

CorMedix Inc.
Form 10-K/A
March 04, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K /A
Amendment No. 1

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	(I.R.S. Employer
Organization)	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 ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant, based upon the closing price of the registrant's common stock on the last business day of the registrant's most recently completed second fiscal quarter was approximately \$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.

Form 10-K/A

For the Year Ended December 31, 2012

EXPLANATORY NOTE

CorMedix Inc. (the “Company”) is filing this Amendment No. 1 to its Annual Report on Form 10-K for the year ended December 31, 2012, filed with the Securities and Exchange Commission on March 27, 2013 (the “Original Filing”), to correct its audited financial statements included in the Original Filing. The error was due to an inadvertent over-accrual of a royalty under a license agreement. We also have amended “Part II. Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” to reflect these adjusted amounts.

We have amended “Part I. Item 1A. Risk Factors,” and “Part II. Item 9A. Controls and Procedures” to reflect a material weakness in our internal control over financial reporting which resulted in the restatement of our financial statements included in our Form 10-K for the year ended December 31, 2012.

In addition to the corrections above, this Amendment also restates “Part II. Item 6. Exhibits” to include the consent of the Company’s independent registered public accounting firm, which is attached as Exhibit 23.1, and currently dated certifications pursuant to Section 302 and Section 906 of the Sarbanes-Oxley Act of 2002, which are attached as Exhibits 31.1, 31.2, 32.1 and 32.2 to this Amendment No. 1.

Except as set forth above, the Original Filing has not been amended, updated or otherwise modified, and does not reflect events occurring after March 27, 2013, the date of the Original Filing, or modify or update those disclosures that may have been affected by subsequent events.

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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,” “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

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 \$46.2 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trial and commercialization activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. 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 quantities of Neutrolin®. If, for any reason, we become unable to rely on our current sources for the manufacture of Neutrolin® or any other product candidates, 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 material weaknesses 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.

In the preparation of our financial statements for the year ended December 31, 2013, we identified a material weakness in our internal control over financial reporting with respect to the inadvertent over-accrual of a royalty under a license agreement which was not detected in the ordinary course of business through existing internal controls over financial reporting. This material weakness resulted in a restatement of the 2012 and 2011 financial statements in our December 31, 2012 Annual Report on Form 10-K.

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.

PART II

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 \$46,233,234. 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, 203 ,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		2011		2012	
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, 142 ,631 for the year ended December 31, 2012, a decrease of \$2, 915 ,594, from \$4, 058 ,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 \$3,380,682 for the year ended December 31, 2012 was higher than cash used in operating activities by \$1,104,422. 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 \$6,671,273 for the year ended December 31, 2011 was higher than cash used in operating activities by \$374,548. 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 \$170,783 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 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.

In the preparation of our financial statements for the year ended December 31, 2013, we identified a material weakness in our internal control over financial reporting with respect to the inadvertent over-accrual of a royalty under a license agreement which was not detected in the ordinary course of business through existing internal controls over financial reporting. This material weakness resulted in a restatement of the financial statements in our December 31, 2012 Annual Report on Form 10-K.

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 weaknesses 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.

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	

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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.**

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- * 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 4, 2014

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

March 4, 2014

By: /s/ Steven Lefkowitz
Steven Lefkowitz
Interim Chief Financial Officer
(Principal Financial Officer and Principal
Accounting Officer)

CORMEDIX INC.
(A Development Stage Company)

FINANCIAL STATEMENTS

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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.

As discussed in Note 12, the Company restated its financial statements as of December 31, 2012 and 2011 and for the years then ended and for the period from July 28, 2006 (Inception) to December 31, 2012.

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 \$3,380,682 for the year ended December 31, 2012 and, as of that date, had a deficit accumulated during the development stage of \$46,233,234. 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, except for the effects of the matter discussed in paragraph four above
and Note 12 to the financial statements which are as of March 3, 2014

CORMEDIX INC.
(A Development Stage Company)

BALANCE SHEETS

	December 31, 2012 (Restated)	December 31, 2011 (Restated)
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	\$928,553	\$913,493
Accrued expenses	261,983	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	1,476,456	1,210,005
Deferred rent	12,185	14,472
TOTAL LIABILITIES	1,488,641	1,224,477
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	(46,233,234)	(42,852,552)
TOTAL STOCKHOLDERS' EQUITY (DEFICIENCY)	(335,376)	1,331,528
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)	\$1,153,265	\$2,556,005

The accompanying Notes are integral part of these financial statements.

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CORMEDIX INC.
(A Development Stage Company)

STATEMENTS OF OPERATIONS

	Year Ended December 31, 2012 (Restated)	Year Ended December 31, 2011 (Restated)	Cumulative Period from July 28, 2006 (Inception) Through December 31, 2012 (Restated)
OPERATING EXPENSES			
Research and development	\$ 1,142,631	\$ 4,058,225	\$ 23,203,305
General and administrative	1,857,080	3,148,759	12,776,034
Total operating expenses	2,999,711	7,206,984	35,979,339
LOSS FROM OPERATIONS	(2,999,711)	(7,206,984)	(35,979,339)
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	(3,380,682)	(7,165,128)	(47,008,009)
State income tax benefit	-	493,855	774,775
NET LOSS	\$ (3,380,682)	\$ (6,671,273)	\$ (46,233,234)
NET LOSS PER COMMON SHARE – BASIC AND DILUTED			
	\$ (0.30)	\$ (0.58)	
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 (Restated)	Total Stockholders' Equity (Deficiency) (Restated)
Shares	Amount	Shares	Amount	Shares	Amount				
Common stock issued to founders at \$0.008 per share in July 2006									
510,503	\$510						\$3,490		\$4,000
Common stock issued and held in escrow to licensor at \$0.008 per share in August 2006									
				1,000,000	\$1,000	\$(1,000)			-
Common stock issued to employee at \$0.008 per share in November 2006									
53,743	54						367		421
Stock-based compensation									
							4,726		4,726
Net loss								\$(975,317)	(975,317)
Balance at December 31, 2006									
564,246	564			1,000,000	1,000	(1,000)	8,583	(975,317)	(966,170)
Common stock issued to									
27,056	27						185		212

employees at \$0.008 per share in January and March 2007											
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)

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 (Restated)	Total Stockholders' Equity (Deficiency) (Restated)
	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)	\$(4,395,939
Common stock issued to licensor at \$8.23 per share in January 2008	39,980	40						328,908		328,948
Common stock issued to licensor and held in escrow in January 2008	15,992	16					(125)	109		-
Common stock issued to consultant at \$8.23 per share in May 2008	939	1						7,720		7,721
Debt discount on senior convertible notes								747,215		747,215
Stock-based compensation								281,652		281,652
Net loss									(8,996,745)	(8,996,745

Balance at December 31, 2008	648,213	648	193,936	194	1,000,000	1,000	(1,125)	5,181,723	(17,209,588)	(12,027,148)
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