreement. Such expenses must be pre-approved in writing by the Company. The Consulting Agreement will terminate on November 9, 2013, unless sooner terminated in accordance with its terms. The Consulting Agreement may be extended for additional one-year periods upon mutual written agreement by the parties. The Consulting Agreement may be terminated upon 90 days' prior written notice by either party.

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, brought an action against the Sodemann patent covering the Company's Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to the Company pursuant to the License and Assignment Agreement between the Company and ND Partners LLC. The action that was brought against the 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. The Company filed a response to the appeal of Geistlich on March 25, 2009 where the Company requested a dismissal of the appeal and to maintain the patent as

granted. As of March 27, 2013, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, the Company became aware that the Board of Appeals of the European Patent Office issued on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the Sodemann patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the Sodemann patent claims. The Company believes it will receive the Appeals Board final written decision sometime in the first half of 2013. The Company intends to continue to vigorously defend the patent. 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, 2012. The Company does not anticipate recognizing any significant losses relating to these arrangements.

Note 6 — Convertible Notes:

On September 20, 2012, the Company completed an initial closing of its private placement of 850 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 Note, 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 a Subscription Agreement dated September 20, 2012 (the "Subscription Agreement"). The Units were offered on a "reasonable efforts, all-or-none" basis as to 500 Units for a minimum amount of $500,000 and thereafter on a "reasonable efforts" basis as to the remaining 2,500 Units for a maximum amount of $3,000,000 (the "Maximum Amount"). The Company received gross proceeds of $850,000. The maturity date of the Notes issued in the initial closing is September 20, 2013.

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On November 13, 2012, the Company completed the second and final closing of the private placement, and issued an additional 474 Units for a total gross amount of $474,000. The maturity date of the Notes issued in the final closing is November 13, 2013. Together with the sale of 850 Units at the initial closing, the Company issued and sold in the private placement an aggregate total of 1,324 Units for 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, including $689,000 net proceeds previously received at the initial closing and $406,600 net proceeds received in the final closing. The Company issued to the investors Warrants to purchase an aggregate of 3,310,000 shares of its common stock. 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 bear interest at 9% per annum payable quarterly in arrears. The Company shall have 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 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 accounts for the beneficial conversion feature (“BCF”) and warrant valuation in accordance with FASB ASC 470-20, Debt with Conversion and Other Options. The Company records a BCF related to the issuance of convertible debt that has conversion features at fixed rates that are “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 recognized as non-cash interest expense and is amortized over the term of the convertible note. 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	%

Senior convertible notes consist of the following at December 31, 2012:

9% Senior convertible notes	$664,000
Debt discount/beneficial conversion feature	(647,939)
Balance	$16,061
Accrued interest	$10,763
9% Senior convertible notes, related parties	$660,000
Debt discount/beneficial conversion feature	(406,316)
Balance	$253,684
Accrued interest, related parties	$16,175

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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).

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).

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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.

Common Stock Options:

In 2006, the Company established a stock incentive plan (the “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 Plan from 925,000 to 2,300,000. Options issuable under the Plan have a maximum term of ten years, vest over a period to be determined by the Company’s Board of Directors (the “Board”), and have an exercise price at or above the fair market value on the date of

grant. At December 31, 2012, there were 164,370 stock options available for issuance under the Plan.

During the year ended December 31, 2012, the Company granted the following stock options to purchase shares of common stock under the Plan:

· An aggregate of 765,000 ten-year stock options was granted to various directors and officers of the Company 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 will vest as to 50% on the date of the issuance of the CE Mark approval in Europe for the Company's Neutrolin® product candidate, if the CE Mark approval is obtained on or before March 31, 2013, and 50% will vest on December 31, 2013. The Company believes that it is not probable that the objective will be achieved by the end of March 2013. Subsequently, in March 2013, the vesting of the 50% performance options was amended to vest on the date of issuance of the CE Mark if issued on or before June 30, 2013 as opposed to March 31, 2013. At December 31, 2012, the Company did not record any expense related to the 50% performance options and is expensing the vesting of the remaining 50% options through December 31, 2013. The Company expects that by June 30, 2013, it is probable that such objective will be achieved and will record the expense from January 1, 2013 through June 30, 2013. There will be accounting implications during the first quarter of 2013 as a result of this modification.

