CorMedix Inc.
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Prospectus

1,705,000 Shares of Common Stock Issuable upon Exercise of Warrants

2,406 Units Underlying the Underwriter's Unit Purchase Warrant, 4,812 Shares of Common Stock Underlying the Underwriter's Units, 2,406 Warrants Underlying the Underwriter's Units, and 2,406 Shares of Common Stock Underlying the Warrants in the Underwriter's Units

This prospectus relates to the issuance of up to 1,705,000 shares of our common stock, $0.001 par value per share, issuable upon the exercise of outstanding warrants, at an exercise price of $3.4375 per share, that were issued by us on March 30, 2010, pursuant to a master warrant agreement, dated as of March 30, 2010, or the Warrant Agreement, between us and Onyx Stock Transfer, LLC (now VStock Transfer, LLC). This prospectus also relates to the issuance of the following securities to the underwriter of our initial public offering: (i) the 2,406 Units underlying the underwriter's Unit purchase warrant, (ii) the 4,812 shares of common stock underlying the underwriter's Units, (iii) the 2,406 warrants underlying the underwriter's Units, and (iv) the 2,406 shares of common stock underlying the warrants in the underwriter's Units. The Unit purchase warrant has an exercise price of $7.80 per Unit and the underlying warrants have an exercise price of $3.4375 per share, and all expire on March 24, 2015.

We are not offering any shares of our common stock for sale under this prospectus, and we will not receive any of the proceeds from the sale or other disposition of the shares of our common stock covered by this prospectus. However, we will receive the exercise price of any of the warrants exercised for cash.

Our common stock trades on the NYSE MKT under the trading symbol "CRMD." On February 11, 2015, the last reported sale price of our common stock was $3.20 per share.

You should read carefully this prospectus, including the information incorporated by reference herein, before you invest. See "Where You Can Find More Information" and "Incorporation of Documents by Reference" for more information.

Investing in our securities involves a high degree of risk. These risks are discussed in this prospectus under "Risk Factors" beginning on page 6 and in the documents incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 12, 2015.

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ABOUT THIS PROSPECTUS

This prospectus is part of a post-effective amendment to a registration statement on Form S-1 that we filed with the Securities and Exchange Commission, or the SEC. This prospectus relates to the offer and sale of up to 1,705,000 shares of our common stock issuable upon the exercise of outstanding warrants, at an exercise price of $3.4375 per share. This prospectus also relates to the issuance of the following securities to the underwriter of our initial public offering: (i) the 2,406 Units underlying the underwriter's Unit purchase warrant with an exercise price of $7.80 per Unit, (ii) the 4,812 shares of common stock underlying the underwriter's Units, (iii) the 2,406 warrants underlying the underwriter's Units with an exercise price of $3.4375 per share, and (iv) the 2,406 shares of common stock underlying the warrants in the underwriter's Units.

You should read this prospectus and the information and documents incorporated by reference carefully because these documents contain important information you should consider when making your investment decision. See "Where You Can Find More Information" and "Incorporation of Documents by Reference."

You should rely only on the information provided in this prospectus and the information and documents incorporated by reference into this prospectus. We have not authorized anyone to provide you with different information. This prospectus is not an offer to sell these securities. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front cover of this prospectus, or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

In this prospectus, unless otherwise indicated or the context otherwise requires, references to "CorMedix," "the company," "we," "us," or "our" refer to CorMedix Inc. and our subsidiary.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus or incorporated by reference into this prospectus. Because it is a summary, it might not contain all of the information that is important to you. Accordingly, you are urged to carefully review this prospectus in its entirety, including "Risk Factors" beginning on page 6 and our financial statements and related notes thereto incorporated by reference herein, as well as any prospectus supplement before making an investment decision.

Overview

We seek to in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious diseases in cardiac, renal and oncology patients. As of the date of this prospectus, we have in-licensed all of the product candidates in our pipeline.

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

Our primary product is Neutrolin for the prevention of catheter-related infections in dialysis and non-dialysis markets. Neutrolin is a liquid formulation designed to prevent central venous catheter infection as well as catheter obstruction, also referred to as maintenance of catheter patency, in central venous catheters, which we initially launched in Germany in December 2013 for use in hemodialysis catheters. There are approximately 780,000 hemodialysis patients in the United States and the European Union, or EU. We believe the patients undergoing hemodialysis using a tunneled central vein catheter will be our initial target market. We project that 91,000 patients in the European Union and 104,000 patients in the United States have these catheters in place. These patients represent nearly 30 million hemodialysis sessions per year, which we believe represents a market potential of approximately $300 - $400 million.

