

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 (State or Other Jurisdiction of Incorporation or Organization)	20-5894890  (I.R.S. Employer Identification No.)
745 Rt. 202-206, Suite 303, Bridgewater, NJ (Address of Principal Executive Offices)	08807 (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.

PART I

Item 1A.	Risk Factors.	3
----------	---------------	---

PART II

Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations.	15
Item 9A.	Controls and Procedures.	20

PART IV

Item 15.	Exhibits and Financial Statement Schedules.	22
----------	---	----

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.