· 25,000 ten-year stock options were granted to a consultant of the Company 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 will vest as to 50% on the date of the issuance of the CE Mark approval in Europe for the Company's Neutrolin® product candidate, if the CE Mark approval is obtained on or before March 31, 2013, and 50% will vest on December 31, 2013. The Company believes that it is not probable that the objective will be achieved by the end of March 2013. Subsequently, in March 2013, the vesting schedule of the 50% performance options was amended to vest on the date of issuance of the CE Mark if issued on or before June 30, 2013 as opposed to March 31, 2013. Since such objective was not achieved as of December 31, 2012, no expense related to the 50% performance options was recorded at December 31, 2012. The Company is expensing the vesting of the remaining 50% options through December 31, 2013.

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· 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®. For the year ended December 31, 2012, the Company recorded the expense related to the 50,000 stock options that vested immediately. For the remaining 150,000 stock options, no expense was recorded for the year ended December 31, 2012 since such milestones were not achieved at 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. Since such objective was not achieved as of December 31, 2012, no expense related to this grant was recorded by the Company for the year ended December 31, 2012.

· 50,000 ten-year stock options were awarded to a consultant of the Company 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. This consultant met the classification of an employee but the Company expects that it is not probable that such objective will be achieved by March 2013. Subsequently, in March 2013, the Company amended the timeline of the CE Mark that it will be issued on or before June 30, 2013 as opposed to March 31, 2013. The Company expects that it is probable that such objective will be achieved by June 30, 2013. Therefore, the Company did not expense the vesting of these options at December 31, 2012 and will record the expense from January 1, 2013 through June 30, 2013.

· 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.

During the year ended December 31, 2011, the Company granted options to purchase 886,000 shares of common stock under the Plan to various employees, officers, directors and a consultant ranging from $1.10 to $2.10 per share

exercise price. Each option granted to employees during the year ended December 31, 2011 has a ten-year term and vests equally over a three-year period.

The Company recorded $274,358, $692,403 and $2,599,238 of stock-based compensation expense during the years ended December 31, 2012 and 2011 and the period from July 28, 2006 (inception) to December 31, 2012, 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, 2012		Year Ended December 31, 2011	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	1,236,342	$ 2.47	1,662,827	$ 3.15
Granted	1,380,000	$ 0.56	886,000	$ 1.67
Cancelled	(217,662)	$ 3.13	-	$ -
Forfeited	(263,050)	$ 1.72	(1,312,485)	$ 2.79
Outstanding at end of year	2,135,630	$ 1.26	1,236,342	$ 2.47
Outstanding at end of year expected to vest	961,034	$ 1.26	1,236,342	$ 2.47
Options exercisable	758,297	$ 2.16	476,014	$ 3.02
Weighted-average fair value of options granted during the year		$ 0.46		$ 1.33

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The weighted average remaining contractual life of stock options outstanding at December 31, 2012 is 7.4 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, 2012 for those options that have an exercise price below the quoted closing price. As of December 31, 2012, the aggregate intrinsic value of all stock options outstanding is $201,950.

The Company has experienced forfeitures of stock options issued to its former officers, board members and employees. As a result of such forfeitures during 2011 and 2012, the Company has established a forfeiture rate of 55% for stock option expense for the year ended December 31, 2012. The Company will continue to evaluate the estimated forfeiture rate derived from previous forfeitures of employees, officers and directors and may adjust such forfeiture rate accordingly. As of December 31, 2012, the total compensation expense related to non-vested options not yet recognized totaled $702,880. The weighted-average vesting period over which the total compensation expense related to non-vested options not yet recognized at December 31, 2012 was approximately 0.6 years.

Warrants

The following table is the summary of warrants outstanding at December 31, 2012:

	Number of Warrants	Exercise Price	Expiration Date
Issued to various consultants	17,869	$10.66	1/30/2013
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	4,263,569	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
	212,500	0.40	9/20/2017

Issued to placement agent in connection with September 20, 2012 private placement of convertible notes			
Issued in connection with November 13, 2012 private placement of convertible notes	1,185,000	0.40	11/13/2017
Issued to placement agent in connection with November 13, 2012 private placement of convertible notes	118,500	0.40	11/13/2017
Total warrants outstanding at December 31, 2012	8,448,534		

Note 8 — Fair Value Measurements:

The fair value of the Company’s cash and cash equivalents, convertible notes and accounts payable at December 31, 2012 and 2011 are estimated to approximate their carrying values due to the relative liquidity and short term nature of these instruments.

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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, is $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.

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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, 2011, no milestone payments have been earned by or paid to NDP.

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, 2012, the Company expensed $2,515,782 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 $90,000. 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, 2012 and 2011 and the period from July 28, 2006 (Inception) to December 31, 2012, the Company expensed approximately $90,000, $93,000 and $561,000, 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.