During the third quarter of 2011, we received a notice from the U.S. Food and Drug Administration, or FDA, that Neutrolin had been assigned to the Center for Drug Evaluation and Research, or CDER, for review as a drug rather than a device. As a result of this, and given our limited resources, we decided to change our business strategy and focus the majority of our resources on the research and development of Neutrolin, rather than CRMD004 and to seek regulatory and commercialization approval for Neutrolin in Europe through a CE Mark application rather than pursue FDA approval at that time. During the first half of 2011, we submitted our design dossier to TÜV SÜD, the European notified body managing our CE Mark application. In the fourth quarter of 2011, we successfully completed our stage 1 audit with TÜV SÜD and we successfully completed the stage 2 audit in the third quarter of 2012.

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

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

catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia and The Netherlands for such treatment.

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

In late 2013, we met with the FDA to determine the pathway for U.S. approval of Neutrolin, Based on our discussions with the FDA, we expect to conduct at least one Phase III clinical trial in hemodialysis catheters and one Phase III clinical trial in oncology/total parenteral nutrition. We have worked with the FDA to design the protocol for a planned Phase III trial in hemodialysis patients with a central venous catheter; this protocol was accepted in August 2014 and we filed an investigational new drug application, or IND, in September 2014. In October 2014, the FDA informed us that it had determined that the IND is not subject to a clinical hold, and that the Phase III clinical trial in hemodialysis patients can be initiated in the U.S. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

In January 2015, the FDA granted our request for Fast Track designation for Neutrolin and also designated Neutrolin as a Qualified Infectious Disease Product for oncology, hemodialysis and intensive care unit patients, where catheter-related blood stream infections and clotting can be life threatening.

We have entered into agreements with human4farma, a German contract sales company, and with Arabian Trade House, a Saudi Arabian company, to market and sell Neutrolin for hemodialysis and oncolytic patients in Germany and Saudi Arabia, respectively, and with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis and oncolytic patients in that country upon receipt of regulatory approval. We also have independent sales representatives in The Netherlands and Austria.

Our other product candidate is CRMD004, which is the gel formulation of Neutrolin that we may develop for a variety of indications that include but are not limited to the treatment of wounds, skin infections, the prevention of catheter exit site infections and, based on the gel's thixotropic properties which cause it to liquefy under pressure/kinetic energy, as a follow-on to our Neutrolin catheter lock solution. CRMD004 is currently in the pre-clinical stage of development.

Recent Developments

In January 2015, we issued an aggregate of 857,324 shares of our common stock upon the cashless exercise of 467,779 warrants issued in May 2013 and 750,000 warrants issued in October 2013.

In January 2015, we issued an aggregate of 125,000 shares of our common stock upon the exercise of 125,000 warrants issued in January 2014 resulting in gross proceeds of $112,500.

In January 2015, we issued an aggregate of 15,000 shares of our common stock upon the conversion of 1,500 Series C-3 preferred stock we issued in January 2014.

Corporate History and Information

We were organized as a Delaware corporation on July 28, 2006 under the name "Picton Holding Company, Inc." and we changed our corporate name to "CorMedix Inc." on January 18, 2007. Our operations to date have been primarily limited to organizing and staffing, licensing product candidates, developing clinical trials for our product candidates,

seeking regulatory approvals for Neutrolin, establishing manufacturing for our product candidates and maintaining and improving our patent portfolio and launching Neutrolin in the E.U and other foreign countries.

Our executive offices are located at 745 Route 202-206, Suite 303, Bridgewater, NJ 08807. Our telephone number is (908) 517-9500. Our website address is www.cormedix.com. Information contained in, or accessible through, our website does not constitute part of this prospectus.

The Offering

Securities offered by us	Up to 1,705,000 shares of our commons stock issuable from time to time upon exercise of the investor warrants. The exercise price of the warrants is $3.4375 per share. The warrants are currently exercisable and expire on March 24, 2015. Up to 2,406 Units upon exercise of the underwriter's Unit purchase warrant; up to 4,812 shares of common stock underlying the underwriter's Units; up to 2,406 warrants underlying the underwriter's Units; and up to 2,406 shares of common stock underlying the warrants in the underwriter's Units. The Unit purchase warrant has an exercise price of $7.80 per Unit and the underlying warrants have an exercise price of $3.4375 per share, and all are currently exercisable and expire on March 24, 2015.
Common stock to be outstanding immediately after this offering	24,173,886 shares of our common stock if the warrants are exercised in full.(1)
Use of proceeds	We may receive up to a total of approximately $5,887,957 in gross proceeds, and up to a total of approximately $5,807,975 after deducting estimated expenses of $80,000. However, as we are unable to predict the timing or amount of potential exercises of the warrants, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds are allocated to working capital. It is possible that the warrants may expire and may never be exercised.
Risk Factors	Investing in our securities involves a high degree of risk. See "Risks Factors" beginning on page 6 of this prospectus otherwise incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities.
NYSE MKT listing	Our common stock is listed on the NYSE MKT under the symbol "CRMD."

(1) The number of shares of our common stock that will be issued and outstanding immediately after this offering as shown above is based on 22,461,668 shares of common stock issued and outstanding as of December 31, 2014 and excludes the following:

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

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

967,779 shares of common stock issuable upon exercise of the warrants issued in May 2013 with an exercise price of $0.65 per share that expire on May 30, 2019 (decreased to 500,000 shares as of January 31, 2015);

warrants for 125,000 shares issued to ND Partners in April 2013 in connection with the amendment to the license and assignment

agreement with an exercise price of $1.50 per share that expire on April 11, 2018;

warrants for 2,338,569 shares of our common stock issued upon the conversion of convertible notes in connection with and as a result of our IPO with an exercise price of $3.4375 per share that expire on March 24, 2015;

warrants for 503,034 shares of our common stock issued in our 2010 initial public offering to holders of bridge warrants issued in our 2009 private placement, which warrants have an exercise price of $3.4375 per share and expire on March 31, 2015;

options to purchase an aggregate of 1,065,000 shares of our common stock issued to our officers, directors, employees and non-employee consultants under our Amended and Restated 2006 Stock Incentive Plan, or the 2006 Stock Plan, with a weighted average exercise price of $0.77 per share;

options to purchase an aggregate of 2,599,500 shares of our common stock issued to our officers, directors and non-employee consultants under our 2013 Stock Plan, with a weighted average exercise price of $1.44 per share;

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

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

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

1,500,000 shares of common stock issuable upon exercise of warrants with an exercise price of $0.90 that expire on October 22, 2019 (decreased to 750,000 shares as of January 31, 2015);

1,000,000 shares of common stock issuable upon exercise of warrants with an exercise price of $0.90 that expire on January 8, 2020;

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

1,790,000 shares of common stock issuable upon conversion of the Series C-3 Preferred Stock;

1,479,240 shares of common stock issuable upon conversion of the Series D Preferred Stock;

2,021,358 shares of common stock issuable upon conversion of the Series E Preferred Stock; and

1,036,000 shares of common stock issuable upon exercise of warrants issued in March 2014 with an exercise price of $2.50 per shares that expire on September 9, 2019.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This prospectus and the documents we have filed with the SEC that are incorporated herein by reference contain such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.

Words such as "may," "might," "should," "anticipate," "estimate," "expect," "projects," "intends," "plans," "believes" and wor of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. Forward-looking statements represent management's current judgment regarding future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to: the cost, timing and results of the planned Phase III trial for Neutrolin® in the U.S.; obtaining regulatory approvals to conduct clinical trials and to commercialize our product candidates, including marketing of Neutrolin in countries other than Europe; the risks associated with the launch of Neutrolin in new markets; our ability to enter into, execute upon and maintain collaborations with third parties for its development and marketing programs; our ability to maintain our listing on the NYSE MKT; the risks and uncertainties associated with our ability to manage our limited cash resources; the outcome of clinical trials of our product candidates and whether they demonstrate these candidates' safety and effectiveness; our dependence on our collaborations and our license relationships; achieving milestones under our collaborations; obtaining additional financing to support our research and development and clinical activities and operations; our dependence on preclinical and clinical investigators, preclinical and clinical research organizations, manufacturers, sales and marketing organizations, and consultants; protecting the intellectual property developed by or licensed to us; the unpredictability of the market acceptance of any of our products, including Neutrolin; our ability to sell any approved products and the prices we are able to realize; our ability to retain and hire necessary employees and to staff our operations appropriately; our ability to compete in our industry and innovation by our competitors; and our ability to stay abreast of and comply with new or modified laws and regulations that currently apply or become applicable to our business. Please also see the discussion of risks and uncertainties under "Risk Factors" below and contained in any supplements to this prospectus, and in our most recent annual report on Form 10-K, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus or in any document incorporated herein by reference might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this prospectus or the date of the document incorporated by reference in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