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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. For the years ended December 31, 2012 and 2011 and from July 28, 2006 (inception) through December 31, 2012, the Company has recorded $11,370, $26,651 and $44,390, respectively, of required contributions in accordance to the Safe Harbor provision of the 401(k) Plan.

Note 11 — Subsequent Events:

On January 9, 2013, the Company filed a registration statement with the SEC to register the resale of the shares of common stock issuable upon the conversion of the Notes and the exercise of the Warrants, which filing was within 60 days after the final closing, as required. Also, the Company agreed to use its commercially reasonable efforts to have the registration statement declared effective within 120 days after the date of the final closing, which is March 13, 2013. Because the registration statement was not declared effective by March 13, 2013, the Company is obligated to pay as partial liquidated damages an aggregate amount equal to 1.0% per month of $875,000 (the aggregate purchase price of the notes for which the underlying shares are being registered), or $8,750 per month (prorated if less than a month) until the registration statement is declared effective, but these payments may not exceed 5% of the aggregate principal amount of the notes outstanding, or $43,750 in the aggregate.

On February 19, 2013, the Company sold to an existing institutional investor, 761,429 shares of its newly created 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 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 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. In the event of the Company's liquidation, dissolution, or winding up, holders of the Series A Stock will receive a payment equal to $0.001 per share of Series A Stock before any proceeds are distributed to the holders of common stock. Shares of the Series A Stock will not be entitled to receive any dividends, unless and until specifically

declared by the Company's board of directors, and will rank:

- senior to all common stock;
- senior to any class or series of capital stock hereafter created specifically by its terms junior to the Series A Stock;
- on parity with our Series A Preferred Stock and any class or series of capital stock hereafter created specifically ranking by its terms on parity with the Series A Stock; and
- junior to any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A Stock;
- in each case, as to distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

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. In a separate transaction, on February 19, 2013, the Company repurchased from the same institutional investor outstanding warrants to purchase an aggregate of 220,000 shares of the Company's common stock at a purchase price of $0.15 per share underlying the warrant. The warrants were issued in the Company's initial public offering and have an exercise price of $3.4375. The repurchased warrants were cancelled.

On February 22, 2013, an aggregate of 474,105 shares of the Series A non-voting convertible preferred stock was converted into 474,105 shares of common stock.

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On March 5, 2013, the Company was informed by TÜV SÜD, the European notified body managing the CE Mark application for the Company's product candidate Neutrolin®, that the Medicinal Evaluation Board of the Netherlands, or MEB, gave the Company a positive response on the clinical aspect of our application. The MEB 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. The Company is now working on the final packaging for Neutrolin® with internationally recognized consultants and a leading packaging systems company to meet TÜV-SÜD requirements. As a result, the Company anticipates final approval for the CE Mark certification for Neutrolin® during the second quarter in 2013. Additionally, to lead the commercialization of Neutrolin® in the European Union, the Company formed a European subsidiary, CorMedix Europe GmbH.

On March 6, 2013, the Company's board of directors approved an amendment to the vesting schedule of the options granted on December 5, 2012. Given the anticipated final approval for the CE Mark certification for Neutrolin® during the first half of 2013, such options will now vest as to 50% on the date of issuance of the CE Mark certification for Neutrolin® in Europe, if the CE Mark approval is obtained on or before June 30, 2013 (as opposed to March 31, 2013 as previously provided by our Board), and 50% on December 31, 2013.

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. Also on March 20, 2013, the Company granted non-statutory stock options covering an aggregate of 1,400,000 shares of the Company's common stock to all consultants and directors. The consultant options vest upon specified performance milestones, with vesting over one to three years. The director options vest over two years, but do not have performance milestones. The 2013 Plan and the options granted under it are subject to the approval of the Company's stockholders.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Form of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
3.2	Form of Amended and Restated By-laws (incorporated by reference to Exhibit 3.4 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
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 (incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K, filed on February 19, 2013).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.2	Specimen Unit certificate (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.3	Specimen warrant certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.4	Form of warrant agreement (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.5	Common Stock Exchange and Stockholder Agreement, dated as of October 6, 2009, by and between CorMedix Inc. and Shiva Biomedical, LLC (incorporated by reference to Exhibit 4.6 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.6	Stockholder Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC (incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.11	Form of Third Bridge Warrant (incorporated by reference to Exhibit 4.18 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on January 20, 2010).
4.12	Form of 9% Senior Convertible Note due 2013 (incorporated by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q, filed on November 13, 2012).
4.13	Form of Purchaser Warrant (incorporated by reference to Exhibit 4.2 to the Quarterly Report on Form 10-Q, filed on November 13, 2012).
4.14	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Quarterly Report on Form 10-Q, filed on November 13, 2012).
4.15	Form of Subscription Agreement (incorporated by reference to Exhibit 4.4 to the Quarterly Report on Form 10-Q, filed on November 13, 2012).
4.16	Form of Registration Rights Agreement (incorporated by reference to Exhibit 4.5 to the Quarterly Report on Form 10-Q, filed on November 13, 2012).
4.17	Form of Registered Direct Warrant (incorporated by reference to Exhibit 4.13 to the Current Report on Form 8-K, filed on February 19, 2013).
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. (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.2	