RISK FACTORS

Investing in our common stock involves risk. Prior to making a decision about investing in our common stock, you should carefully consider the specific factors discussed below, together with all of the other information contained or incorporated by reference in this prospectus.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and a history of operating losses, and expect to have an operating loss for the year ended December 31, 2014.

We were established in July 2006 and have only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in the early stages of operation. We incurred a net loss of approximately $9.1 million for the year ended December 31, 2013, and a net loss of approximately $18.2 million for the nine months ended September 30, 2014. As of September 30, 2014, we had an accumulated deficit of approximately $74.0 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trial and commercialization activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Having only launched Neutrolin in December 2013, we have no products that have generated any significant commercial revenue, do not expect to generate substantial revenues from Neutrolin until 2015 at the earliest, and might never generate significant revenues from the sale of Neutrolin or any other products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following: successfully marketing Neutrolin in Germany and other countries in which it is approved for sale; obtaining necessary regulatory approvals for Neutrolin from the other applicable European and Middle East agencies, other foreign agencies and the FDA and international regulatory agencies for any other products; successful completion of the development of our other product candidates; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur losses and negative operating cash flow in the fiscal year ended December 31, 2014, and we may never achieve or maintain profitability. Until we successfully commercialize Neutrolin or other product candidates and generate substantial earnings from those products, we expect to incur losses and may never become profitable. We also expect to continue to incur significant operating and capital expenditures as we pursue the U.S. development of Neutrolin and anticipate that our expenses will increase substantially in the foreseeable future as we continue to undertake development and commercialization of Neutrolin and our other product candidates, undertake clinical trials of our product candidates, seek regulatory approvals for product candidates, implement additional internal systems and infrastructure, and hire additional personnel.

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

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

our stockholders and may require us to relinquish valuable rights.

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

Based on our expected cash resources at September 30, 2014, we previously believed that existing cash would be sufficient to enable us to fund our projected operating requirements into the third quarter of 2015. Due to higher than anticipated costs in sales and marketing to support oncology label expansion, increased business development activities, increased legal costs to defend our intellectual property and additional research and development activities to support product registration and future commercialization initiatives, we believe that our expected cash resources as of December 31, 2014 will be sufficient to enable us to fund our projected operating requirements into the second quarter of 2015. However, we may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them if the conditions for raising capital are favorable.

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

We anticipate that our independent registered public accounting firm will express substantial doubt as to our ability to continue as a going concern and may do so again in the future.

Based on our expected cash resources at December 31, 2014, we believe that existing cash will be sufficient to enable us to fund our projected operating requirements into the second quarter of 2015. As a result, we anticipate that in their report to accompany our audited financial statements for the year ended December 31, 2014, our independent registered public accounting firm will express 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. 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 successfully commercialize Neutrolin, which is uncertain. 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.

Risks Related to the Development and Commercialization of Our Product Candidates

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

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

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

CRMD003 (Neutrolin) – IND filed with the FDA for a planned Phase III trial was accepted in October 2014 and we are seeking one or more strategic partners or other sources of capital to undertake the planned Phase III trial and to

complete the development of Neutrolin in the U.S.; and

CRMD004 - currently in the pre-clinical phase.

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

We have entered into an agreement with human4farma to market and sell Neutrolin in Germany, which launched in Germany in the fourth quarter of 2013. We also have entered into agreements with Arabian Trade House to market and sell Neutrolin in Saudi Arabia, and with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin in South Korea upon receipt of regulatory approval in that country. We also have independent sales representatives in Austria and The Netherlands. Consequently, we will be dependent on these companies and individuals for the success of sales in those countries and any other countries in which we receive regulatory approval and in which we contract with third parties for the marketing, sale and/or distribution of Neutrolina. If these companies or individuals do not perform for whatever reason, our business, prospects and results of operations will me materially adversely affected. Finding a suitable replacement organization or individual for these or any other companies or individuals with whom we might contract could be difficult, which would further harm our business, prospects and results of operations.

Successful development and commercialization of our products is uncertain.

Our development and commercialization of current and future product candidates is subject to the risks of failure and delay inherent in the development of new pharmaceutical products, including but not limited to the following:

inability to produce positive data in pre-clinical and clinical trials;

delays in product development, pre-clinical and clinical testing, or manufacturing;

unplanned expenditures in product development, clinical testing, or manufacturing;

failure to receive regulatory approvals;

emergence of superior or equivalent products;

inability to manufacture our product candidates on a commercial scale on our own, or in collaboration with third parties; and

failure to achieve market acceptance.

Because of these risks, our development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained or any approved products are not commercialized successfully, our business, financial condition, and results of operations will be materially harmed.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is uncertain.

In order to obtain FDA or foreign approval to market a new drug or device product, we must demonstrate proof of safety and effectiveness in humans. Foreign regulations and requirements are similar to those of the FDA. To meet FDA requirements, we must conduct “adequate and well-controlled” clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. The length of time may vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which we are directly conducting clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

inability to manufacture sufficient quantities of qualified materials under the FDA’s cGMP requirements for use in clinical trials;

slower than expected rates of patient recruitment;

failure to recruit a sufficient number of patients;

modification of clinical trial protocols;

changes in regulatory requirements for clinical trials;

lack of effectiveness during clinical trials;

emergence of unforeseen safety issues;

delays, suspension, or termination of clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and

government or regulatory delays or “clinical holds” requiring suspension or termination of the trials.

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

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

Clinical trials may not demonstrate statistically significant safety and effectiveness to obtain the requisite regulatory approvals for product candidates. As an example, in late 2011, we terminated development of CRMD001 due to disappointing data from our Phase 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 NDA or any Premarket Approval Application, or PMA, with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operations.

If we fail to comply with international regulatory requirements we could be subject to regulatory delays, fines or other penalties.

Regulatory requirements in foreign countries for international sales of medical devices often vary from country to country. The occurrence and related impact of the following factors would harm our business:

delays in receipt of, or failure to receive, foreign regulatory approvals or clearances;

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

The CE Mark is a mandatory conformity mark for products to be sold in the European Economic Area. Currently, 28 countries in Europe require products to bear CE Marking. To market in Europe, a product must first obtain the certifications necessary to affix the CE Mark. The CE Mark is an international symbol of adherence to the Medical Device Directives and the manufacturer's declaration that the product complies with essential requirements. Compliance with these requirements is ascertained within a certified Quality Management System (QMS) pursuant to ISO 13485. In order to obtain and to maintain a CE Mark, a product must be in compliance with the applicable quality assurance provisions of the aforementioned ISO and obtain certification of its quality assurance systems by a recognized European Union notified body. We received CE Mark approval for Neutrolin on July 5, 2013. However, certain individual countries within the European Union require further approval by their national regulatory agencies. Failure to receive or maintain these other requisite approvals could prohibit us from marketing and selling Neutrolin in the entire European Economic Area or elsewhere.

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

While we have received the CE Mark approval for Neutrolin in Europe, certain individual countries within the European Union require further approval by their national regulatory agencies. Failure to receive or maintain these other requisite approvals could prohibit us from marketing and selling Neutrolin in the entire European Economic Area. In addition, we will need regulatory approval to market and sell Neutrolin in foreign countries outside of Europe.

In the United States, we have no current application for, and have not received the regulatory approvals required for, the commercial sale of any of our products. None of our product candidates has been determined to be safe and effective in the United States, and we have not submitted an NDA or PMA to the FDA for any product. Although we have received approval from the FDA to proceed with a planned Phase III trial for Neutrolin, we do not have immediate plans to initiate that trial and are seeking one or more strategic partners or other sources of capital to start that trial. However, we might not obtain any commercial partner or financing and may never start the Phase III trial.

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