	Amendment to Contribution Agreement, dated as of October 6, 2009, by and between Shiva Biomedical, LLC and CorMedix, Inc. (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.3	Amendment No. 2 to Contribution Agreement, dated as of February 22, 2010, by and between the Company and Shiva Biomedical, LLC (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.4	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC. (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡

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 (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.6	Exclusive License and Consulting Agreement, dated as of January 30, 2008, between the Company and Hans-Dietrich Polaschegg (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).‡
10.7	Amended and Restated Consulting Agreement, dated as of January 10, 2008, between the Company and Sudhir V. Shah, M.D. (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.8	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.9	Supply Agreement, dated as of December 7, 2009, between the Company and Navinta, LLC (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).‡
10.10	Manufacture and Development Agreement, dated as of March 5, 2007, by and between the Company and Emcure Pharmaceuticals USA, Inc. (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.13	Employment Agreement, dated as of February 4, 2010, between the Company and Brian Lenz (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.14	Amendment to Employment Agreement, dated as of January 14, 2011, by and between CorMedix Inc. and Brian Lenz (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed with the SEC on January 19, 2011).
10.15	Employment Agreement, dated as of February 25, 2011, between the Company and Mark Klausner, M.D. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on March 3, 2011).
10.16	Amended and Restated 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.17	Form of Indemnification Agreement between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.18	Separation and General Release Agreement, effective as of September 30, 2011, by and between the Company and John C. Houghton (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2011).
10.19	Amendment No. 3 to Contribution Agreement, effective as of August 31, 2011, by and between the Company and Shiva Biomedical , LLC (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2011). ‡
10.20	Amendment to Employment Agreement, dated February 29, 2012, by and between CorMedix, Inc. and Mark A. Klausner, M.D. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed on February 27, 2012).
10.21	Amendment to Employment Agreement, dated March 22, 2012, by and between CorMedix Inc. and Brian Lenz (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, filed on May 15, 2012).
10.22	Subscription Agreement by and between the Company and certain accredited investors (with attached schedule of parties thereto) (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed on November 15, 2012).
10.23	Amended and Restated Investment Banking Agreement, dated August 20, 2012, between the Company and John Carris Investments, LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K,

	filed on November 15, 2012).
10.24	Agreement for Work on Pharmaceutical Advertising dated January 10, 2013 by and between MKM Co-Pharma GmbH and CorMedix Inc. (incorporated by reference to Exhibit 10.22 to the Current Report on Form 8-K, filed on January 16, 2013).
10.25	Form of Securities Purchase Agreement, dated February 18, 2013, between CorMedix Inc. and the investor named therein (incorporated by reference to Exhibit 10.23 to the Current Report on Form 8-K, filed on February 19, 2013).

10.26	Consulting Agreement, as amended December 24, 2012, between the Company and MW Bridges LLC.*
10.27	2013 Stock Incentive Plan.*
21.1	List of Subsidiaries.*
23.1	Consent of Independent Registered Public Accounting Firm.*
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following materials from CorMedix Inc. Form 10-K for the year ended December 31, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2012 and December 31, 2011, (ii) Statements of Operations for the years ended December 31, 2012 and 2011 and for the Cumulative Period from July 28, 2006 (inception) through December 31, 2012, (iii) Statements of Changes in Stockholders' Equity for the year ended December 31, 2012, (iv) Statements of Cash Flows for the years ended December 31, 2012 and 2011 and for the Cumulative Period from July 28, 2006 (inception) through December 31, 2012 and (v) Notes to the Financial Statements.**

* Filed herewith.

‡ 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 and Exchange Act of 1934, as amended and otherwise are not subject to liability under those sections.